PERRINE DUPONT SETTLEMENT
SPELTER VOLUNTEER FIRE DEPARTMENT CLAIMS OFFICE
55 B Street
P. O. BOX 257
Spelter, WV 26438
(304) 622-7443
(800) 345-0837
www.perrinedupont.com
perrinedupont@gtandslaw.com

October 10, 2011

CLAIMS ADMINISTRATOR'S MEDICAL MONITORING PLAN
UNRESOLVED ISSUES REPORT TO THE COURT

VIA HAND DELIVERY

The Honorable Thomas A. Bedell
Circuit Judge of Harrison County
301 West Main Street, Room 321
Clarksburg, West Virginia 26301

Re: Perrine, et al. v. DuPont, et al.; Civil Action No. 04-C-296-2 (Circuit Court of Harrison County, West Virginia) - Claims Administrator's Unresolved Issues Report and Proposed Working Order for October 17, 2011 10:00 a.m. Eastern Time Medical Monitoring Plan Design Finalization Hearing; Our File Nos. 4609-1 {R}, 4609-1 {NN} and 4609-1 {GG}

Dear Judge Bedell:

In preparation for the referenced hearing, your Claims Administrator submits this Report on the unresolved issues respecting the Medical Monitoring Plan, after considering the very helpful input of the Finance Committee and the Guardian Ad Litem for children. Also submitted on paper medium and in electronic format (in PDF, Word and WordPerfect) is a proposed Working Order in Attachment VIII with alternative findings based on my understanding of the positions of the Parties on key issues.

This week, I will try to have a pre-hearing conference call with the Parties to obtain their edits to the proposed Working Order and will try to submit a final proposed hearing version to you at or before the beginning of the October 17, 2011 10:00 a.m. Eastern time hearing.

I.
SUMMARY OF THE MEDICAL MONITORING PLAN UNRESOLVED ISSUES

As described in the Court's previous applicable Orders in Attachment I[1], the Medical Monitoring Plan unresolved issues are:

1. Whether the Medical Monitoring Plan is a primary or secondary Plan for Medical testing benefits as asked in the June 3, 2011 Order;

2. Because the Court decided on August 24, 2011 that a Medical Monitoring Plan database will be established to facilitate and assist in future scientific and medical research, it is necessary to design an optional data collection consent form that Medical Monitoring Plan participating Claimants should be allowed to sign during their initial Medical Monitoring Provider visit if they choose the option to have their medical data so collected (the "Data Collection Consent Form"), with a preliminary form having been submitted by the Claims Administrator to the Court and the Parties for briefing on September 20, 2011 which is Attachment II to this Report;

3. In connection with the Medical Monitoring Implementation Plan approved by the Court on August 31, 2011, two issues are unresolved:

   a. (i) How to handle so-called "No" box minor Medical Monitoring Claimants whose parent or guardian checked the "No" box and therefore did not choose Medical Monitoring, when these Minor "No" box Claimants become adults; and (ii) when may an "inactive" Medical Monitoring Claimant (an "Inactive" Claimant is a Claimant who checked the "yes" box for Medical Monitoring but does not show up for Medical Monitoring) become "active" (collectively, the "Minor No-Inactive Claimant Rules"), with preliminary Minor No-Inactive Claimant Rules having been submitted by your Claims Administrator to the Court and the Parties for briefing on August 19 and 24, 2011, which is in Attachment III to this Report; and

   b. In connection with CT Scans,

[1]Final Order Approving TPA Agreement and Establishing Briefing Schedule on Unresolved Issues dated June 3, 2011; Order Permitting the Establishment of a Medical Monitoring Program Database to Facilitate and Assist in Future Scientific and Medical Research dated August 24, 2011; Final Order Approving Certain Aspects of Settlement Administration and Establishing Briefing Schedule for Preliminarily Recommended or Unresolved Matters dated August 31, 2011; Order Establishing Medical Monitoring Program Preliminary Optional Data Collection Consent and CT Scan Verification Forms Briefing Schedule dated September 21, 2011; and Order Setting Hearing on the Implementation of the Medical Monitoring Program dated September 29, 2011. All these Orders are on the Settlement Website, www.perrinedupont.com.

(i) In my opinion, we need to develop guidelines for the attending physician to consider in deciding whether to diagnose a CT Scan for CT Scan eligible (35 and older per the Dr. Werntz Report) Medical Monitoring Participating Claimants (the "CT Rule"), as contemplated in Paragraph 3 of the CT Scan Utilization Protocols contained in the Medical Monitoring Implementation Plan approved by the Court on August 31, 2011, with the CT Rule being in Attachment IV to this Report. The Preliminary CT Rule in Attachment IV was submitted by your Claims Administrator to the Court and the Parties for briefing on September 1, 2011, and the proposed final version is in Attachment IV; and

(ii) In my opinion, we need to prepare a form for the attending physician to complete in making the CT Scan diagnosis determination (the "CT Scan Verification Form"), with a Preliminary CT Scan Verification Form having been submitted by your Claims Administrator to the Court and the Parties for briefing on September 20, 2011 which is in Attachment V to this Report, and the proposed Final CT Scan Verification Form being in Attachment V.

4. In connection with financing the Medical Monitoring Plan for the period beginning November 1, 2011, when actual testing is expected to begin, and ending August 31, 2012, what is the appropriate budget new money amount for DuPont to deposit into the Perrine DuPont Medical Monitoring Qualified Settlement Fund (the "Medical Monitoring Fund") by October 31, 2011, to timely provide funding by the November 1, 2011, testing commencement date, to fulfill the following provision in the November 19, 2011 Settlement Memorandum of Understanding (the "MOU") at p. 2, paragraph b:

> "After said (6 month Medical Monitoring Claimant) enrollment period has expired, a Finance Committee comprised of representatives from Class Counsel, DuPont, and the Settlement Administrator shall be created for purposes of advising the Court on the structure and execution of the Medical Monitoring Program. On an annual basis, the Court, with the recommendation of the Finance Committee, shall direct DuPont to pay a sum certain that will be set aside for each such calendar year that reasonably secures such expenditures for each such calendar year." (emphasis added)

Preliminary Medical Monitoring Budgets were submitted to the Court and the Parties on August 19 and August 24, 2011 (assuming 3,000 Medical Monitoring Participants) and to the Court and the Parties for briefing on September 1, 2011 (assuming 3,500 Medical Monitoring Participants).

The proposed Final Medical Monitoring Budget (the "Budget") (assuming 4,000 Medical Monitoring Participants) is in Attachment VII to this Report.

5. Whether DuPont through an additional payment to the Medical Monitoring Fund or whether the initial DuPont Settlement funding already received by the Medical Monitoring Fund shall pay the $26,524.57 in the Bridge Funding described in the August 19 and 24, 2011 Claims Administrator Reports approved by the Court on August 31, 2011, with the Bridge Funding being for CTIA's (the Third Party Administrator for the Medical Monitoring Program) Medical Monitoring Program expenses in September and October 2011.

II.
PRIOR SUBMISSIONS OF YOUR CLAIMS ADMINISTRATOR AND THE PARTIES RESPECTING THE UNRESOLVED ISSUES

The Court has received to date the following submissions to help resolve these issues:

1. August 19, 2011 Report of Claims Administrator respecting a second proposed Administration Budget (for September 1, 2011 through August 31, 2012) (for both Property Remediation and Medical Monitoring) and the Medical Monitoring Implementation Plan;

2. August 19, 2011 Objections of DuPont to Proposed Second Budget;

3. August 24, 2011 Claims Administrator Supplement to the August 19, 2011 Report;

4. September 1, 2011 Report of Claims Administrator Providing Preliminary CT Rule and Preliminary Medical Monitoring Budget for briefing by the Parties;

5. September 20, 2011, Claims Administrator Proposed Preliminary Data Collection Consent Form and CT Scan Verification Form submitted to the Court and the Parties for briefing on September 20, 2011;

6. September 21, 2011 Plaintiffs' Response to Proposed CT Scan Rule;

7. September 21, 2011 Submission of DuPont in connection with Preliminary CT Scan Guidelines and Preliminary Medical Monitoring Budget;

8. September 21, 2011 Submission of Guardian ad Litem regarding the Preliminary CT Scan Rule and Preliminary Medical Monitoring Budget;

9. October 3, 2011 Class Counsel Response to DuPont's Submission in connection with Proposed CT Guidelines and Preliminary Medical Monitoring Budget;

10. October 3, 2011 Reply Submission of DuPont in connection with Preliminary CT Guidelines and Preliminary Medical Monitoring Budget;

11. October 3, 2011 Response of Guardian ad Litem to the submission of DuPont Related to Preliminary CT Scan Guidelines and Medical Monitoring Budget;

12. October 5, 2011 DuPont submission regarding the proposed Preliminary CT Scan Physician Verification Form and Preliminary Medical Monitoring Program Scientific and Health Research Data Collection Claimant Consent Form; and

13. October 5, 2011 submission of Guardian ad Litem regarding Medical Monitoring Program Preliminary Optional Data Collection Consent and CT Scan Verification Forms.

All submissions are on the Settlement Website, www.perrinedupont.com.

III.
CLAIMS ADMINISTRATOR'S SUGGESTED RESOLUTION OF MEDICAL MONITORING PLAN ISSUES

1. There is agreement that the Medical Monitoring Plan is a primary and not a secondary Plan for medical testing benefits.

The Parties have taken this position in ongoing negotiations with governmental agencies. The proposed Working Order in Attachment VIII reflects this finding.

2. The Parties have agreed on a Medical Monitoring Plan Data Collection Consent Form.

The Data Collection Consent Form in Attachment II has been agreed to by DuPont and the Guardian ad Litem for Children. Class Counsel did not express an opinion on the form, and we therefore assume that it is acceptable. We have made some typographical edits at the suggestion of the Guardian ad Litem, which are shown in the red-lined version in Attachment II. The Proposed Order in Attachment VIII would approve the so-edited form.

3. Suggested Resolution of the Medical Monitoring Implementation Plan Issues.

a. The Minor No-Inactive Claimant Rules.

Your Claims Administrator's suggested Minor No-Inactive Claimant Rules in Attachment III were first submitted to the Court on August 19, 2011, after previously sharing them

with the Parties for input. In their Briefs, the Guardian ad Litem and DuPont take antipodal positions respecting these proposed rules. The Guardian ad Litem accepts them and DuPont rejects them. In a nutshell, as noted by the Guardian ad Litem,

> "The proposed rule regarding the "Inactive" claimants provides in essence that the claimant be provided biennial correspondence regarding the program, and invites the claimant to reactivate his/her participation status by providing written good cause for the lapse. The proposed rule regarding the "Minor-No" claimants, provides that upon turning 18, the claimant will be notified by the Claims Administrator of the program and afforded an opportunity to participate by responding affirmatively. It is proposed that both the "Inactive" and "Minor-No" claimants continue to receive biennial correspondence regarding the program availability for the duration of the thirty years."

In supporting these proposed rules, the Guardian ad Litem states that neither the Orders nor the MOU respecting the Settlement, "required that participant avail himself to the program testing biannually. Thus, claimant medical monitoring participation is a negotiated right, not a requirement." Thus, we understand the Guardian ad Litem to advocate that the Medical Monitoring Program be treated similarly to health insurance which you can use in the future if you ever need it, but doesn't have to be used to prevent its waiver. Thus, failure to use it every two years would not be a waiver.

It its October 3 submission, DuPont challenges these rules as being unnecessary, wasteful and unreasonable, objecting to the Medical Monitoring Plan, under the proposed Rules, continuing to "woo" Inactive Claimants or to continued biannual contact with Minor No-Claimants by the Medical Monitoring Plan, with non-responsive claimants being deemed by DuPont to have waived their Medical Monitoring rights. DuPont objects to the three notices to be given to active claimants before they are declared Inactive and to the biennial follow-up thereafter, and also objects to the biennial invitation to the Minor No-Claimants to join the Plan.

It is respectfully suggested that the Court should determine whether the Medical Monitoring Plan is a right that cannot be waived during the 30 year period or a right that can be waived. The proposed Order in Attachment VIII contains alternative language for these possible positions.

b. In Connection with CT Scans. Submitted Are:

(i) Your Claims Administrator's proposed final Guidelines for the Attending Physician to consider in deciding whether to diagnose a CT Scan eligible (35 and older) Medical Monitoring Participating Claimants (the "CT Rule") in Attachment IV; and

(ii) Your Claims Administrator's proposed final form for the attending physician to complete when making the CT Scan diagnosis determination (the "CT Scan Verification Form") in Attachment V.

The CT Rule submitted for briefing on September 1, 2011, has been modified in Attachment IV by omitting old Paragraph 7 in the September 1 draft, which was objected to by the Guardian ad Litem and Class Counsel. As stated by the Guardian ad Litem on Page 4 of her September 21, 2011 submission, to retain old Paragraph 7 would implement, "a signs and symptoms - based approach, limiting access to CT Scans to only symptomatic Class Members, and thereby effectively excluding that screening tool."

The proposed final version of the CT Scan Verification Form in Attachment V also has this same language omitted.

It is my understanding that the so edited CT Rule and CT Scan Verification are now acceptable to DuPont. The so-edited documents should address a major concern of the Guardian ad Litem (as noted above) and Class Counsel. See, for example, Class Counsel's September 21, 2011 submission on pages 2 and 3.

See, for example, page 5 of Class Counsel's September 21, 2011 Submission which suggests that, "(1) all eligible participants be offered a CT Scan upon entry into the medical monitoring (program) and (2) that diagnostically medically necessary CT scans for the participants be based purely on exposure, without the need for the participant to be symptomatic."

However, I understand that the Guardian ad Litem and Class Counsel recommend providing baseline CT Scans to all CT-Scan eligible (35 and over) Medical Monitoring Plan participants, when Medical Monitoring begins. I assume the baseline CT Scan would also be available to younger Claimants as they reach 35. Thereafter, I am not aware of any objection to use of the CT Rule and CT Verification Form during future biennial rounds of Medical Monitoring screenings for the Claimants.

Elimination of Paragraph 7 of the CT Rule and CT Verification Form does remove the symptoms. However, if the Guardian ad Litem and Class Counsel are also advocating that all CT Scan eligible Claimants be CT scanned routinely once (baseline CT Scan), then it is respectfully suggested the Court may need to decide whether this approach violates Paragraph C of Page 2 of the MOU, which provides that,

> "The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT Scans shall be performed as part of the Medical Monitoring Program. The Defendant does agree to provide CT Scans that are diagnostically medically necessary as determined by a

competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation." [Emphasis added]

The proposed Order in Attachment VIII contains alternative language, which would either (i) adopt the so-edited CT Rule in Attachment IV and CT Scan Verification Form in Attachment V, to be used at the commencement of the Medical Monitoring Plan; or (ii) would adopt my understanding of Class Counsel's and the Guardian Ad Litem's approach, which would result in one round of baseline CT Scans followed by the use of the CT Rule and CT Scan Verification Form.

According to the Expert Opinion of Dr. Jubal Watts in Attachment IX (with his resume and a list of documents he reviewed also being provided), a cardiopulmonary radiologist at the University of Alabama at Birmingham, and as more fully set out in Section I of the Revised CT Rule in Attachment IV, there is no scientific data to suggest that asymptomatic screening is appropriate for CT Scan eligible claimants. Furthermore, Dr. Watts is of the opinion that "CT screening based solely on heavy metal exposures for zones 2 and 3 may create more cancers than it would detect and cure." See Dr. Watts Expert Opinion in Exhibit IX.

Therefore, in both the CT Rule and the CT Scan Verification Form, your Claims Administrator proposes that the physician will, in his discretion, make a determination of whether to recommend a CT Scan for a Claimant as being medically necessary and relevant to possible exposure to heavy metals contamination only after the physician has reviewed the Claimant's vital signs, conducted a general health interview (including the number of years the Claimant resided in the Class Area), and reviewed the Claimant's prior medical history. However, as noted above, as suggested by Class Counsel and the Guardian ad Litem, and as recommended by Dr. Watts in Attachment IX, specific signs and symptions should not be a prerequisite to a CT Scan, and your Claims Administrator has removed that requirement (old paragraph 7) from the proposed final CT Scan Rule in Attachment IV and proposed final CT Scan Verification Form in Attachment V.

4. Final Proposed First Medical Monitoring Plan Implementation Budget.

This Budget equals either $2,789,984.94, if the CT Rule and CT Scan Verification Form suggested by your Claims Administrator above are implemented by the Court, or $3,143,097.77 if there are baseline (routine) CT Scans offered all eligible Medical Monitoring Participants (35 and older), during the first year of Medical Monitoring.

This Budget takes into account the revised Third Party Administrator Medical Provider pricing Budget contained in Attachment VII based on actual negotiations with the Medical Providers in the Spelter, West Virginia area, which have resulted in substantial discounts from the prices we projected on our previous Budget at September 1, 2011, and are now materially accurate.

The Budget also takes into account the materially accurate projection of the final number of Medical Monitoring Participating Claimants contained in Attachment VI, and equaling 4,000.

The two alternative Budget amounts, based upon whether (i) the above CT Rule and CT Scan Verification Form are used, on the one hand; or whether (ii) there are baseline CT Scans during year one of the Medical Monitoring Program, and as younger Claimants reach age 35, on the other hand are summarized as follows:

1.	Column C of both Budgets in Attachment VII (Medical Monitoring Implementation Budget without Incremental CT Scan Costs)	$1,977,207.41
2.A	Column D of Budget in Attachment VII B (Incremental CT Scan Costs if Claims Administrator Suggested CT Rule and CT Scan Verification Form are used at the beginning of the Medical Monitoring Program)	$839,302.10
	or	
2.B	Column D of Budget in Attachment VII C (Incremental CT Scan Costs if there are Baseline (Routine) CT Scans) during year one of the Medical Monitoring Program	$1,192,414.93
3.	Less Bridge Funding (payment by new DuPont contribution or old DuPont contribution to be determined by the Court)	($ 26,524.57)

TOTAL DUPONT NEW CONTRIBUTION DUE BY OCTOBER 31, 2011:

4.A	(Claims Administrator CT Rule and CT Scan Verification Form approved by Court at the beginning of the Medical Monitoring Program) (1 + 2A - 3)	$2,789,984.94
	or	
4.B	(Baseline (Routine) CT Scans during year one of the Medical Monitoring Program)(1 + 2B - 3)	$3,143,097.77

As contemplated by the MOU, this Budget is to be funded by an additional DuPont contribution to the Medical Monitoring Fund on or before October 31, 2011 (i) in the amount of the above $2,789,984.94, if the Claims Administrator's suggested CT Rule and CT Scan Verification

Form are utilized at the beginning of the Medical Monitoring Program; or (ii) if there are baseline CT Scans during year one of the Medical Monitoring Program, and as younger Claimants reach age 35, in the amount of $3,143,097.77, as finally determined by the Court following the October 17, 2011 Hearing.

The proposed Order in Attachment VIII, has these alternative decisions for the Court's consideration.

Much as in the September 1, 2011 Submission, in an attempt to narrow the unresolved issues, the Budget in Attachment VII has been divided into the following two components:

(a) A separate Budget component without CT Scans totaling $1,950,682.84 ($1,977,207.41 in Column C of Budget in Attachment VII minus Bridge Funding of $26,524.57 for September and October 2011) that does not include the budget incremental costs of the CT Scan portion of the Medical Monitoring Plan for the Budget period, in an attempt to reach closure with the Parties on this portion of the final Budget (the "Non-CT Scan Budget"); and

(b) A separate Preliminary Budget component totaling (i) $839,302.10 in Column D of Budget Alternative I in Attachment VII B which applies if the Claims Administrator's suggested CT Rule and CT Verification Form at the beginning of the Medical Monitoring Program are implemented by the Court; or (ii) $1,192,414.97 in Column D of Budget Alternative II in Attachment VII C if there are baseline CT Scans at the beginning of the Medical Monitoring Program, and as younger Claimants reach age 35, that only contains the Medical Monitoring Plan's budgeted incremental costs of conducting CT Scans for the budget period (the "CT Scan Incremental Cost Budget").[2] Incremental costs are only included in this second component of the Preliminary Budget, based on the assumption that both Budget components (non-CT Scan and CT Scan) will be resolved and carried out in tandem, with all aspects of the Medical Monitoring Plan to timely begin on November 1, 2011.

If, however, the CT Scan component of the Medical Monitoring Plan is delayed by litigation, then,

(a) The Medical Monitoring Program, with the CT Scan portion delayed, may proceed under the Non-CT Scan Budget described in Paragraph (a) above; but

(b) The CT Scan Incremental Cost Budget will have to be materially increased (whether we have baseline CT Scans or apply the CT Rule at the commencement of CT Scanning), due to the cost savings that will not be realized if both components of the

[2]Guardian Ad Litem expenses are included, as the design and implementation of the CT Scan program will assist minor Claimants as they become CT Scan eligible adults.

Medical Monitoring Program (non-CT Scan and CT Scan) are not executed in tandem.

In reviewing the Budget, the Court and the Parties may keep in mind that the proposed final version of (i) the September 1, 2011 through August 31, 2012, Perrine DuPont Property Remediation Qualified Settlement Fund (the "Remediation Fund") Budget; and (ii) the Medical Monitoring Fund September 1, 2011 through October 31, 2011 Budget were filed with the Court on August 19, 2011 (collectively the "Finalized Two Budgets"), with the only unresolved issue respecting these Finalized Two Budgets being whether DuPont shall or shall not pay for the Bridge Funding with an additional contribution to the Medical Monitoring Fund. The Finalized Two Budgets were approved by the Court on August 31, 2011.

However, these Finalized Two Budgets, unaltered from the August 19, 2011 Claims Administrator's submission and now approved by the Court, are still included with the enclosed Budget for the Medical Monitoring Fund for November 1, 2011 through August 31, 2012, to depict cost-sharing by the Finalized Two Budgets and the Budget.

Further input from the Parties respecting the Finalized Two Budgets was not requested.

If the Court accepts that the two major issues that apparently are a concern to DuPont, namely having (i) a reasonable estimate of the final number of Medical Monitoring Participants; and (ii) a reasonable estimate of Medical Monitoring prices, are now resolved, it is suggested by your Claims Administrator that the big remaining Budget issue is whether there will be CT Scans in accordance with the Claims Administrator's suggested CT Rule or whether there will be baseline CT Scans during the first year of Medical Monitoring, and as younger Claimants reach age 35.

In projecting costs for these two alternative CT Scan approaches under the Medical Monitoring Program, your Claims Administrator suggests that, of the approximately 2,680 (67% x 4,000) participating Claimants that are 35 or older, and therefore are CT Scan eligible, only 75% will show up for Medical Monitoring at all.

Utilizing the CT Rule suggested by your Claims Administrator, we estimate that half of the CT Scan eligible claimants that show up for Medical Monitoring will undergo CT scans. If CT scans are baseline during year one instead, we estimate that 75% of those that show up for Medical Monitoring will undergo CT Scans.

The bottom line, therefore, is that (i) under our suggested CT Rule, we estimate that 75% x 50%, or 37.5%, of CT Scan eligible Claimants will be CT Scanned; (ii) while under a baseline CT Scan approach, we estimate that 75% x 75%, or 56.25%, of CT Scan eligible claimants will be CT Scanned.

These projections are just that. In the end, each attending physician will decide whether a CT Scan is necessary for each CT Scan eligible Medical Monitoring Participant. We will not know the CT Scan rate for some time. However, it seems reasonable to predict that application of the suggested CT Rule will result in a materially less number of CT Scans than baseline CT Scanning during year one, and as younger Claimants reach age 35.

In its brief, DuPont suggests that the above projected CT Scan percentages under the CT Rule are too high. However, DuPont does not suggest an alternative percent. At this point, we have no way of knowing if we are right or wrong. We do know that the Medical Monitoring Plan needs to be implemented in order to detect disease and save people's lives.

We are reminded of language used in our August 24,2011 Report when we were first creating a Budget. In the end, a Budget is only a Budget. As with all Budgets, not all aspects of this Budget will be finalized when the Budget is submitted to the Court for approval, and will only be finalized as each month's financial expenditures are experienced.

For example, the exact number of Medical Monitoring Registrant Claimants will not be known for some time. This was contemplated by the Finance Committee and your Claims Administrator in the Medical Monitoring Timeline and Punch List approved by the Court. In the Punch List, we contemplated a September 1, 2011 Medical Monitoring Plan Implementation Date, but we contemplated that we would not know the exact number of Medical Monitoring Registrants until 45 days later or even longer. This is a fair estimate of what the Court should expect, with a November 1, 2011 Medical Monitoring Implementation Date and the number of Registrants not being reasonably finalized until sometime in January 2012. Moreover, we will not know how many Medical Monitoring Registrant Claimants will show up for testing until testing begins and we have some testing experience. Likewise, we will not know the CT Scan rate until we have experience.

Most importantly, in arriving at this budget for Court approval, we are only asking for DuPont to provide funding for reasonably estimated post-Implementation Date expenses for the first ten months of the Medical Monitoring Program. If there is more money than required, it will continue to be invested and is merely carried over to the next year, and it is not lost. Indeed, the prudent financial planning goal is to come in on budget and not to exceed it. If we waited until all factors are finalized with total precision, there could not be a budget or a Medical Monitoring Program in the foreseeable future.

Likewise, this Settlement's first Budget, covering the period from January 1, 2011 through August 31, 2011, was created with input from the Finance Committee, when we didn't know how many Medical Monitoring Forms (higher than expected) or Property Clean-Up Forms (lower than expected) would be received, how difficult it would be to determine that a Claimant lived in the Class Area, how many Claims Office Claimant visits or phone calls we would have, and how much DuPont would audit the Medical Monitoring Claimant Forms (the most auditing I've experienced in over $2 billion of Settlements). Nevertheless, the actual results from the first Budget period

equaled 81.2% of the first Budget. Moreover, 5% of the first Budget was for the FASB 5 material unknown contingencies, making the actuals even closer to the Budget. We expect a similar materially accurate financial result with this Budget.

Based upon the foregoing and the current state of the Medical Monitoring Program, your Claims Administrator submits that the Budget is ripe to be approved by the Court and the Medical Monitoring Program is ripe to commence on November 1, 2011, which can only occur if it is funded by DuPont by October 31, 2011.

5. The $26,524.57 Bridge Funding Can be Paid with Old Money.

In recognition that this issue is debatable and in an effort to limit the issues to material disputes, the Claims Administrator suggests that these expenses of the Third Party Administrator incurred in September and October 2011, before testing actually begins, be paid from the original DuPont contribution to the Settlement's Medical Monitoring Fund. Approximately half of this amount, or $15,440, is attributed to monthly charges of CTIA, the Medical Monitoring Third Party Administrator, under its contract with the Settlement, which are not directly related to actual testing. The other costs are for communications materials, production and distribution of ID cards, and the scheduling of appointments and reminder letters, and design consulting services. Although some of these costs are reasonably related to actual testing, there is a reasonable basis to find that none of them deal with testing itself until the testing actually begins.

The proposed Order in Attachment VIII reflects this suggestion of the Claims Administrator.

We would like to thank the Finance Committee and the Guardian Ad Litem for their hard work in providing thoughtful and helpful input in the design of the Medical Monitoring Program.

Thank you for the Court's consideration.

Yours very truly,

Edgar C. Gentle, III
Claims Administrator

ECGIII/kjm
Attachments (Schedule of Attachments Included)

cc: (with enclosures)(by e-mail)(confidential)
Stephanie D. Thacker, Esq., DuPont Representative on the Settlement Finance Committee
Virginia Buchanan, Esq., Plaintiff Class Representative on the Finance Committee

cc: (continued)
Meredith McCarthy, Esq., Guardian Ad Litem for Children
Clerk of Court of Harrison County, West Virginia, for filing (via hand delivery)
Terry D. Turner, Jr., Esq.
Diandra S. Debrosse, Esq.
Katherine A. Harbison, Esq.
Paige F. Osborn, Esq.
Michael A. Jacks, Esq.
William S. ("Buddy") Cox, Esq.
J. Keith Givens, Esq.
McDavid Flowers, Esq.
Farrest Taylor, Esq.
Ned McWilliams, Esq.
Perry B. Jones, Esq.
Angela Mason, Esq.
Mr. Don Brandt
Ms. Pat Gagne
James B. Lees, Jr., Esq.
Leigh Anne Hodge, Esq., Outside Counsel for Claims Administrator

SCHEDULE OF ATTACHMENTS TO CLAIMS ADMINISTRATOR'S OCTOBER 10, 2011 MEDICAL MONITORING UNRESOLVED ISSUES REPORT TO THE COURT

ATTACHMENT NUMBER	ATTACHMENT DESCRIPTION
I.	Applicable Previous Orders
II.	A. Preliminary Data Collection Consent Form;
	B. Red-lined Revisions Recommended by the Guardian Ad Litem; and
	C. Proposed Final Data Collection Consent Form
III.	Preliminary Minor No-Inactive Claimant Rules
IV.	A. Preliminary CT Rule; and
	B. Proposed Final CT Rule
V.	A. Preliminary CT Scan Verification Form; and
	B. Red-line Revisions Recommended by the Guardian Ad Litem; and
	C. Proposed Final CT Scan Verification Form
VI.	October 3, 2011 Materially Accurate Projection of 4,000 Total Medical Monitoring Participants
VII.	Proposed Final Medical Monitoring Budget for November 1, 2011 to August 31, 2012, Inclusive, to be Funded by New Money Deposit of DuPont, with Detailed Memorandum and Footnotes of Explanation with Attachments:
	A. Detailed Memorandum of Explanation;
	B. Alternative I (CT Rule and CT Scan Verification Form Utilized); and
	C. Alternative II (Baseline CT Scans)
VIII.	Proposed Working Order on Paper and Electronic Media
IX.	Expert Opinion of Dr. Jubal Watts, with Resume and List of Documents He Reviewed

I. Applicable Previous Orders

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al.,

Plaintiffs,

v.

Case No. 04-C-296-2
Judge Thomas A. Bedell

E. I. DUPONT DE NEMOURS & COMPANY, et al.,

Defendants.

FINAL ORDER APPROVING TPA AGREEMENT AND ESTABLISHING BRIEFING SCHEDULE ON UNRESOLVED ISSUES

Presently before the Court is the Claims Administrator's June 1, 2011 Report recommending that a proposed Health Care Provider Third Party Administrator Agreement ("TPA Agreement") with CTIA of Des Moines, Iowa be approved. In his report, the Claims Administrator points out that (i) whether the medical monitoring program is a primary or secondary plan for medical testing benefits; and (ii) whether the program database should provide necessary details to facilitate future scientific research, are two issues which have not been resolved by the Finance Committee, with these two issues being referred hereinafter as the "Unresolved Issues". Accordingly, to facilitate the Court's decision on the Unresolved Issues, the following briefing schedule is established:

(i) DuPont, Class Counsel, the Guardian ad litem for children, and any other interested Parties shall provide their initial submissions to the Court on the Unresolved Issues within 30 days; and

(ii) Reply submissions shall be submitted within 15 days thereafter.

After receiving submissions and reply submissions, the Unresolved Issues shall be deemed submitted to the Court for consideration.

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&
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After a careful review of the Claims Administrator's submission, and in consideration of the applicable law, the Court ORDERS that the proposed TPA Agreement is hereby APPROVED and that the Claims Administrator, on behalf of the Settlement, is hereby authorized, empowered and directed to enter into the TPA Agreement on behalf of the Settlement, with the Claims Administrator's execution and delivery of the TPA Agreement to CTIA to be conclusively presumed to be the valid and binding act of the Settlement.

IT IS SO ORDERED.

The Clerk of this Court shall provide certified copies of this Order to the following:

Stephanie D. Thacker, Esq.
Allen, Guthrie & Thomas, PLLC
P.O. Box 3394
Charleston, WV 25333-3394
DuPont's Finance Committee Representative

Meredith McCarthy, Esq.
Guardian Ad Litem for Children
901 W. Main St.
Bridgeport, WV 26330

Virginia Buchanan, Esq.
Levin, Papantonio, Thomas, Mitchell,
Rafferty & Proctor, P.A.
P.O. Box 12308
Pensacola, FL 32591
Plaintiffs' Finance Committee Representative

Order Prepared By:

Edgar C. Gentle, III, Claims Administrator
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438

Michael A. Jacks, Esq.
Gentle, Turner & Sexton
W.Va. Bar No 11044
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438

ENTER: June 3, 2011

Thomas A. Bedell, Circuit Judge

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E.I. DU PONT DE NEMOURS AND COMPANY, et al.,

Defendants.

ORDER PERMITTING THE ESTABLISHMENT OF A PROGRAM DATABASE TO FACILITATE AND ASSIST IN FUTURE SCIENTIFIC AND MEDICAL RESEARCH

Pending before the Court is the issue of whether a program database containing the depersonalized information of the medical monitoring candidates of the Perrine / Dupont settlement should be made available to facilitate future scientific research. This Court was first made aware of this issue in the Claims Administrator's *June 1, 2011 Report.*

Accordingly, it set out a *Briefing Schedule* regarding the database issue on June 3, 2011. Pursuant to that *Schedule,* Defendant E. I. du Pont de Nemours and Company ("Defendant") filed a *Submission in Opposition to the Maintenance of a Database of Claimants' Medical Test Results for Potential Future Scientific Research* on June 6, 2011. The Plaintiffs' *Memorandum Regarding Third Party Administrator Issues in the Spelter Medical Monitoring Program* and the *Submission of Guardian Ad Litem to*

Unresolved Issues in the Health Care Provider Third Party Administrator Agreement on that same day.

After the initial round of submissions, the Plaintiffs' Finance Committee Representative filed her *Response to DuPont's Brief Regarding Maintenance of a Database* on July 20, 2011. Also on that day, this Court received *DuPont's Reply in Further Opposition to the Maintenance of a Database of Claimants' Medical Test Results for Potential Future Scientific Research.* Finally, the Guardian Ad Litem filed a *Submission of the Guardian Ad Litem in Response to Defendant's Opposition to Maintenance of Medical Monitoring Program Database* on July 21, 2011.

This Court has reviewed these submissions and responses and conducted a thorough examination of the record and pertinent legal authority. Accordingly, it hereby **ORDERS** that, after a claimant provides informed consent, that claimant's information may be placed into a research database and provided upon request to assist in a legitimate medical or scientific purpose.

Relevant Procedural History

1. This action was initially filed on June 15, 2004, against Defendants E.I. du Pont de Nemours and Company ("DuPont"), T. L. Diamond & Company, Inc., Meadowbrook Corporation, Matthiessen & Hegeler Zinc Company, Inc., Nuzum Trucking Company ("Nuzum"), and Joseph Paushel ("Mr. Paushel").
2. On September 14, 2006, this Court granted class certification and certified both a Property Class and a Medical Monitoring Class ("Plaintiff Classes") in this case pursuant to the provisions of Rule 23 of the West Virginia Rules of Civil Procedure. Upon appeal, the certification of both classes was upheld by the W.

Va. Supreme Court. "Having found no error in the circuit court's disposition of each of the elements to be considered in certifying a class under Rule 23(a) and (b), we find that certification was proper. Consequently, DuPont's claim that class certification violated its due process rights by preventing it from presenting individualized evidence and individualized defenses is without merit." *Perrine v. E.I. du Pont de Nemours and Co.* 694 S.E.2d 815, 861 (2010).

3. After extensive discovery and pre-trial litigation, this matter proceeded to trial beginning on September 10, 2007, and the trial lasted for approximately six weeks. The trial consisted of four phases, and the jury returned verdicts in favor of the Plaintiffs. The verdicts were ultimately rendered as awards of fifty-five million five hundred and thirty-seven thousand five hundred and twenty-two dollars and twenty-five cents ($55,537,522.25) for property damage and associated remediation costs, an estimated award of approximately one hundred and thirty million dollars ($130,000,000.00) for a future medical monitoring program to last for 40 years, and a punitive damages award of one hundred and ninety-six million and two hundred thousand dollars ($196,200,000.00).
4. Said verdicts were the result of the jury finding that the Plaintiffs' property and persons were exposed to elevated and dangerous levels of lead, cadmium, and arsenic, among other heavy metals, due to the long operation of a smelting facility in Spelter which polluted the class area.
5. On November 16, 2007, this Court entered an *Amended Final Judgment Order* finalizing the jury's verdict in the amounts described above against Defendant DuPont.

6. Thereafter, both the Plaintiffs and Defendants appealed numerous aspects of this Court's pre-trial, trial, and post-trial rulings to the West Virginia Supreme Court of Appeals.

7. On March 26, 2010, after a lengthy appellate process, the West Virginia Supreme Court of Appeals remanded this litigation to the Court with directions to conduct a trial on DuPont's statute of limitations defense.

8. The Supreme Court modified the punitive damages award, but conditionally affirmed the remainder of the verdict, which then consisted of approximately three hundred million dollars ($300,000,000.00). The Supreme Court determined that this Court erred in granting judgment as a matter of law in favor of the Plaintiffs on the affirmative defense of the statute of limitations and directed this Court to hold a second trial to determine if the defense was merit worthy.

9. The effect of the Supreme Court's directive created an all or nothing proposition for the parties. If the Plaintiffs prevailed on the statute of limitations issue, they would receive the relief obtained in the 2007 trial, as modified by the Supreme Court opinion. If DuPont prevailed, this Court would set aside the 2007 verdicts and render judgment in favor of DuPont, and the Plaintiffs would receive nothing. *Perrine v. E.I. du Pont de Nemours and Co.*, 694 S.E.2d 815, 854 (2010).

10. The Plaintiffs and Defendant both considered the directives of the Supreme Court's opinion and prepared for trial, which was set for the month of March, 2011. The Parties reached this settlement after considering the substantial amount of risk and expense remaining in the case for both sides. On November 19, 2010, the Parties advised the Court that a proposed compromise and settlement had been

reached. Thereafter, on November 24, 2010, the Court set a December 30, 2010, hearing to hear the Parties and to receive evidence and argument as to the fairness of the proposed settlement.

11. On December 6, 2010, the Court appointed Meredith McCarthy, a discrete and competent attorney practicing before this Court who is familiar with the facts involved in this case, to serve as guardian *ad litem* to protect the interests of any minors who may be members of the Plaintiff Classes. Mrs. McCarthy previously served as a guardian *ad litem* in this matter and is uniquely familiar with this issues presented.

12. After determining that proper notice of the settlement was given to all members of the Plaintiff classes and determining that the settlement was fair, this Court entered its *Final Order Approving Settlement* on January 4, 2011.

13. Alongside that *Final Order Approving Settlement*, this Court entered a *Final Order Setting forth the Scope and Operation of the Medical Monitoring Plan.* ("Medical Plan Order").

14. In that Medical Plan Order, this Court ruled that the scope of the medical monitoring plan should be in accordance with the plan suggested by Dr. Werntz, the Plaintiffs' medical monitoring trial expert.

15. Dr. Werntz testified in post-trial proceedings about the potential maintenance of a database that could be used to assist in future scientific studies regarding the types of injuries sustained by the Plaintiffs and how monitoring programs address those injuries.

16. Dr. Werntz also wrote that "a central repository of screening, referrals, and outcomes data will be maintained and depersonalized data made available for epidemiological evaluations" in his *March 30, 2007 Report.*

17. In his *June 1, 2011* report, Perrine / Dupont Claims Administrator Ed Gentle requested that this Court issue a ruling on whether a database maintained during the course of the medical monitoring program could provide depersonalized medical information to facilitate future scientific studies.

18. In response, this Court issued a *Briefing Schedule* for submissions regarding that issue.

19. In their submissions, the Plaintiffs' Representative and the guardian ad litem for the minor children and incompetent adults both advocated for making the database available for scientific studies. To support this notion, they suggested the following:

    a. that the database would better serve the Plaintiffs themselves by allowing for the authoring and distribution of summaries quantifying the observed effects, of any, of the toxic exposures to arsenic, cadmium, and lead; and

    b. that the database would be a substantially beneficial resource for the medical, scientific, business and legal communities by establishing a large database which could be utilized, in good faith, by researchers to evaluate the possible impacts of the toxic exposure to the Plaintiff class during the run of the Medical Monitoring Program.

20. The Defendant advocated against the maintenance of the database for future scientific research. It listed its reasons for doing so as follows:

a. there was no notification for the class claimants of the database,

b. the database was not a part of the settlement, and

c. the Claims Administrator failed to explain with specificity what was meant by "scientific research."

Analysis

The grounds shared by the Guardian Ad Litem and Plaintiffs' Representative on this matter are policy-based and simple to understand. The Defendant's assertions, however, are more specific and provide a better structure with which to frame this Court's reasoning. Accordingly, their grounds will be addressed in turn.

i. **Problems regarding a lack of notice to the plaintiffs regarding the disclosure of their depersonalized data can be dispelled using a consent form at a plaintiff's first monitoring appointment.**

The lion's share of the Defendant's argument is dedicated to the notion that, because no notification to the participants of the medical monitoring program to this date, test results cannot be retained for research purposes. It asserts that the option for the creation of a database has expired, and that now, it is simply "too late now" to ask the monitoring participants if they would consent to their depersonalized data to be used for such purposes. (*Defendant's Submission*, p. 9)

In support of that argument, the Defendant lists several opportunities that the Claims Administrator and Class Counsel might have mentioned the research database, beginning at the commencement of the medical monitoring program establishment process. It relies heavily on the fact that there was no indication at the onset of the program that data might have been used for scientific research.

It also relies on *Tolbert, et al. v. Monsanto Company, et al.*[1] in its assertion that that "claimant[s] should execute a written medical authorization [...] for the purpose of complying with the applicable laws relating to the use of medical information for research purposes and to facilitate certain studies and surveys that may be performed." *Id.* at par. 14.

This Court wholeheartedly agrees with this last assertion. Claimants *should* execute a written medical authorization for the purpose of complying with the applicable laws relating to the use of medical information for research purposes and to facilitate certain studies that may be performed. However, it disagrees with the Defendant in that it sees no reason why this authorization could not be obtained at the onset of the claimant's visits with medical monitoring professionals.

The Defendant asserts that the Plaintiffs "have not given appropriate notice of and information concerning the Medical Monitoring program's terms." (*Defendant's Submission*, p. 9). It states that the Plaintiffs should "have been so advised *prior* to signing up to participate such that they could make a fully informed decision." *Id.*

Again, this Court disagrees. It fails to see why the claimant, when presented with an authorization packet that informed them of the applicable laws, their statutory rights, and the purposes of the database could not make a rational and well-informed decision. Although some matters in this case are hugely complicated and would be outside of the domain of a laymen's understanding, this decision is not. The decision to make one's depersonalized information available for future research does not require any specialized degree of understanding. Claimants will be perfectly capable of making that decision

[1] *Tolbert, et al. v. Monsanto Company, et al.*, Dec 31, 2003 Order, N.D. Al. CA No. CV-01-C-C-1407-S)

when presented with sufficient information at their initial screenings or other first monitoring participatory visit.

That being said, this Court wants to emphasize to all parties involved that the claimant, before effectively consenting to his or her depersonalized information being used for research purposes, must be presented with sufficient information to make this decision. This information, alongside the authorization form, must give the claimant all the information he or she needs to possess the requisite knowledge to give informed consent pursuant to all applicable statutes and regulations.

ii. The maintenance of a medical monitoring database was anticipated and understood throughout the litigation process.

In its second argument, the Defendant asserts that the creation and maintenance of a medical monitoring program was not a part of the Perrine / Dupont settlement or part of the Medical Plan Order. However, the express writing of Dr. Werntz, the Plaintiff's expert, rebuts this notion:

> That a central repository of the screening, referrals, and outcomes data will be maintained, and depersonalized data made available for epidemiological evaluations. It is clear from my literature review in preparing this document that there is incomplete scientific evidence in the literature on screening programs, participation rates, referral rates, etc. This data could serve as the basis for answering many of these scientific questions.

This idea was reinforced by this Court's adoption of the medical monitoring plan envisioned by Dr. Werntz "in its entirety" in this Court's *Final Order Regarding the Scope, Duration, and Cost of the Medical Monitoring Plan*, entered February 25, 2008. Prior to its current *Submission*, the Defendant never made an objection or appeal to Dr. Werntz's idea of a database used for research. Furthermore, any modification of the

original entry of the Medical Plan Order or *Final Order Approving Settlement* did not affect Dr. Werntz's idea of a database used for research.

iii. The meaning of "scientific research" can be determined on a case-by-case basis by the Claims Administrator.

Instead of issuing a broad decree on what constitutes "scientific research," this Court finds it prudent for the Claims Administrator to make that determination on a case-by-case basis. Requests for such information contained in the database should only be given out after approval from the Claims Administrator, and this approval should be subject to objections by the Defendant. If such an objection is made, this Court will decide if such an objection shall be sustained.

This Court believes that the legitimacy of each request calls for a very subjective assessment. Therefore, a broad definition of what constitutes scientific research, or even a set of parameters that must be followed regarding database information distribution, would be clumsy and awkward if applied by this Court at this time. By approving requests on a case-by-case basis, they may be screened to ensure that they assist in a legitimate scientific or medical purpose.

Conclusion

Underlying this Court's current decision is the immense value that a database of this kind would provide to both the Plaintiffs and the scientific and medical community at large. Testimony in this case has already established that this field of study is barren of the kind of knowledge that the proposed database could provide.[2] This data could be tremendously helpful in assessing the sorts of harms, if any, that prolonged exposure to arsenic, cadmium, and lead can incur. It would also assist in determining the interplay

[2] See *Overall Medical Surveillance Assumptions*, Werntz, at 10.

between these potential harms and the medical monitoring process. Furthermore, any privacy concerns may be dealt with by a waiver. Because the benefits of such a database far outweigh the costs, it would be a mistake to neglect this opportunity.

Accordingly, it is **ORDERED** that the that the program database may be used to facilitate and assist in future scientific research so long as monitoring participants are informed of the database and its uses, and they explicitly consent to their unidentifiable information being used in this manner.

It is further **ORDERED** that the Claims Administrator of the Dupont / Perrine settlement shall determine, on a case-by-case basis, which requests for access to this database shall be granted. Access to the database should only be granted for legitimate scientific or medical purposes.

It is further **ORDERED** that this Court shall have jurisdiction over all objections stemming from requests for medical monitoring data.

Finally, it is **ORDERED** that the Clerk of this Court shall provide certified copies of this Order to the following:

Stephanie D. Thacker
David B. Thomas
Guthrie & Thomas, PLLC
500 Lee St. East, Suite 800
P.O. Box 3394
Charleston, WV 25333-3394

Virginia M. Buchanan
Levin, Papantonio, Thomas, Mitchell, Echner, Rafferty & Proctor, P.A.
316 S. Baylen St., Suite 400
Pensacola, FL 32502

Edgar C. Gentle, Claims Administrator
C/O Spelter Volunteer Fire Dept. Office
55 B St.
P.O. Box 257
Spelter, WV 26438

Meredith McCarthy, Esq.
901 W. Main St.
Suite 201
Bridgeport, WV 26330

J. Farrest Taylor, Esq.
Cochran, Cherry, Givens, Smith, Lane & Taylor P.C.
163 W. Main St.
Dothan, AL 36301

ENTER: August 24 2011

THOMAS A. BEDELL, Judge

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E.I. DU PONT DE NEMOURS AND COMPANY, et al.,

Defendants.

FINAL ORDER APPROVING CERTAIN ASPECTS OF SETTLEMENT ADMINISTRATION AND ESTABLISHING BRIEFING SCHEDULE FOR PRELIMINARILY RECOMMENDED OR UNRESOVLED MATTERS

Presently pending before the Court are:

(a) The second budget for the Medical Monitoring and Property Remediation Programs (for the twelve months beginning September 1, 2011 and ending August 31, 2012) submitted by the Claims Administrator on August 19, 2011;

(b) The Medical Monitoring Implementation Plan, with claimant testing to begin November 1, 2011 also submitted by the Claims Administrator on August 19, 2011;

(c) DuPont's August 19, 2011, Objection (the "DuPont Objection"); and

(d) The Claims Administrator's August 24, 2011, Supplemental Report addressing the DuPont Objection.

These four submissions are considered below.

I. THE SECOND BUDGET

Respecting the budget, the Court notes that it is divided into three parts: Property Remediation Fund, Medical Monitoring Fund Pre-Implementation Date Expenses, and Medical Monitoring Fund Post-Implementation Date Expenses, with this third portion of the budget to be funded by additional contributions from DuPont.

In the Claims Administrator's report submitted with the budget, the Claims Administrator has explained that the first two parts of the budget and the months of September and October 2011 for the third part have been finalized by the Claims Administrator, but that the months of November 2011 through August 2012 for the third part, being the final 10 months of the Post-Implementation Date Medical Monitoring Expense Budget during the budget year (the "Preliminary Medical Monitoring Budget" or the "Preliminary Budget"), is an estimate and has not been finalized because (i) the number of claimants participating in the Medical Monitoring Program is unknown, with the working estimate being 3,000, the best available estimate at this time; (ii) the Court has not decided whether the Medical Monitoring Program will include the storage of claimant test results for possible future research; and (iii) the Claims Administrator, in collaboration with CTIA, the Finance Committee and the Guardian Ad Litem for children, is still developing a CT Scan Utilization Guideline (the "CT Rule") for the Medical Monitoring Implementation Plan, with the report suggesting a briefing schedule respecting (i) the last 10 months of the budget year for the Medical Monitoring Plan

Post-Implementation Expense Budget; and (ii) the CT Rule under the Medical Monitoring Implementation Plan, so as to facilitate Claims Administrator preparation of his final recommendations on these matters to the Court by October 10, 2011, as outlined in this Order below. The DuPont Objection has raised additional unresolved issues respecting the Preliminary Budget, which the Claims Administrator, as noted in his Supplemental Report, should try to reasonably resolve with the Parties to the extent practicable, while keeping the implementation of Medical Monitoring on schedule under the Implementation Plan to begin testing on November 1, 2011. Not all of these factors will be resolved to finality when the budget is established, but the Claims Administrator shall do the best he can under the circumstances to prepare a budget fair to DuPont and to implement Medical Monitoring testing as soon as practicable in fairness to the Class.

The Claims Administrator's budget contemplates, however, that DuPont shall make a small additional contribution of $26,524.57 by August 31, 2011 (the "Bridge Funding"), to fund the Medical Monitoring Expenses to be incurred by CTIA, the Court approved Medical Monitoring Third Party Administrator ("TPA"), under the Court approved TPA contract, in September and October 2011, and that the Post-Implementation Date DuPont contribution for November 2011 through August 2012, now preliminarily estimated by the Claims Administrator to be $3,928,210.82, will be finalized in a supplemental submission by the Claims Administrator to the Court by October 10, 2011, and to be funded by DuPont by October 31, 2011. The DuPont Objection, however, takes issue with its payment of the Bridge Funding, contending that

it is a Pre-Implementation Date Medical Monitoring Expense that has already been paid by DuPont. This issue will be resolved at the hearing described below, with the Claims Administrator to pay the Bridge Funding expenses from current Medical Monitoring Fund monies, and with the Court, as suggested in the Claims Administrator's Supplemental Report, to decide at a later date whether they should or should not be reimbursed by DuPont.

After a careful review of the second Settlement budget, and in consideration of the applicable law, the Court **ORDERS** that the same is hereby **APPROVED** with respect to (i) the Property Remediation Fund; (ii) the Medical Monitoring Fund Pre-Implementation Date Expenses; and (iii) the small September and October 2011 $26,524.57 Bridge Funding parts and shall be used in administration of the Settlement. The Bridge Funding shall be paid from DuPont's initial deposit into the Medical Monitoring Fund, with the Court to decide following the hearing described below, if DuPont will or will not reimburse the Medical Monitoring Fund for such payments. The Preliminary Medical Monitoring Budget Post-Implementation Date Expense component for November 2011 through August 2012 shall be finalized by the Claims Administrator as described above, following the briefing by the parties scheduled below, and subject to a subsequent hearing described below.

II. THE MEDICAL MONITORING IMPLEMENTATION PLAN

The Medical Monitoring Implementation Plan consists of a proposed logo, definitions of "active" and "inactive" claimant for purposes of the TPA Contract previously approved by the Court, procedures involving "no" minor claimant when they

become adults, and when an "inactive" claimant can be "active" for Medical Monitoring, a suggested list of Medical Providers, an Implementation Time Line, and a proposed CT Scan Protocol, which contemplates that the preliminary CT Rule will be shared by the Claims Administrator with the Court and the Parties, by September 1, 2011. In addition, the August 24, 2011 Supplemental Report notes that DuPont would like the opportunity to have the Court review the Claims Administrator's suggested procedure on how to handle "no" box minor Medical Monitoring claimants when they become adults and when may an "inactive" Medical Monitoring claimant become "active" (the "Minor No-Inactive Claimant Rules").

After a careful review of the Medical Monitoring Implementation Plan, and a consideration of the applicable law, the Court **ORDERS** that the components of the Medical Monitoring Implementation Plan, other than the yet-to-be developed CT Rule and the Minor No-Inactive Claimant Rules, are hereby **APPROVED** and shall be used in the administration of the Settlement.

III. BRIEFING SCHEDULE ON PRELIMINARILY RECOMMENDED AND UNRESOLVED MATTERS

The Claims Administrator, after further collaboration, shall share with the Court and the Parties by September 1, 2011 (i) a revised Preliminary Budget reasonably accommodating the DuPont Objection; and (ii) the preliminary CT Rule. Within 20 days thereafter, DuPont, Class Counsel, the Guardian Ad Litem for children, or any other interested Parties, may submit comments, briefs or factual evidence to the Court and the Claims Administrator, for consideration, respecting (i) the Preliminary Budget; and/or

(ii) the Claim's Administrator's preliminarily recommended CT Rule in the Medical Monitoring Implementation Plan; and/or (iii) the Minor No-Inactive Claimant Rules. Thereafter, DuPont, Class Counsel, the Guardian Ad Litem, or any other interested Parties, whether or not they initially sought Claims Administrator consideration, may reply to any such consideration submission made to the Court and the Claims Administrator within 10 days thereafter.

The Court contemplates that it will make a determination on whether the Medical Monitoring Program is to store Medical Monitoring test results for possible scientific research prior to October 1, 2011.

By October 10, 2011, the Claims Administrator, after considering the submissions of the Finance Committee, the Guardian Ad Litem for children and all other interested parties, and using the best evidence available to him at the time, shall submit his final recommendations to the Court respecting: (i) the November 2011 through August 2012 portion of the Medical Monitoring Fund Post-Implementation Date Budget; (ii) the CT Rule under the Medical Monitoring Implementation Plan; and (iii) the Minor No-Inactive Claimant Rules..

The Court will then set down for a hearing (i) the question of whether DuPont shall or shall not reimburse the Medical Monitoring Fund for the Bridge Funding; (ii) the November 1, 2011 through August 31, 2012 portion of the Medical Monitoring Fund Post-Implementation Date Budget; and (iii) the CT Rule under the Medical Monitoring Plan; and (iv) the Minor No-Inactive Claimant Rule.

Lastly, pursuant to Rule 54(b) of the West Virginia Rules of Civil Procedure, the Court directs entry of this Order as a Final Order as to the claims and issues above upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

IT IS SO ORDERED.

The Clerk of this Court shall provide certified copies of this order to the following:

Stephanie Thacker, Esq.
Guthrie & Thomas, PLLC
500 Lee St., East, Suite 800
P.O. Box 3394
Charleston, WV 25333-3394
DuPont's Finance Committee Representative

Virginia Buchanan, Esq.
Levin, Papantonio, Thomas, Mitchell,
Rafferty & Proctor, P.A.
P.O. Box 12308
Pensacola, FL 32591
Plaintiffs' Finance Committee Representative

Meredith McCarthy, Esq.
Guardian Ad Litem for Children
901 W. Main St.
Bridgeport, WV 26330
Guardian Ad Litem for Children

Edgar C. Gentle, III, Esq.
Gentle, Turner, & Sexton
55 B Street
P.O. Box 257
Spelter, WV 26438
Special Master and Claims Administrator

Order Prepared By:

Edgar C. Gentle, III, Claims Administrator
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438

Michael A. Jacks, Esq.
W. Va. Bar No. 1044
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438

ENTER: August 31, 2011

Thomas A. Bedell, Circuit Judge

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al.,

Plaintiffs,

v.

Case No. 04-C-296-2
Judge Thomas A. Bedell

E. I. DUPONT DE NEMOURS & COMPANY, et al.,

Defendants.

ORDER ESTABLISHING MEDICAL MONITORING PROGRAM PRELIMINARY OPTIONAL DATA COLLECTION CONSENT AND CT SCAN VERIFICATION FORMS BRIEFING SCHEDULE

Presently before the Court is the Claims Administrator's September 20, 2011 Report to the Court submitting preliminary versions of the following two forms, together with their manner of use in the Medical Monitoring Program, which needs to be finalized for the Medical Monitoring Program, and were developed by the Claims Administrator following input from the Finance Committee and the Guardian Ad Litem for children: (i) Preliminary Medical Monitoring Program Scientific and Health Data Collection Claimant Consent Form; and (ii) Preliminary Medical Monitoring Program Physician CT Scan Verification Form (collectively, the "Two Forms"). In order to facilitate the Court's finalization of these Two Forms and their manner of use in the Medical Monitoring Program, DuPont, the Class Representative on the Finance Committee, the Guardian Ad Litem for Children, and all other interested Parties are invited to submit briefs on the Two Forms and their manner of use in the Medical Monitoring Program, to the Court and the Claims Administrator in accordance with the following schedule:

Within fourteen (14) days of the date of this Order, DuPont, the Class Representative on the Finance Committee, the Guardian Ad Litem for Children, and all other interested Parties may make

a submission respecting either or both forms and their manner of use in the Medical Monitoring Program.

By October 10, 2011, the Claims Administrator, after considering any such submissions, shall submit his final proposed Two Forms and their manner of use in the Medical Monitoring Program to the Court. After considering the submissions of the Claims Administrator and the parties, the Court will either schedule a hearing and subsequently rule upon this matter or render a decision based upon the submissions when no further information is available to aid the Court in making its ruling.

Lastly, pursuant to Rule 54(b) of the West Virginia Rules of Civil Procedure, the Court directs entry of this Order as a Final Order as to the claims and issues above upon an express determination that there is no just reason or delay and upon an express direction for the entry of judgment.

IT IS SO ORDERED.

The Clerk of this Court shall provide certified copies of this Order to the following:

Stephanie Thacker, Esq.
Allen, Guthrie & Thomas, PLLC
P.O. Box 3394
Charleston, WV 25333-3394
DuPont's Finance Committee Representative

Meredith McCarthy
Guardian Ad Litem for Children
901 W. Main St.
Bridgeport, WV

Virginia Buchanan, Esq.
Levin, Papantonio, Thomas, Mitchell
Rafferty & Proctor, P.A.
P.O. Box 12308
Pensacola, FL 32591
Plaintiffs' Finance Committee Representative

Edgar C. Gentle, III, Esq.
Claims Administrator
Michael Jacks, Esq.
Gentle, Turner & Sexton
P.O. Box 257
Spelter, WV 26438

ENTER: September 21, 2011

THOMAS A. BEDELL, Judge

STATE OF WEST VIRGINIA
COUNTY OF HARRISON, TO-WIT:

I, Donald L. Kopp II, Clerk of the Fifteenth Judicial Circuit and the 18th Family Court Circuit of Harrison County, West Virginia, hereby certify the foregoing to be a true copy of the ORDER entered in the above styled action on the 21st day of September, 2011.

IN TESTIMONY WHEREOF, I hereunto set my hand and affix Seal of the Court this 21st day of September, 2011.

Donald L. Kopp, II
Fifteenth Judicial Circuit & 18th Family Court
Circuit Clerk
Harrison County, West Virginia

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E.I. DU PONT DE NEMOURS AND COMPANY, et al.,

Defendants.

ORDER SETTING HEARING ON THE IMPLEMENTATION OF THE MEDICAL MONITORING PROGRAM

Presently before the Court are several unresolved issues related to the implementation of the Medical Monitoring Program, including but not limited to the CT Rule, the Unresolved Budget, the "Active Claimant" definition, and forms to be used by physicians related to the CT Rule and potential future scientific research.

In order to allow the Parties to be heard on these issues and all other issues related to the implementation of the Medical Monitoring Program, the Court hereby sets a hearing on **October** 17, **2011, at** 10:00 **o'clock** am/pm, and said hearing shall be held before the Honorable Thomas A. Bedell, Judge of the Circuit Court of Harrison County, West Virginia, in the Division 2 Courtroom located on the 4th Floor of the Harrison County Courthouse, 301 West Main Street, Clarksburg, West Virginia.

1) cc Dan Bratt - via email
Lopez Mr. Gladee
Jubal Watts

2/ 4609-1-88

3/ 4609-1 [illegible]

4) [illegible] - put on website

5/ inbox

IT IS SO ORDERED.

Finally, it is **ORDERED** that the Clerk of this Court shall provide certified copies of this Order to the following:

David B. Thomas
James S. Arnold
Stephanie Thacker
Guthrie & Thomas, PLLC
P.O. Box 3394
Charleston, WV 25333-3394

Meredith McCarthy
901 W. Main St.
Bridgeport, WV 26330
Guardian ad litem

Edgar Gentle, III
Michael Jacks
Settlement Claims Office
P.O. Box 257
Spelter, WV 26438
Special Master

J. Farrest Taylor
Cochran, Cherry, Givens, Smith,
Lane & Taylor, P.C.
163 West Main St.
Dothan, AL 36301

Virginia Buchanan
Levin, Papantonio, Thomas, Mitchell
Eshsner & Proctor, P.A.
316 South Baylen St., Suite 600
Pensacola, FL 32502-5996

This Order Prepared By:

Edgar C. Gentle, III, Esq.
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438
Claims Administrator

Michael A. Jacks, Esq.
W. Va. Bar No. 11044
P.O. Box 257
Spelter, WV 26438

ENTER: September 29, 2011

Thomas A. Bedell, Circuit Judge

STATE OF WEST VIRGINIA
COUNTY OF HARRISON, TO-WIT:

I, Donald L. Kopp II, Clerk of the Fifteenth Judicial Circuit and the 18th Family Court Circuit of Harrison County, West Virginia, hereby certify the foregoing to be a true copy of the ORDER entered in the above styled action on the 29 day of September, 2011.

IN TESTIMONY WHEREOF, I hereunto set my hand and affix Seal of the Court this 29 day of September, 2011.

Donald L Kopp II

Fifteenth Judicial Circuit & 18th Family Court
Circuit Clerk
Harrison County, West Virginia

II.

A. Preliminary Data Collection Consent Form;

THE PERRINE MEDICAL MONITORING PROGRAM
A PRODUCT OF THE PERRINE DUPONT SETTLEMENT
OPTIONAL CLAIMANT AUTHORIZATION OF LIMITED ANONYMOUS DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR POSSIBLE SCIENTIFIC AND HEALTH RESEARCH

I authorize the disclosure of my protected health information,[1] or the protected health information for _____ (minor child), as described below. This authorization is voluntary and made because I want this information to be released for possible scientific and health research as described below. **I understand that the Claims Administrator will take reasonable measures to protect the information, but it is possible that the information which is being released may be sent to an individual or entity (described below) which may not be subject to federal or state privacy laws and may be later disclosed again by that individual or entity and no longer be protected.** I understand that I do not have to sign this form, and that signing this form is not a condition to enrollment in The Perrine Medical Monitoring Program a product of the Perrine DuPont Settlement.

1. I authorize the following person(s) and/or organization(s) (specified below) to disclose my protected health information:

   ED GENTLE
   CLAIMS ADMINISTRATOR
   THE PERRINE MEDICAL MONITORING PROGRAM, A PRODUCT OF THE PERRINE DUPONT SETTLEMENT
   P.O. Box 257
   Spelter, WV 26438
   (800) 345-0837
   www.perrinedupont.com

2. I authorize the following person(s) and/or organization(s) to receive my protected health information, as disclosed by the person(s) and/or organization(s) above:

   The Perrine Medical Monitoring Program, c/o the Claims Administrator

---

[1]Protected health information means health information, that identifies a person, and which relates to that person's 1) past, present, or future physical or mental health or condition; 2) the provision of health care to that person; or 3) the past, present, or future payment for the provision of health care to that person. 45 C.F.R. § 164.501. Here, the protected health information will be the results of medical tests, physical examinations, and the collection of medical histories in the Perrine Medical Monitoring Program.

The Circuit Court of Harrison County, West Virginia
Judge Thomas A. Bedell
Any and All Special Masters Appointed By the Circuit Court of Harrison County, West Virginia, Who Work On or With the Perrine DuPont Settlement

3. I authorize the following person(s) and/or organization(s) to receive my depersonalized protected health information, with unique identifiers instead of individual information as disclosed by the person(s) and/or organization(s) above, if so ordered by the Court (with any and all information that would permit the identification of the subject of the test and the use of unique identifiers in place of such identifying information. My name, address, and social security number shall not be disclosed under any circumstances to the person(s) or organization(s) identified in paragraph 3).

Meredith McCarthy - Current Guardian Ad Litem for the Minor Plaintiffs in the Perrine DuPont Settlement
Any Other Guardian Ad Litem for Minor Plaintiffs in the Perrine DuPont Settlement
Plaintiffs' Counsel and Plaintiffs' Liaison Counsel in connection with the Perrine DuPont Settlement
Research Departments of Accredited (as determined by the Court) Universities and Colleges
Research Department of Accredited (as determined by the Court) Research Hospitals and Medical Institutions
E. I. DuPont DeNemours and Company
The United States of America and any department or agency or service thereof
The State of West Virginia and any department or agency or service thereof
The United States Environmental Protection Agency
The United States Food and Drug Administration
The United States Occupational Safety and Health Administration
The World Health Organization
Environmental Protection Agency
Agency for Toxic Substances and Disease Registry
Centers for Disease Control
United States Department of Health and Human Services
National Health and Nutrition Examination Survey
National Institutes of Health

4. I direct that all protected health information that may be in the possession of the CLAIMS ADMINISTRATOR, THE PERRINE MEDICAL MONITORING PROGRAM (the "Claims Administrator") may be disclosed, released, revealed, and otherwise given to all person(s) and/or organization(s) identified in number 2 above. In addition, I specifically direct that the following information may be disclosed, released, revealed, and otherwise given to those person(s) and/or organization(s) identified in number 3 above:

Depersonalized, with unique identifiers instead of individual information, samples, reports, results, diagnoses, findings, and other depersonalized information obtained from the Perrine Medical Monitoring Program.

5. The additional specific reason and purpose for the disclosure as described above is as follows:

To allow the individuals, institutions and organizations named in section 2 to facilitate and 3 above to facilitate and to engage in scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, possible or alleged prolonged exposure to arsenic, cadmium, zinc and lead in Spelter, West Virginia, and like areas, and other scientific and health studies and purposes.

6. I understand that I may revoke this authorization in writing at any time, except to the extent that the person(s) and or organization(s) named above have taken action in reliance on this authorization. This authorization may be revoked through a letter stating my name, address, telephone number, date of birth, and social security number, along with the following statement or similar statement: "I wish to revoke the AUTHORIZATION OF DISCLOSURE OF PROTECTED HEALTH INFORMATION which I signed and gave to your office." I must then sign the letter and date it, and have my signature witnessed. Then mail the letter to the following address:

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(800) 345-0837
www.perrinedupont.com

After the Claims Administrator receives my signed and witnessed letter, in the proper format, his office will notify me by phone or letter and confirm that my consent has been revoked.

7. I understand that I may inspect or copy my protected health information to be used and/or disclosed, as long as said information is in the possession of the Claims Administrator. I also understand that I have no right to inspect or copy the following: 1) psychotherapy notes; 2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and 3) protected health information in the possession of the Claims Administrator to which federal law prohibits my access.

8. I understand that I may refuse to sign this authorization.

9. I understand that the Claims Administrator is creating information for the purpose, in whole or in part, of scientific or health research. I understand that the extent to which the information will be used to carry out the Medical Monitoring Program, includes: using my PHI (as authorized in section 4 above), to further scientific or health research into the human health effects of prolonged potential, alleged or possible contamination of arsenic, cadmium, zinc, and lead in Spelter, West Virginia. In addition, this PHI may be used to investigate other sites and compare contamination in those sites as well, and treat other individuals exposed to similar

contamination. I understand that this PHI could be used for scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, alleged or possible contamination in Spelter, West Virginia, and like areas, and other scientific studies and purposes. I also understand that it could be used by other entities to aid in preventing other types of contamination, or treating other types of contamination or sickness. It might also be used solely for statistical purposes or any other purpose deemed useful by the individuals, institutions, or organizations named in section 3.

10. I understand that no protected health information will be used or disclosed unless I agree to such disclosure herein.

11. I understand that the statements made in this document are binding.

I understand and acknowledge that the Perrine Medical Monitoring Program does not include any provision for the funding of any of the potential scientific research, studies, investigations or other programs outlined in this disclosure and that this authorization does not create any expectation by me or by the medical monitoring class or any obligation on the part of DuPont or the Claims Administrator for DuPont or the Claims Administrator to provide any money to support such programs.

I have had the opportunity to read and consider the contents of this authorization. I confirm that the contents are consistent with my direction. I have been given a copy of this authorization.

_____ _____

Signed Date

Print Name: _____

Address: _____

Telephone: _____

D.O.B.: _____

Social Security Number: _____

☐ Check here if Social Security number is for a minor child

_____

Relationship or Authority of Personal Representative (if applicable)

(If you have signed this form as a personal representative of the individual whose personal health information is being released, state your relationship to the individual, or your authority for signing for the individual here.)

II.

B. Redlined Revisions Recommended by the Guardian Ad Litem; and

THE PERRINE MEDICAL MONITORING PROGRAM
A PRODUCT OF THE PERRINE DUPONT SETTLEMENT
OPTIONAL CLAIMANT AUTHORIZATION OF LIMITED ANONYMOUS DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR POSSIBLE SCIENTIFIC AND HEALTH RESEARCH

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1. I authorize the following person(s) and/or organization(s) (specified below) to disclose my protected health information:

   ED GENTLE
   CLAIMS ADMINISTRATOR
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   P.O. Box 257
   Spelter, WV 26438
   (800) 345-0837
   www.perrinedupont.com

2. I authorize the following person(s) and/or organization(s) to receive my protected health information, as disclosed by the person(s) and/or organization(s) above:

---

[1]Protected health information means health information, that identifies a person, and which relates to that person's 1) past, present, or future physical or mental health or condition; 2) the provision of health care to that person; or 3) the past, present, or future payment for the provision of health care to that person. 45 C.F.R. § 164.501. Here, the protected health information will be the results of medical tests, physical examinations, and the collection of medical histories in the Perrine Medical Monitoring Program.

The Perrine Medical Monitoring Program, c/o the Claims Administrator
The Circuit Court of Harrison County, West Virginia
Judge Thomas A. Bedell
Any and All Special Masters Appointed By the Circuit Court of Harrison County, West Virginia, Who Work On or With the Perrine DuPont Settlement

3. I authorize the following person(s) and/or organization(s) to receive my depersonalized protected health information, with unique identifiers instead of individual information as disclosed by the person(s) and/or organization(s) above, if so ordered by the Court (with any and all information that would permit the identification of the subject of the test and the use of unique identifiers in place of such identifying information. My name, address, and social security number shall not be disclosed under any circumstances to the person(s) or organization(s) identified in paragraph 3).

Meredith McCarthy - Current Guardian Ad Litem for the Minor Plaintiffs in the Perrine DuPont Settlement
Any Other Guardian Ad Litem for Minor Plaintiffs in the Perrine DuPont Settlement
Plaintiffs' Counsel and Plaintiffs' Liaison Counsel in connection with the Perrine DuPont Settlement
Research Departments of Accredited (as determined by the Court) Universities and Colleges
Research Department of Accredited (as determined by the Court) Research Hospitals and Medical Institutions
E. I. DuPont DeNemours and Company
The United States of America and any department or agency or service thereof
The State of West Virginia and any department or agency or service thereof
The United States Environmental Protection Agency
The United States Food and Drug Administration
The United States Occupational Safety and Health Administration
The World Health Organization
Environmental Protection Agency
Agency for Toxic Substances and Disease Registry
Centers for Disease Control
United States Department of Health and Human Services
National Health and Nutrition Examination Survey
National Institutes of Health

4. I direct that all protected health information that may be in the possession of the CLAIMS ADMINISTRATOR, THE PERRINE MEDICAL MONITORING PROGRAM (the "Claims Administrator") may be disclosed, released, revealed, and otherwise given to all person(s) and/or organization(s) identified in number 2 above. In addition, I specifically direct that the following information may be disclosed, released, revealed, and otherwise given to those person(s) and/or organization(s) identified in number 3 above:

Depersonalized, with unique identifiers instead of individual information, samples, reports, results, diagnoses, findings, and other depersonalized information obtained from the Perrine Medical Monitoring Program.

5. The additional specific reason and purpose for the disclosure as described above is as follows:

To allow the individuals, institutions and organizations named in sections 2 ~~to facilitate~~ and 3 above to facilitate and to engage in scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, possible or alleged prolonged exposure to arsenic, cadmium, zinc and lead in Spelter, West Virginia, and like areas, and other scientific and health studies and purposes.

6. I understand that I may revoke this authorization in writing at any time, except to the extent that the person(s) and or organization(s) named above have taken action in reliance on this authorization. This authorization may be revoked through a letter stating my name, address, telephone number, date of birth, and social security number, along with the following statement or similar statement: "I wish to revoke the AUTHORIZATION OF DISCLOSURE OF PROTECTED HEALTH INFORMATION which I signed and gave to your office." I must then sign the letter and date it, and have my signature witnessed. Then mail the letter to the following address:

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P.O. Box 257
Spelter, WV 26438
(800) 345-0837
www.perrinedupont.com

After the Claims Administrator receives my signed and witnessed letter, in the proper format, his office will notify me by phone or letter and confirm that my consent has been revoked.

7. I understand that I may inspect or copy my protected health information to be used and/or disclosed, as long as said information is in the possession of the Claims Administrator. I also understand that I have no right to inspect or copy the following: 1) psychotherapy notes; 2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and 3) protected health information in the possession of the Claims Administrator to which federal law prohibits my access.

8. I understand that I may refuse to sign this authorization.

9. I understand that the Claims Administrator is creating information for the purpose, in whole or in part, of scientific or health research. I understand that the extent to which the information will be used to carry out the Medical Monitoring Program, includes: using my ~~PHI~~rotected Health Information (as authorized in section 4 above), to further scientific or health research into the human health effects of prolonged potential, alleged or possible contamination of arsenic, cadmium, zinc, and lead in Spelter, West Virginia. In addition, this ~~PHI~~rotected Health Information may be used to investigate other sites and compare contamination in those sites as

well, and treat other individuals exposed to similar contamination. I understand that this PHIrotected Health Information could be used for scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, alleged or possible contamination in Spelter, West Virginia, and like areas, and other scientific studies and purposes. I also understand that it could be used by other entities to aid in preventing other types of contamination, or treating other types of contamination or sickness. It might also be used solely for statistical purposes or any other purpose deemed useful by the individuals, institutions, or organizations named in section 3.

10. I understand that no protected health information will be used or disclosed unless I agree to such disclosure herein.

11. I understand that the statements made in this document are binding.

I understand and acknowledge that the Perrine Medical Monitoring Program does not include any provision for the funding of any of the potential scientific research, studies, investigations or other programs outlined in this disclosure and that this authorization does not create any expectation by me or by the medical monitoring class or any obligation on the part of Plaintiffs Counsel, DuPont or the Claims Administrator ~~for DuPont or the Claims Administrator~~ to provide any money to support such programs.

I have had the opportunity to read or have had this document read to me, and have considered the contents of this authorization. I confirm that the contents are consistent with my direction. I have been given a copy of this authorization.

_____ _____

Signed Date

Print Name: _____

Address: _____

Telephone: _____

D.O.B.: _____

Social Security Number: _____

☐ Check here if Social Security number is for a minor child

_____

Relationship or Authority of Personal Representative (if applicable)

(If you have signed this form as a personal representative of the individual whose personal health information is being released, state your relationship to the individual, or your authority for signing for the individual here.)

II.

C. Proposed Final Data Collection Consent Form

THE PERRINE MEDICAL MONITORING PROGRAM
A PRODUCT OF THE PERRINE DUPONT SETTLEMENT
OPTIONAL CLAIMANT AUTHORIZATION OF LIMITED ANONYMOUS DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR POSSIBLE SCIENTIFIC AND HEALTH RESEARCH

I authorize the disclosure of my protected health information,[1] or the protected health information for _____ (minor child/incompetent adult), as described below. This authorization is voluntary and made because I want this information to be released for possible scientific and health research as described below. **I understand that the Claims Administrator will take reasonable measures to protect the information, but it is possible that the information which is being released may be sent to an individual or entity (described below) which may not be subject to federal or state privacy laws and may be later disclosed again by that individual or entity and no longer be protected.** I understand that I do not have to sign this form, and that signing this form is not a condition to enrollment in The Perrine Medical Monitoring Program a product of the Perrine DuPont Settlement.

1. I authorize the following person(s) and/or organization(s) (specified below) to disclose my protected health information:

   ED GENTLE
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   P.O. Box 257
   Spelter, WV 26438
   (800) 345-0837
   www.perrinedupont.com

2. I authorize the following person(s) and/or organization(s) to receive my protected health information, as disclosed by the person(s) and/or organization(s) above:

_____

[1]Protected health information means health information, that identifies a person, and which relates to that person's 1) past, present, or future physical or mental health or condition; 2) the provision of health care to that person; or 3) the past, present, or future payment for the provision of health care to that person. 45 C.F.R. § 164.501. Here, the protected health information will be the results of medical tests, physical examinations, and the collection of medical histories in the Perrine Medical Monitoring Program.

The Perrine Medical Monitoring Program, c/o the Claims Administrator
The Circuit Court of Harrison County, West Virginia
Judge Thomas A. Bedell
Any and All Special Masters Appointed By the Circuit Court of Harrison County, West Virginia, Who Work On or With the Perrine DuPont Settlement

3. I authorize the following person(s) and/or organization(s) to receive my depersonalized protected health information, with unique identifiers instead of individual information as disclosed by the person(s) and/or organization(s) above, if so ordered by the Court (with any and all information that would permit the identification of the subject of the test and the use of unique identifiers in place of such identifying information. My name, address, and social security number shall not be disclosed under any circumstances to the person(s) or organization(s) identified in paragraph 3).

Meredith McCarthy - Current Guardian Ad Litem for the Minor Plaintiffs in the Perrine DuPont Settlement
Any Other Guardian Ad Litem for Minor Plaintiffs in the Perrine DuPont Settlement
Plaintiffs' Counsel and Plaintiffs' Liaison Counsel in connection with the Perrine DuPont Settlement
Research Departments of Accredited (as determined by the Court) Universities and Colleges
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The United States of America and any department or agency or service thereof
The State of West Virginia and any department or agency or service thereof
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Environmental Protection Agency
Agency for Toxic Substances and Disease Registry
Centers for Disease Control
United States Department of Health and Human Services
National Health and Nutrition Examination Survey
National Institutes of Health

4. I direct that all protected health information that may be in the possession of the CLAIMS ADMINISTRATOR, THE PERRINE MEDICAL MONITORING PROGRAM (the "Claims Administrator") may be disclosed, released, revealed, and otherwise given to all person(s) and/or organization(s) identified in number 2 above. In addition, I specifically direct that the following information may be disclosed, released, revealed, and otherwise given to those person(s) and/or organization(s) identified in number 3 above:

Depersonalized, with unique identifiers instead of individual information, samples, reports, results, diagnoses, findings, and other depersonalized information obtained from the Perrine Medical Monitoring Program.

5. The additional specific reason and purpose for the disclosure as described above is as follows:

To allow the individuals, institutions and organizations named in sections 2 and 3 above to facilitate and to engage in scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, possible or alleged prolonged exposure to arsenic, cadmium, zinc and lead in Spelter, West Virginia, and like areas, and other scientific and health studies and purposes.

6. I understand that I may revoke this authorization in writing at any time, except to the extent that the person(s) and or organization(s) named above have taken action in reliance on this authorization. This authorization may be revoked through a letter stating my name, address, telephone number, date of birth, and social security number, along with the following statement or similar statement: "I wish to revoke the AUTHORIZATION OF DISCLOSURE OF PROTECTED HEALTH INFORMATION which I signed and gave to your office." I must then sign the letter and date it, and have my signature witnessed. Then mail the letter to the following address:

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7. I understand that I may inspect or copy my protected health information to be used and/or disclosed, as long as said information is in the possession of the Claims Administrator. I also understand that I have no right to inspect or copy the following: 1) psychotherapy notes; 2) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding; and 3) protected health information in the possession of the Claims Administrator to which federal law prohibits my access.

8. I understand that I may refuse to sign this authorization.

9. I understand that the Claims Administrator is creating information for the purpose, in whole or in part, of scientific or health research. I understand that the extent to which the information will be used to carry out the Medical Monitoring Program, includes: using my Protected Health Information (as authorized in section 4 above), to further scientific or health research into the human health effects of prolonged potential, alleged or possible contamination of arsenic, cadmium, zinc, and lead in Spelter, West Virginia. In addition, this Protected Health Information may be used to investigate other sites and compare contamination in those sites as

well, and treat other individuals exposed to similar contamination. I understand that this Protected Health Information could be used for scientific research, studies, investigations, environmental evaluations and comparisons, statistical analysis, and the development of programs to further understanding regarding the health effects of the potential, alleged or possible contamination in Spelter, West Virginia, and like areas, and other scientific studies and purposes. I also understand that it could be used by other entities to aid in preventing other types of contamination, or treating other types of contamination or sickness. It might also be used solely for statistical purposes or any other purpose deemed useful by the individuals, institutions, or organizations named in section 3.

10. I understand that no protected health information will be used or disclosed unless I agree to such disclosure herein.

11. I understand that the statements made in this document are binding.

I understand and acknowledge that the Perrine Medical Monitoring Program does not include any provision for the funding of any of the potential scientific research, studies, investigations or other programs outlined in this disclosure and that this authorization does not create any expectation by me or by the medical monitoring class or any obligation on the part of Plaintiffs Counsel, DuPont or the Claims Administrator to provide any money to support such programs.

I have had the opportunity to read or have had this document read to me, and have considered the contents of this authorization. I confirm that the contents are consistent with my direction. I have been given a copy of this authorization.

_____ _____

Signed Date

Print Name: _____

Address: _____

Telephone: _____

D.O.B.: _____

Social Security Number: _____

☐ Check here if Social Security number is for a minor child

_____

Relationship or Authority of Personal Representative (if applicable)

(If you have signed this form as a personal representative of the individual whose personal health information is being released, state your relationship to the individual, or your authority for signing for the individual here.)

III. Preliminary Minor No-Inactive Claimant Rules

2. Suggested definition of "active" and "inactive" claimant for purposes of Third Party Administrator Contract and how to handle "no" box minor claimants when they become adults and when may an "inactive" claimant become "active";

Definition of Active Claimant and Procedure for Assessing the Active Claimant Charge

Active Claimant is defined as a Claims Administrator Verified Medical Monitoring Class Member who checked the Medical Monitoring yes box or who is otherwise determined by the Court (such as in connection with a Minor Claimant) to be a Verified Registrant, who is not declared inactive as described below.

The per Active Claimant Charge in Exhibit G of this Agreement shall be computed, assessed and charged on the first day of each calendar month following the approval date of this Agreement and until this Agreement is terminated, based on the number of Active Claimants at that time. As explained further in the next paragraph, an Active Claimant shall be active unless declared inactive. Thus, for purposes of computing this charge, the number of Active Claimants shall be those previously found to be active that have not been found inactive at the time the charge is assessed.

An Active Claimant shall be active until declared inactive, and shall be declared inactive on the first day of the calendar month succeeding the time that the Claimant first either (i) notifies the Claims Administrator or CTIA that the Claimant no longer wishes to participate in the Medical Monitoring Program; or (ii) fails to schedule or show up for a given Medical Monitoring appointment after CTIA or the Provider tries to set up the appointment through correspondence 3 times; or (iii) is first discovered by CTIA to be deceased. The 3 times described in (ii) above is appropriate, as Medical Monitoring is an important right. Neither CTIA nor the Claims Administrator has a duty to monitor when a Claimant becomes deceased. However, CTIA and the Claims Administrator shall timely provide each other any notice they receive of a Claimant being deceased. The Claims Administrator, at the expense of the Medical Monitoring Program, and therefore DuPont, may periodically conduct a deceased Claimant Internet search, if agreed to by the Finance Committee. The frequency of such searches shall be determined by the Finance Committee. However, CTIA, having no duty to monitor when an Active Claimant dies, shall have no duty to reimburse the Settlement if it is later determined that an Active Claimant died.

The Claims Administrator, in collaboration with the Finance Committee, shall attempt to determine if an inactive Claimant can become active again in the future, and, if so, under what circumstances, by the end of July 2011. If this effort fails, the Court shall determine this issue.

Attached is an example of how the Active Claimant Charge would be applied if we started with 3,000 Claimants and experienced the Active Claimant attrition rate projected by the expert report of Dr. Michael Brookshire. Also included is an overall projection of CTIA Administrative Fees for the first five years of the Medical Monitoring Program. This additional projection is non-binding, and is being submitted solely for the purpose of facilitating budgeting for the Medical Monitoring Program.

The Active Claimant rate will be revisited after 3 years.

PERRINE DUPONT SETTLEMENT CLAIMS OFFICE
ATTN: EDGAR C. GENTLE, CLAIMS ADMINISTRATOR
C/O SPELTER VOLUNTEER FIRE DEPARTMENT OFFICE
55 B Street
P. O. BOX 257
Spelter, West Virginia 26438
(304) 622-7443
(800) 345-0837
www.perrinedupont.com
perrinedupont@gtandslaw.com

MEMORANDUM

BY E-MAIL
CONFIDENTIAL

TO: Virginia Buchanan, Esq.
Stephanie D. Thacker, Esq.
Meredith McCarthy, Esq.

FROM: Edgar C. Gentle, III, Esq.

DATE: July 21, 2011

RE: Perrine v. DuPont Settlement - Medical Monitoring Plan Design; Our File No. 4609-1 (GG)

Dear Virginia, Stephanie and Meredith:

I hope that you are well.

To update you on the "No" Minor Claimant issue, of the 285 Verified Registrant Minors, 41 have the "No" box checked.

As you know, in accordance with the undersigned's "active" claimant report to the Court in connection with the Third Party Administrator ("TPA") contract, we are to attempt to agree on the circumstances under which an inactive claimant is considered active for purposes of the Medical Monitoring Program (and by definition for purposes of TPA billing).

Below is a draft for your consideration:

REACTIVATION OF INACTIVE CLAIMANT RULE

A. General Inactive Claimant Rule.

A claimant who previously was active for purposes of the Medical Monitoring Program, who has been classified as inactive under the Court-approved definition of an "active" claimant, shall

receive every two (2) years at the expense of the Medical Monitoring Program a letter from the Claims Administrator sent to the inactive claimant's best known address based on an internet search using the claimant's Social Security Number, reminding the claimant that he or she originally wanted to participate in the Medical Monitoring Program, and inviting the claimant to become an active claimant upon checking a box and providing written good cause for having become inactive.

Upon receiving such a request from an inactive claimant to become active again, the Claims Administrator shall share the request (with the claimant's identification information being redacted) with the Finance Committee to determine if there is agreement on whether to readmit the claimant to active status.

If there is agreement, then the claimant's future status (active or inactive) shall be by agreement of the Finance Committee. Absent agreement, the request shall be submitted to the Court for determination.

B. Special Rule for "No" Box Minor Claimant or Inactive Minor Claimants Who Become Adults

For inactive or "No" box claimants who registered* while minors, and who turn age 18, the following special rule applies: Whether the claimant's parent or guardian checked the "No" box when registering or checked the "Yes" box but the claimant subsequently was classified as inactive, the claimant, upon reaching age 18, shall be notified by the Claims Administrator at the claimant's best known address using Internet and Social Security Number search engines, of the Medical Monitoring Program and invited to participate by checking a box. Upon checking such a box, the claimant will be classified as active.

Upon reaching adulthood, minor "No" box or minor inactive claimants shall receive the biennial reminder letter described in part A of this rule.

Thank you for the opportunity to help administer this very interesting Settlement.

Yours very truly,

Ed Gentle,
Claims Administrator

ECGIII/kah

*

In this context, register means to prove Class Membership and be admitted as a Verified Registrant. The parent or legal guardian of the claimant may have checked the "Yes" box or the "No" box.

cc: (via e-mail)(confidential)
Diandra S. Debrosse, Esq.
Katherine A. Harbison, Esq.
Paige F. Osborn, Esq.
Michael A. Jacks, Esq.
William S. ("Buddy") Cox, Esq.
J. Keith Givens, Esq.
McDavid Flowers, Esq.
Farrest Taylor, Esq.
Ned McWilliams, Esq.
Perry B. Jones, Esq.
Angela Mason, Esq.

IV.

A. Preliminary CT Rule; and

September 1, 2011
Claims Administrator
Preliminary CT Rule for Briefing

THE PERRINE MEDICAL MONITORING PROGRAM, A PRODUCT OF THE PERRINE DUPONT SETTLEMENT

CT SCAN UTILIZATION GUIDELINES

FOR MEDICAL MONITORING BEGINNING NOVEMBER 1, 2011

These CT Scan Utilization Guidelines, which will be updated every 2 years based upon the state of scientific research respecting radiology and input from the Program's Medical Advisory Committee, is to be utilized by the examining physician in carrying out Step 3 of the CT Scan Utilization Protocols in Exhibit 1 for a Medical Monitoring participating Claimant who is CT Scan eligible, with eligibility to be determined in accordance with Dr. Brookshire's Report.

I. PREFACE

The proposed guidelines address the position that CT Scans should be allowed for any and all claimants due to their exposure. Furthermore, they address prior suggestions that we attempt to quantify the approximate number of CT Scans which may occur as a result of Medical Monitoring.

The most recent scientific trial involving the benefit of CT Scans in the early detection of lung cancer[1] qualifies its finding of a 20% decrease in mortality by stating that the current data alone is insufficient to fully inform a decision to unilaterally recommend CT Scans to a high risk population. Similarly, the Lung Cancer Alliance states that all "...those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening...".

As suggested in the below guidelines, after a review of the Claimant's history and exposure, the examining physician will determine whether to recommend a CT Scan for the Claimant as being medically necessary. No definitive determination is recommended for all CT Scan eligible Medical Monitoring Participating Claimants at this time. The NCI Division of Cancer Prevention, the Lung Cancer Alliance, the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and Prevention, and the National Institute of Health appear to agree with this approach.

We note that DuPont is in agreement with our position. Specifically, in the Memorandum of James B. Lees, Jr., Esq., Counsel for DuPont, of August 29, 2011, which is in Exhibit A, DuPont states:

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[1]National Lung Screening Trial Research Team; Reduced Lung Cancer Mortality with Low-Dose Computed Tomographic Screening, N Engl J Med 2011; 365:395-409, August 4, 2011, in Exhibit B.

"The words "medically necessary" were inserted to preclude the lawyers and the Court from attempting to interfere with the medical judgments made by competent physicians. The words "medically necessary" were used to make absolutely sure that decisions in the future are being made by physicians and not pursuant to some lawyer-created criteria."

We agree. In sum, the examining physician is to decide whether to recommend a CT Scan for a given claimant, as reflected in the guidelines recommended below.

We understand that Mr. Lees has also suggested linking putative disease with cadmium, arsenic, zinc and lead exposure resulting from the former zinc smelter, prior to having a CT scan. To the extent contemplated in the Settlement, we try to accommodate this suggestion in Section 3b of the below guidelines, giving weight to additional exposure, and in Paragraph 6, as described below. However, medical screening is just that, an examination for disease. Often, the etiology (cause) of disease is unknown and debatable. See, for example, respecting cancer, The Emperor of All Maladies, by Siddhartha Mukherjee. To apply a more wooden exposure rule, other than the agreed "relevant to possible exposure to heavy metal contamination" term in the November 19, 2011, Settlement Memorandum of Understanding (the "MOU") by removing the term "possible", as apparently suggested by Mr. Lees, may remove the very "physician decisions" he advocates in the above quote, and was therefore rejected by your Claims Administrator as possibly medically ethically improper.

On September 1, 2011, we received a second Memorandum from Mr. Lees in Exhibit A, which suggests edits to the guidelines in paragraphs 2 and 3 of the Memorandum.

We agree with the substance of paragraph 2, that there should be CT Scan diagnosis and consent documentation. As to consent documentation, the Court on August 31, 2011, has already ordered it. See August 19, 2011 CT Scan Protocols approved by the Court at paragraph 6 that are Exhibit 1 hereto. We have added language to CT Scan Guidelines paragraph 6 stating that the diagnosis will also be documented. However, DuPont's suggestion in the Memo that these forms be collected by the Claims Office before a CT Scan is authorized as opposed to carrying out the CT Scan as soon as practicable, may have a chilling effect on this component of Medical Monitoring.

We do not agree with Memo paragraph 3 suggesting that the physician find the disease to be "related to" and not "relevant to possible exposure to heavy metal contamination" (the MOU standard), for the reasons stated above. We do agree to include the specific MOU standard on this issue. See revised Paragraph 6 of the CT Scan Guidelines.

We also received an August 19, 2011 letter, also in Exhibit A, from Dr. Andrea H. McGuire, who was asked by CTIA, the Medical Monitoring Plan's Third Party Administrator, to critique an earlier draft of these guidelines, which are not materially different from these guidelines. In response to Dr. McGuire's comments which are critical of the guidelines, and recommend that all eligible Claimants be provided a CT Scan, we note that although Dr. McGuire correctly notes that the reports cited in the guidelines describe Scans other than chest CT Scans, the following issues remain: (1) exposure to CT Scan radiation must be justified and weighted against a benefit to the Claimant; and

(2) we are unaware of evidence that CT scanning of all Claimants would result in a decrease in cancer mortality rates. Furthermore, as noted in these guidelines, recent publications from leading medical authorities establish that no medical authority recommends CT chest scanning of an entire at risk population absent additional research.

A revised protocol is in Section IV of this memorandum and follows an analysis of where current medical and research organizations stand with regard to CT chest scans.

II. SCIENTIFIC BACKGROUND

According to the USFDA Center for Devices and Radiological Health[2], medical professional societies have not endorsed CT scanning for individuals without symptoms, and CT screening of high-risk individuals for specific diseases such as lung cancer are currently being studied. The FDA maintains the position that CT Scans and radiography imaging are to be used *in the diagnosis of syptomatic people*.

As discussed in the American College of Radiology Practice Guideline for the Performance of Pediatric and Adult Chest Radiography[3], the "ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in the light of the circumstances presented." That said, the below CT Scan Guidelines provide that the proper indications and contraindications that are relevant to this matter, which may establish a need for a CT Scan, and which are:

1. Evaluation of signs and symptoms potentially related to the respiratory and cardiovascular system; and
2. Compliance with governmental regulations that may indicate chest radiography (e.g., surveillance PA x-rays for active TB or occupational lung disease).

With regard to total-body CT scanning, the American College of Radiology Board of Chancellors issued the following statement[4]:

> The American College of Radiology (ACR), at this time, does not believe there is sufficient evidence to justify recommending total body computed (CT) screening for patients with no symptoms or a family history suggesting disease.

Robert Smith, Director of cancer screening at the American Cancer Society, says that his organization also discourages full-body scanning CT exams[5].

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[2]See Publication of USFDA in **Exhibit C**; http://www.pueblo.gsa.gov/cic_text/health/fullbody-ctscan/

[3]ACR Practice Guideline, attached as **Exhibit D**.

[4]American College of Radiology (2002, September). Statement on CT Screening Exams. Retrieved March 6, 2006 from http://www.acr.org/s_acr/doc.asp?TrackID=&SID=a&DID=16014&CID, attached as **Exhibit E**.

[5]Please see American Medical News article of September 3, 2011 in **Exhibit E**.

III. CT SCANS IN HIGH RISK POPULATIONS: THE MOST RECENT STUDY AND WHAT IT MEANS

The National Lung Screening Trial (NLST) described in Exhibit B was a randomized trial of screening with the use of low-dose CT as compared screening with the use of chest radiography, and was an effort of the Lung Screening Study (LSS), administered by the NCI Division of Cancer Prevention, and the American College of Radiology Imaging Network (ACRIN), and sponsored by the NCI Division of Cancer Treatment and Diagnosis, Cancer Imaging Program.

The NCI Division of Cancer Prevention conducted the NLST, a randomized controlled trial designed to determine whether screening with LDCT can reduce lung cancer mortality among persons at elevated risks for cancer. The study consisted of more than 50,000 individuals, ages 55 to 74 years with a history of smoking at least 30-pack years. Participants were randomly assigned to receive either three annual Cat Scans or three annual chest x-rays.

In the NLST[6], a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group[7]. Despite this finding, the National Lung Screening Trial Research team went on to say:

> Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone, are in our opinion, insufficient to fully inform such important decisions....
>
> The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and over[-]diagnosis, as well as costs...
>
> Other strategies for early detection of cancer... may one day help select persons who are best suited for low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

As further noted by Dr. Simome Tramma, MD, MS, Eileen Storey, MD, MPH, Douglas B. Trout, MD, MHS, and Marie Haring Sweeney, Ph, MPH of the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and

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[6]Another large ongoing study is the Ducth-Belgian randomized lung cancer screening trial (NELSON). The NELSON trial is investigating whether the 16-detector multislice computed tomography screening will decrease lung cancer mortality compared to no screening. This trial started in August 2003 and is expected to be completed in December 2015. It is expected to include 15, 600 participants. The participants will receive CT screenings or usual care.

[7] *Id.*

Prevention in their NIOSH Science Blog (discussing the breadth of the NLST), attached hereto as Exhibit F[8]:

> "In the occupational setting, there are a number of agents associated with lung cancer. However, the excess risks for lung cancer associated with these occupational exposures vary depending on the actual exposures. Consideration of the use of any screening test in occupationally exposed groups requires a careful assessment of the risk of a given condition. The risk of lung cancer from a specific exposure will directly affect the likelihood that a positive screening test for lung cancer will actually be evidence that the cancer exists. In other words, high risk for lung cancer in the NSLT trial due to a long history of heavy smoking made it more likely that a "positive" funding on a low-dose CT Scan was in fact a lung cancer. The benefit of screening for lung cancer with low-dose CT cannot be easily estimated for populations with risk profiles that are different from those of the NLST participants."

The National Institute for Health states that "[d]ecisions to recommend screening for a population should be based upon the highest possible level of evidence of population benefit from clinical trials."

The Lung Cancer Alliance states its position with regard to lung cancer screening as follows:

> "Lung Cancer Alliance (LCA) has consistently maintained that those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening. Those at risk include smokers and former smokers, first degree relatives of people diagnosed with lung cancer and those with prolonged exposure to radon, asbestos, Agent Orange, radioactive materials and other lung carcinogens. If the decision is made to undergo screening by computed tomography (CT), the scan should only be done at a site which has experience in screening for lung cancer and which follows a lung cancer screening protocol based on best published practices, such as the International Early Lung Cancer Action Program (I-ELCAP) protocol[9]." Emphases Added.

LCA Position on Lung Cancer Screening is attached as Exhibit E.

As noted in the conclusion of the LCA's position statement "[t]hose at high risk for lung cancer and their primary care doctors need to be fully informed in order to reach a decision on screening appropriate to each individual case."

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[8]National Institute of Health, Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations, A. J Bioeth. 2009 April; 9(4):3-14, in Exhibit F.

[9] The above mentioned International Early Lung Cancer Action Program protocol, dated July 1, 2011, is attached hereto as Exhibit G, and was pioneered and developed over the past 17 years by the International Lung Cancer Action Program, and deals with research concerning the efficacy of CT scans in asymptomatic high risk individuals.

See also Radiation Dose Associated with Common Completed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer, Rebecca Smith-Bindman, MD, Archives of Internal Medicine, Vol. 169 No. 22., Dec 14/28, 2009 in Exhibit F; Lung CT scan for cancer: Should you be screened?, Mayo Clinic, mayoclinic.com/health/lung-ct-scan/CA0086/MET in Exhibit G.

In designing the guidelines and carrying out the CT Scan portion of the Medical Monitoring Program, Medicare and Medicaid issues should be considered. Please refer to the Memorandum in Exhibit H, expressing the opinion that these issues should not impact how the Medical Monitoring Program is funded.

Footnote 66 to the West Virginia Supreme Court of Appeals March 26, 2010 Decision might also be considered.

IV. THE CT SCAN GUIDELINES (THE "CT RULE")

In light of the above, and current research regarding the signs and symptoms associated with cancer, the below guidelines are recommended:

1. These rules shall be re-evaluated every two years based upon scientific developments in radiology, and following consultation with the Medical Advisory Committee.

2. CT Scan eligible Claimants are described in Dr. Brookshire's Report.

3. During the CT-Scan eligible Claimant's initial medical monitoring visit with the examining physician, the examining physician will:

    a. Take the Claimant's vital signs;
    b. Conduct a general health interview which shall include the number of years the Claimant has lived in the Class Area in Exhibit 2, with greater weight being given to:
        i. Zone 1 Claimants who have lived in the Class Area for 2 years or more;
        ii. Zone 2 Claimants who have lived in Class Area for 6 years or more; and
        iii. Zone 3 Claimants who have lived in the Class Area of concern for 10 years or more);

    c. Review the Claimant's prior medical record (necessary to determine propensity for cancer); and

    d. Ensure that all female Claimants receive a pregnancy exam.

4. The Claimant will have paragraph C on page 2 of the Memorandum of Understanding in Exhibit 3 read to him or her by the examining physician or will be provided a copy to read.

5. The examining physician will ensure informed consent. Specifically, the examining physician will explain the nature of the radiological imaging, that the results may not be definitive, there may be false outcomes, and that there is a risk associated with radiological imaging and CT Scans specifically.

6. After a review of the Claimant's vital signs, general health interview, and prior medical history, the examining physician will, in his discretion, make a determination on whether to recommend a CT Scan for the Claimant as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination (which will be documented by the examining physician with a signed form provided).

7. Factors which satisfy medical necessity include:

   (1) **Signs and Symptoms**, including but not limited to, paraneoplastic syndromes (production of hormone like symptoms from the tumor cells), unexplained weight loss, fever, fatigue, pain, persistent coughing or hoarseness, hemoptysis, unusual bleeding or discharge, dysphagia, persistent shortness of breath, thickening or lumps in the body, hyper pigmentation, jaundice, shoulder pain (Pancoast's Syndrome), pneumonia, persistent headaches, and/or other medical signs and symptoms which are widely accepted in the medical community as potential indicators of cancer.

   AND/OR

   (2) **Medical history** (including known diagnoses).

8. The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used.

9. The care provider shall not bill Medicaid, Medicare and/or any other third party for the services outlined in these guidelines under any circumstances.

EXHIBITS TO CT SCAN UTILIZATION GUIDELINES

EXHIBIT	DESCRIPTION
1	CT Scan Utilization Protocols
2	Class Area Map
3	Paragraph C, page 2, of Memorandum of Understanding
A	James B. Lees, Jr., Esq., August 29, 2011 and September 1, 2011 Memoranda, and August 19, 2011 letter from Dr. Andrea H. McGuire
B	N. Eng. J. Med. 2011; 365: 395-409, August 4, 2011
C	Publication of USFDA
D	ACR Practice Guideline
E	American College of Radiology September 2002 Statement on CT Screening Exams
F	NIH Publications, J Bioeth. 2009 April; 9(4):3-14
G	Early Lung Cancer Program Protocol dated July 1, 2011
H	August 30, 2011, Memorandum Re DuPont: CT Scans and Medicare

Exhibit 1

CT Scan Utilization Protocols

CT SCAN UTILIZATION PROTOCOLS

1. CT Scan eligible claimants are described in Dr. Brookshire's report.

2. At the initial medical monitoring testing visit, the attending physician will take the CT scan eligible claimant's vital signs and conduct a general health interview of the claimant.

3. After examining the claimant, the examining physician will make a determination on whether to recommend a CT scan for the claimant as being diagnostically medically necessary based on the CT Scan Utilization Guidelines to be developed by the Claims Administrator and to be ultimately determined by the Court.

4. The claimant can accept or decline the recommendation for a CT scan.

5. Prior to agreeing to a CT scan, a claimant will be told by the physician the benefits and risks of a CT scan.

6. Claimants agreeing to a CT scan shall sign a standard CT scan release.

Exhibit 2

Class Area Map

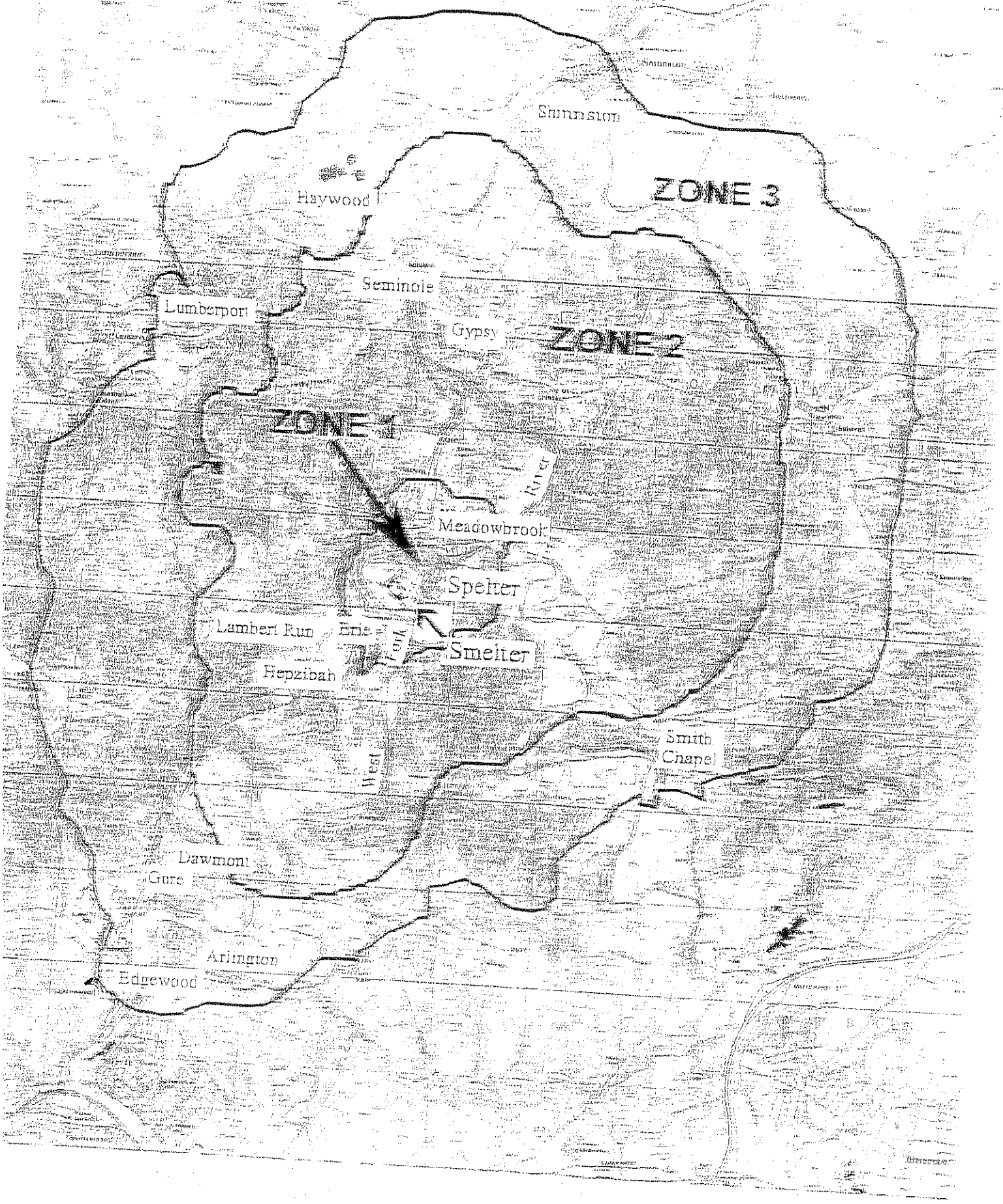

Shinnston
Haywood
ZONE 3
Seminole
Lumberport
Gypsy
ZONE 2
ZONE 1
River
Meadowbrook
Spelter
Lambert Run
Erie
Fork
Smelter
Hepzibah
Smith
Chapel
West
Dawmont
Gore
Arlington
Edgewood

Exhibit 3

Paragraph C, page 2, of Memorandum of Understanding

c. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

Exhibit A

James B. Lees, Jr., Esq., August 29, 2011 and September 1, 2011 Memoranda, and August 19, 2011 letter from Dr. Andrea H. McGuire

MEMORANDUM

TO: Edgar C. Gentle, III, Esq,

FROM: DuPont by James B. Lees Jr. Esq.

DATE: August 29, 2011

RE: Draft CT Scan Utilization Guidelines

Dear Ed

As per your Memorandum dated August 18, 2011 I have been asked by DuPont to step back into this matter for the purpose of helping you deal with the issue of CT scans as they relate to the settlement of this litigation. As the principal attorney who negotiated this settlement with counsel for the plaintiffs and having spent many hours discussing this very subject matter with Ed Hill, then counsel for the plaintiffs, DuPont believed I was in a better position to address this matter with you.

First let me set forth what I hope we do agree upon:

1. There are no Medicare issues relevant to this subject matter. There are no prior created Medicare liens at issue and there will be no future Medicare liens created by the operation of the settlement agreement as it relates to CT scans. DuPont is the primary payor of all services covered under the settlement agreement, and absent a mistaken billing by a physician to Medicare there should be no claims or submissions made to Medicare by any physician or claimant in this matter nor should there be any Medicare liens created. I am not sure how this issue arose but I believe we are in complete agreement with you that Medicare is not relevant to this matter.
2. DuPont is the primary payor for any CT scans that are provided to class members pursuant to the settlement agreement. Whether DuPont pays any such invoices directly upon receipt of an appropriate invoice or whether you pay such invoices from monies deposited with you in advance is an issue still undecided. However it is clear that DuPont is obligated under the settlement agreement and will pay the cost of CT scans covered under the settlement agreement.
3. The settlement agreement changed the original Court Order relevant to medical monitoring in that the settlement agreement removes routine CT scans for screening purposes as part of the medical monitoring program. This of course was the subject of much negotiation among the parties, some of which you and the Court were parties to at the mediation which resulted in the settlement of this matter. All parties agreed that CT scans would not be routinely performed on class members as a screening tool, and

this agreement was specifically referenced in paragraph 3(c) of the agreement so as to remove screening CT scans as part of the medical monitoring program.

Hopefully these are three points in which you and I agree. I can tell you that I was somewhat taken back by some written comments by the current representative for the class members to the extent that she expressed surprise that CT scans were not part of the medical monitoring screening process in the settlement. This is the very issue that was negotiated by the parties and was an absolute condition precedent for DuPont to enter into the settlement agreement for a number of reasons, not the least of which is accurately referenced in your draft guidelines that the FDA states that CT scans are to be used for the diagnosis of illness and disease in symptomatic people and not as a tool used to screen non-symptomatic people for possible medical problems.

Ct scans pursuant to the settlement agreement are to be used when a physician determines that a patient (or in this case a class member) likely has a disease or medical condition that is related to exposure to heavy metal exposure and that a CT scan is medically necessary as a "diagnostic" tool to rule in or rule out the disease. In such a case DuPont under the terms of the settlement agreement stands ready and willing to pay for that diagnostic test to confirm the presence or absence of the heavy metal-related disease in the class member. This is precisely what was discussed in the settlement negotiations, and it is precisely what is set forth in the settlement agreement.

The question then becomes what if anything is necessary to be done by you to make sure this provision of the settlement agreement is carried out in an organized fashion. Most importantly in my view one of the main purposes of addressing this issue in advance of the commencement of the medical monitoring program is to develop a way in which to insure that physicians that order such CT scans for the reasons stated above:

a. Notify your office in some manner as to the conclusions they have reached about a given class member and their determination for the need to do the diagnostic CT scan to rule in or rule out the disease.
b. Bill the correct party.....or more precisely know that they are not to bill Medicare.

These are two relevant issues that need addressed by you in advance of the commencement of the program, and DuPont is certainly amenable to working with you to create some method or system for insuring that these matters are addressed.

Where I believe you and I may disagree is the need for your office to attempt to set out "Guidelines" that in my opinion cross the line from administering a program to one of attempting to dictate how the practice of medicine is carried out. I do think we need to be very careful in this area for a number of reasons, not the least of which is that I do not want your office or DuPont in any way named as a defendant in a medical malpractice case sometime in the future because you or DuPont interfered with a competent physician's judgment as to when a diagnostic CT scan is needed to rule in or rule out a disease thought to be related to the heavy metal exposure relevant in this litigation.

I believe is it a mistake to attempt in any written document to set out "signs and symptoms" that attempt to give competent physicians instructions on how to practice medicine. This is not

our role in this matter, and the language of the settlement agreement was drafted specifically to keep the lawyers and administrators out of the business of practicing medicine. Since you do have counsel available to you I would urge you to discuss this issue with counsel, particularly with respect to the issue of setting out specific criteria for physicians to use in determining how to best manage and treat those class members that come before them. I foresee you being dragged into future medical negligence litigation needlessly by taking this approach.

As an alternative I believe the settlement agreement is crystal clear on this matter and should govern when CT scans are ordered and when they are not ordered. The settlement agreement specifically states CT scans are to be used only as part of a diagnostic process. That is why the word "diagnostically" was inserted in paragraph 3(c) of the settlement so as to make clear that CT scans would only be ordered consistent with the FDA mandates as part of a diagnostic process to rule in or rule out a disease.

The words "medically necessary" were inserted to preclude the lawyers and the Court from attempting to interfere with the medical judgments made by competent physicians. The words "medically necessary" were used to make absolutely sure that decisions in the future are being made by physicians and not pursuant to some lawyer-created criteria.

And of course the words "relevant to the heavy metal contamination at issue in this litigation" were inserted to make it clear that DuPont pays only for diagnostic CT scans that are related to ruling in or ruling out a disease related to the heavy metal exposure. Otherwise DuPont would end up paying for CT scans for suspected lung cancers and other diseases that are related to cigarette smoking, life styles, and or simply genetic disease processes.

I believe the language of the settlement agreement is very precise and very clear on this subject. I however am cognizant of the fact that physicians need to be aware of the fact that they can order diagnostic CT scans in certain circumstances and that the CT scans will be paid for by DuPont. It is therefore my suggestion that in lieu of "Guidelines" or any attempt to set forth medical symptomology or medical "triggers" you simply communicate to all physicians involved in medical monitoring the following information:

1. CT scans for screening purposes will not be paid for under the medical monitoring program.
2. Ct scans will be paid for under this program if you as the physician determine:
   a. A class member, based upon testing and examination, most likely has a disease.
   b. The disease is most likely related to heavy metal exposure from three heavy metals: arsenic, cadmium, or lead.
   c. You as the medical professional have determined that a diagnostic CT scan is medically necessary to rule in or rule out the disease in the class member.
3. In the event you make such a medical judgment simply submit your findings and conclusions to my office (deleting of course patient identification) together with your order for a CT scan.
4. Do not under any circumstances bill or invoice Medicare, Medicaid, or any other third-party provider for these CT scans. My office will handle all billing and payment.

This is essentially the information that we believe should be given to the physicians as the program commences. We are of course open to discussion as to whether DuPont needs to

deposit some monies into an account in advance of the program to pay invoices for any such diagnostic CT scans and, if so, how much. I believe the best practice is to simply have DuPont pay for the CT scans if and when they are ordered but this is something we are certainly willing to work with you on.

Because Ct scans are not parts of routine screening in the medical monitoring program but will only be ordered to rule in or rule out a disease that a physician believes is related to the heavy metal exposure we do not believe any monies for the non-screening CT scans should be included in the medical monitoring budget. DuPont agreed to pay for these limited CT scans as part of a diagnostic process if needed and not as part of any broad-based medical monitoring screening program. DuPont would be amenable to depositing advance monies with you in an escrow account that was designated specifically for these diagnostic CT scans so long as these monies were segregated from the overall medical monitoring budget if you were not satisfied with DuPont's ability and willingness to pay for these CT scans as they are ordered.

I do think we need some certification or document by the physician delivered to you that provides that a CT scan is being ordered for the purpose set forth in the settlement agreement (and provided to them by you at the commencement of the program). In order to protect DuPont's due process rights we do need some method to insure that the parameters of the settlement agreement are being met and not abused by physicians when ordering diagnostic CT scans.

If you need any additional input or information from me please let me know.

Memo: September 1, 2011

To: Edgar C. Gentle III, Esq.

Fr: Jim Lees, Counsel for DuPont

Re: Proposed Letter to Judge Bedell regarding CT Scans

Pursuant to your request in your memorandum of August 30, 2011 to counsel for DuPont I am submitting DuPont's written comments regarding your proposed letter to Judge Bedell as well as your proposed attached submission to the Court. I also am attaching a draft informed consent document which I believe will satisfy both the need for informed consent by a claimant in those situations where a physician is recommending a CT scan as well as some modicum of due process to DuPont to insure that the physician has complied with the relevant language of the settlement Memorandum of Understanding.

In short DuPont makes the following comments about your proposed letter to Judge Bedell as well as the proposed CT Guidelines and the CT Utilization Protocols:

1. We agree with your counsel's memorandum that the Medicare issue is a non-issue in this matter.
2. Under the CT Scan Utilization Protocols we ask that you add a paragraph 7 that reads: "Physicians ordering a CT scan for a claimant shall verify in writing their medical findings consistent with the CT Scan Utilization Guidelines. Both the CT scan Informed Consent form executed by the Claimant and the CT scan Verification executed by the physician shall be submitted to the Settlement Claim Office at the time any such CT scan is ordered."
3. Under paragraph 6 of the CT Scan Utilization Guidelines (as set forth in your proposed attached submission to the Court) we ask that the following language be added to the end of this paragraph so as to comply with the settlement agreement as between the parties:

   ...as being medically necessary **"to diagnose a disease or serious condition that is related to exposure to arsenic, cadmium, or lead."**
4. We ask that you delete costs included in any budgeted estimate for CT scans that are related to the Guardian Ad Litem. Only claimants over the age of 35 are eligible for consideration of a CT scan for diagnostic purposes. The only relevance for participation of the Guardian Ad Litem in this issue is claimants who have been declared legally incompetent. DuPont believes that number is two.
5. We ask that rather than include proposed estimated costs of CT Scans in the Medical Monitoring Budget you simply invoice DuPont for any CT Scans approved by your office at the time of your approval. We believe any attempt by you to "pre-judge" the need or frequency of diagnostic decisions made by competent physicians is improper and ill-

advised and will potentially impact upon the medical decisions made by such physicians. Creating in essence a "pot of money" that is available to pay for a certain discretionary test has in the past led in some situations to abuse of medical decision-making. Your office is not equipped to monitor the use of this "pre-paid" diagnostic procedure in any meaningful manner, and the lessons learned in the past from similar Worker's Compensation systems has led to a much more constrained and cautious approach in dealing with these type issues. DuPont certainly has the ability to pay invoices in a timely fashion for CT Scans approved by your office, and we urge you to reconsider your proposal to simply create a new or additional "pot of money" for the sole purpose of paying for approved CT scans in a timely manner. Of all the services being provided to claimants by DuPont this limited service should be strictly on a pay-as-you-go basis.

6. In the event you persist in your effort to create an advance source of monies from which to pay approved CT scans we respectfully note that a sum of $100,000 should be more than sufficient to cover these limited situations, with said sum being replenished on a regular basis as the need arises. We also would then urge you to amend your letter to Judge Bedell as a middle ground approach on this subject to include the following language in place of your proposed language:

   "As contemplated by the MOU, the Preliminary Budget is to be funded by an additional DuPont contribution to the Medical Monitoring Fund. Because of the uncertainty associated with the frequency in which physicians will order CT scans, DuPont has proposed to provide initial funding of up to $100,000 (the "CT Fund") to provide a source for payment of approved CT scans and has agreed to replenish the CT Fund on a monthly basis as part of the process for the approval of the bills of the Claims Administrator. The Claims Administrator agrees with this proposed modification of the budgeting process for the initial payment of approved CT scans. Once the Claims Administrator, the TPA and the parties have experience with the implementation of the Medical Monitoring program, including the frequency with which CT scans are ordered, the Claims Administrator reserves the right to recommend to the Court that funding for CT scans be included as part of the annual budgeting process."

7. We note that your reference to Footnote 66 of the Supreme Court opinion in your Memorandum to the Court is noteworthy in that DuPont specifically negotiated the Memorandum of Understanding to exclude routine CT scans for screening purposes with that Footnote partially in mind. To the extent you were citing to it in support of the proposition that the language in that Footnote is relevant in light of the agreed-upon settlement of the parties in this matter we respectively disagree with your conclusion.

In summary we believe all parties including DuPont are working in good faith to resolve this matter in a reasonable and timely fashion and we appreciate your efforts to date in this matter.

August 19, 2011

Edgar C. Gentle, III, Esq.

Special Master

Perrine Medical Monitoring Plan, Product of the Perrine DuPont Settlement

Dear Mr. Gentle,

I am a medical consultant with experience in academics, private practice and Medical Management. My education includes a BS in Chemistry, a Medical Doctorate and an MBA. I have additional training in Nuclear Medicine with Board Certification. I have research experience with over 30 publications and a book chapter and over 10 years of experience in reviewing medical claims for medical appropriateness based on medical literature.

I have been asked to review the CT Scan Utilization Guidelines dated November 1, 2011. There are also several Exhibits that are referenced that I have reviewed including:

- Exhibit 1-CT Scan Utilization Protocols
- Exhibit 2-Class Area Map
- Exhibit 3-Paragraph C, page 2, of Memorandum of Understanding
- Exhibit A-Publication of USFDA
- Exhibit B-ACR Practice Guidelines
- Exhibit C-American College of Radiology September 2002 Statement on CT Screening Exams

In my review, I note many inconsistencies related to the information provided and the question at hand.

The first referenced publication under background in the Utilization guidelines is the Publication of the USFDA. First, this publication relates to Whole Body CT scanning in a normal population. It is my understanding that we are addressing Chest CT Scanning in high risk populations and not whole body scanning in normal populations; therefore this article is not applicable. It also is dated March 2003-

more than 8 years ago and is not up to date with the medical literature especially the recent New England Journal article published August 4, 2011 titled, "Reducing Lung-Cancer Mortality with Low-Dose Computed Tomography Screening". Additionally, the article does reference, "that CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available". The study they are referencing is the National Lung Screening Trial (NLST). The data from this study is what the New England Journal article is based on. Therefore, it is my opinion that this reference has no standing because it is addressing a different modality (whole body CT scanning versus specific areas), is outdated and even references that studies are coming in the future that are now available.

The next reference is to Exhibit B-the ACR Practice guideline. The practice guidelines included are for the performance of pediatric and adult chest radiography which is a Chest x-ray. I understood the matter we were discussing is CT scanning in high risk individuals and therefore

an article on Chest x-rays would be a completely different modality and certainly not applicable to this question. The practice guideline is out of date with the most recent medical literature cited in 2005 and the guideline revised in 2006. The other practice guideline in the exhibit was ACR practice guideline for performing FDG-PET/CT in Oncology. An FDG PET/CT utilizes positron emission tomography to assess metabolic activity in different tumors using flourodeoxyglucose, a radioactive sugar. The CT in PET/CT refers to the anatomic registration portion of the metabolic study and again is a completely different modality than CT scanning in high-risk lung cancers. These guidelines are dated 2007 and are therefore dated in this continually evolving field.

The CT scan guidelines that are quoted I believe are taken from the chest radiography practice guidelines and therefore are not applicable to another modality and neither is the reference to the American College of Radiology Board of Chancellors issued statement since it is referencing total body computed (CT) screening for patients with no

symptoms or a family history suggesting disease and we are addressing a different modality CT Scanning of the chest in patients with a high risk of cancer related to their exposure to the heavy metal contamination at issue in this litigation.

The guidelines that are listed (II. Guidelines, Page 2) are said to be based on these references that I have discussed above and therefore to base the guidelines on references about different tests than the one we are interested in and with medical references that are very out dated is not appropriate.

It is by opinion that according to the paragraph c, page 2 of the Memorandum of Understanding that was included as exhibit 3, CT scans should be provided as diagnostically medically necessary because of the high risk of the possible exposure to the heavy metal contamination at issue in this litigation. I base this on the August 4th 2011 article from the New England Journal "Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening" based on

the National Lung Screening Trial (NLST). This article relates directly to this issue because it addresses a large population (53,454) that is at similar high risk of lung cancer (30 pack year history of smoking) to your patients with heavy metal exposure as noted in Exhibit 2-Class Area Maps. The mortality in these similar at risk individuals was 20% less if they had CT scans than if just chest x-ray surveillance. This article is up to date and particularly on point to this situation. It is my opinion that because of this study all participants should have a CT Scan as part of their surveillance because it is medically necessary in a high risk population with possible exposure to heavy metal contaminants.

9/19/11

Andrea H McGuire, MD, MBA

Exhibit B

N. Eng. J. Med. 2011; 365: 395-409, August 4, 2011

Welcome Gues

ORIGINAL ARTICLE

Reduced Lung-Cancer Mortality with Low-Dose Computed Tomographic Screening

The National Lung Screening Trial Research Team

N Engl J Med 2011; 365:395-409 August 4, 2011

Comments open through August 10, 2011

Lung cancer is an aggressive and heterogeneous disease.[1,2] Advances in surgical, radiotherapeutic, and chemotherapeutic approaches have been made, but the long-term survival rate remains low.[3] After the Surgeon General's 1964 report on smoking and health, mortality from lung cancer among men peaked and then fell; among women, the peak occurred later and a slight decline has occurred more recently.[4] Even though the rate of heavy smoking continues to decline in the United States,[5] 94 million current or former smokers remain at elevated risk for the disease,[6] and lung cancer remains the leading cause of death from cancer in this country.[3] The prevalence of smoking is substantially higher in developing countries than in the United States, and the worldwide burden of lung cancer is projected to rise considerably during the coming years.[7]

Although effective mass screening of high-risk groups could potentially be of benefit, randomized trials of screening with the use of chest radiography with or without cytologic analysis of sputum specimens have shown no reduction in lung-cancer mortality.[8] Molecular markers in blood, sputum,

and bronchial brushings have been studied but are currently unsuitable for clinical application.[6] Advances in multidetector computed tomography (CT), however, have made high-resolution volumetric imaging possible in a single breath hold at acceptable levels of radiation exposure,[9] allowing its use for certain lung-specific applications. Several observational studies have shown that low-dose helical CT of the lung detects more nodules and lung cancers, including early-stage cancers, than does chest radiography.[6] Therefore, the National Cancer Institute (NCI) funded the National Lung Screening Trial (NLST), a randomized trial, to determine whether screening with low-dose CT, as compared with chest radiography, would reduce mortality from lung cancer among high-risk persons. The NLST was initiated in 2002.[10] In October 2010, the available data showed that there was a significant reduction with low-dose CT screening in the rates of both death from lung cancer and death from any cause. We report here the findings of the NLST, including the performance characteristics of the screening techniques, the approaches used for and the results of diagnostic evaluation of positive screening results, the characteristics of the lung-cancer cases, and mortality. A comprehensive description of the design and operations of the trial, including the collection of the data and the acquisition variables of the screening techniques, has been published previously.[10]

METHODS

Trial Oversight

The NLST, a randomized trial of screening with the use of low-dose CT as compared with screening with the use of chest radiography, was a collaborative effort of the Lung Screening Study (LSS), administered by the NCI Division of Cancer Prevention, and the American College of Radiology Imaging Network (ACRIN), sponsored by the NCI Division of Cancer Treatment and Diagnosis, Cancer Imaging Program. Chest radiography was chosen as the screening method for the control group because radiographic screening was being compared with community care (care that a participant usually receives) in the Prostate, Lung, Colorectal and Ovarian (PLCO) Cancer Screening Trial (ClinicalTrials.gov number, NCT00002540).[11] The NLST was approved by the institutional review board at each of the 33 participating medical institutions. The study was conducted in accordance with the protocol; both the protocol and the

statistical analysis plan are available with the full text of this article at NEJM.org.

Participants

We enrolled participants from August 2002 through April 2004; screening took place from August 2002 through September 2007. Participants were followed for events that occurred through December 31, 2009 (Fig. 1 in the Supplementary Appendix, available at NEJM.org).

Eligible participants were between 55 and 74 years of age at the time of randomization, had a history of cigarette smoking of at least 30 pack-years, and, if former smokers, had quit within the previous 15 years. Persons who had previously received a diagnosis of lung cancer, had undergone chest CT within 18 months before enrollment, had hemoptysis, or had an unexplained weight loss of more than 6.8 kg (15 lb) in the preceding year were excluded. A total of 53,454 persons were enrolled; 26,722 were randomly assigned to screening with low-dose CT and 26,732 to screening with chest radiography. Previously published articles describing the NLST[10,12] reported an enrollment of 53,456 participants (26,723 in the low-dose CT group and 26,733 in the radiography group). The number of enrolled persons is now reduced by 2 owing to the discovery of the duplicate randomization of 2 participants.

Participants were enrolled at 1 of the 10 LSS or 23 ACRIN centers. Before randomization, each participant provided written informed consent. After the participants underwent randomization, they completed a questionnaire that covered many topics, including demographic characteristics and smoking behavior. The ACRIN centers collected additional data for planned analyses of cost-effectiveness, quality of life, and smoking cessation. Participants at 15 ACRIN centers were also asked to provide serial blood, sputum, and urine specimens. Lung-cancer and other tissue specimens were obtained at both the ACRIN and LSS centers and were used to construct tissue microarrays. All biospecimens are available to researchers through a peer-review process.

Screening

Participants were invited to undergo three screenings (T0, T1, and T2) at 1-year intervals, with the first screening (T0) performed soon after the time of randomization. Participants in whom lung cancer was diagnosed were not

offered subsequent screening tests. The number of lung-cancer screening tests that were performed outside the NLST was estimated through self-administered questionnaires that were mailed to a random subgroup of approximately 500 participants from LSS centers annually. Sample sizes were selected to yield a standard error of 0.025 for the estimate of the proportion of participants undergoing lung-cancer screening tests outside the NLST in each group. For participants from ACRIN centers, information on CT examinations or chest radiography performed outside the trial was obtained, but no data were gathered on whether the examinations were performed as screening tests.

All screening examinations were performed in accordance with a standard protocol, developed by medical physicists associated with the trial, that specified acceptable characteristics of the machine and acquisition variables.[10,13,14] All low-dose CT scans were acquired with the use of multidetector scanners with a minimum of four channels. The acquisition variables were chosen to reduce exposure to an average effective dose of 1.5 mSv. The average effective dose with diagnostic chest CT varies widely but is approximately 8 mSv.[10,13,14] Chest radiographs were obtained with the use of either screen-film radiography or digital equipment. All the machines used for screening met the technical standards of the American College of Radiology.[10] The use of new equipment was allowed after certification by medical physicists.

NLST radiologists and radiologic technologists were certified by appropriate agencies or boards and completed training in image acquisition; radiologists also completed training in image quality and standardized image interpretation. Images were interpreted first in isolation and then in comparison with available historical images and images from prior NLST screening examinations. The comparative interpretations were used to determine the outcome of the examination. Low-dose CT scans that revealed any noncalcified nodule measuring at least 4 mm in any diameter and radiographic images that revealed any noncalcified nodule or mass were classified as positive, "suspicious for" lung cancer. Other abnormalities such as adenopathy or effusion could be classified as a positive result as well. Abnormalities suggesting clinically significant conditions other than lung cancer also were noted, as were minor abnormalities. At the third round of screening (T2), abnormalities suspicious

for lung cancer that were stable across the three rounds could, according to the protocol, be classified as minor abnormalities rather than positive results.

Results and recommendations from the interpreting radiologist were reported in writing to the participant and his or her health care provider within 4 weeks after the examination. Since there was no standardized, scientifically validated approach to the evaluation of nodules, trial radiologists developed guidelines for diagnostic follow-up, but no specific evaluation approach was mandated.

Medical-Record Abstraction

Medical records documenting diagnostic evaluation procedures and any associated complications were obtained for participants who had positive screening tests and for participants in whom lung cancer was diagnosed. Pathology and tumor-staging reports and records of operative procedures and initial treatment were also obtained for participants with lung cancer. Pathology reports were obtained for other reported cancers to exclude the possibility that such tumors represented lung metastases. Histologic features of the lung cancer were coded according to the *International Classification of Diseases for Oncology, 3rd Edition* (ICD-O-3),[15] and the disease stage was determined according to the sixth edition of the *Cancer Staging Manual* of the American Joint Committee on Cancer.[16] At ACRIN sites, additional medical records were also obtained for a number of substudies, including studies of health care utilization and cost-effectiveness.[10]

Vital Status

Participants completed a questionnaire regarding vital status either annually (LSS participants) or semiannually (ACRIN participants). The names and Social Security numbers of participants who were lost to follow-up were submitted to the National Death Index to ascertain probable vital status. Death certificates were obtained for participants who were known to have died. An end-point verification team determined whether the cause of death was lung cancer. Although a distinction was made between a death caused by lung cancer and a death that resulted from the diagnostic evaluation for or treatment of lung cancer, the deaths from the latter causes were counted as lung-cancer deaths in the primary end-point analysis. The

members of the team were not aware of the group assignments (see Section 2 in the Supplementary Appendix).

Statistical Analysis

The primary analysis was a comparison of lung-cancer mortality between the two screening groups, according to the intention-to-screen principle. We estimated that the study would have 90% power to detect a 21% decrease in mortality from lung cancer in the low-dose CT group, as compared with the radiography group. Secondary analyses compared the rate of death from any cause and the incidence of lung cancer in the two groups.

Event rates were defined as the ratio of the number of events to the person-years at risk for the event. For the incidence of lung cancer, person-years were measured from the time of randomization to the date of diagnosis of lung cancer, death, or censoring of data (whichever came first); for the rates of death, person-years were measured from the time of randomization to the date of death or censoring of data (whichever came first). The latest date for the censoring of data on incidence of lung cancer and on death from any cause was December 31, 2009; the latest date for the censoring of data on death from lung cancer for the purpose of the primary end-point analysis was January 15, 2009. The earlier censoring date for death from lung cancer was established to allow adequate time for the review process for deaths to be performed to the same, thorough extent in each group. We calculated the confidence intervals for incidence ratios assuming a Poisson distribution for the number of events and a normal distribution of the logarithm of the ratio, using asymptotic methods. We calculated the confidence intervals for mortality ratios with the weighted method that was used to monitor the primary end point of the trial,[17] which allows for a varying rate ratio and is adjusted for the design. The number needed to screen to prevent one death from lung cancer was estimated as the reciprocal of the reduction in the absolute risk of death from lung cancer in one group as compared with the other, among participants who had at least one screening test. The analyses were performed with the use of SAS/STAT[18] and R[19] statistical packages.

Interim analyses were performed to monitor the primary end point for efficacy and futility. The analyses involved the use of a weighted log-rank statistic, with weights increasing linearly from no weight at randomization to

full weight at 4 years and thereafter. Efficacy and futility boundaries were built on the Lan–DeMets approach with an O'Brien–Fleming spending function.20 Interim analyses were performed annually from 2006 through 2009 and semiannually in 2010.

An independent data and safety monitoring board met every 6 months and reviewed the accumulating data. On October 20, 2010, the board determined that a definitive result had been reached for the primary end point of the trial and recommended that the results be reported.21 The board's decision took into consideration that the efficacy boundary for the primary end point had been crossed and that there was no evidence of unforeseen screening effects that warranted acting contrary to the trial's prespecified monitoring plan. The NCI director accepted the recommendation of the data and safety monitoring board, and the trial results were announced on November 4, 2010.

RESULTS

Characteristics of the Participants

The demographic characteristics and smoking history of the participants were virtually identical in the two groups (Table 1). As compared with respondents to a 2002–2004 U.S. Census survey of tobacco use22 who met the NLST eligibility criteria for age and smoking history, NLST participants were younger, had a higher level of education, and were more likely to be former smokers.12 As of December 31, 2009, vital status was known for 97% of the participants in the low-dose CT group and 96% of those in the radiography group. The median duration of follow-up was 6.5 years, with a maximum duration of 7.4 years in each group.

TABLE 1



Selected Baseline Characteristics of the Study Participants.

Adherence to Screening

The rate of adherence to the screening protocol across the three rounds was high: 95% in the low-dose CT group and 93% in the radiography group. Among LSS participants in the radiography group, the average annual rate of helical CT screening outside the NLST during the screening

phase of the trial was 4.3%, which was well below the 10.0% rate estimated in the trial power calculations.

Results of Screening

In all three rounds, there was a substantially higher rate of positive screening tests in the low-dose CT group than in the radiography group (T0, 27.3% vs. 9.2%; T1, 27.9% vs. 6.2%; and T2, 16.8% vs. 5.0%) (Table 2). The rate of positive tests in both groups was noticeably lower at T2 than at T0 or T1 because the NLST protocol allowed tests showing abnormalities at T2 that were suspicious for cancer but were stable across all three rounds to be categorized as negative with minor abnormalities. During the screening phase of the trial, 39.1% of the participants in the low-dose CT group and 16.0% of those in the radiography group had at least one positive screening result. The percentage of all screening tests that identified a clinically significant abnormality other than an abnormality suspicious for lung cancer was more than three times as high in the low-dose CT group as in the radiography group (7.5% vs. 2.1%).

TABLE 2

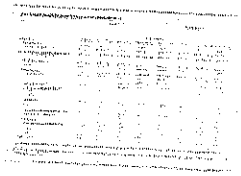


Results of Three Rounds of Screening.

Follow-up of Positive Results

More than 90% of the positive screening tests in the first round of screening (T0) led to a diagnostic evaluation (Table 3). Lower rates of follow-up were seen at later rounds. The diagnostic evaluation most often consisted of further imaging, and invasive procedures were performed infrequently. Across the three rounds, 96.4% of the positive results in the low-dose CT group and 94.5% of those in the radiography group were false positive results. These percentages varied little by round. Of the total number of low-dose CT screening tests in the three rounds, 24.2% were classified as positive and 23.3% had false positive results; of the total number of radiographic screening tests in the three rounds, 6.9% were classified as positive and 6.5% had false positive results.

TABLE 3



Diagnostic Follow-up of Positive Screening Results in the Three Screening Rounds.

Adverse Events

Adverse events from the actual screening examinations were few and minor. The rates of complications after a diagnostic evaluation procedure for a positive screening test (listed by category in Table 1 in the Supplementary Appendix) were low; the rate of at least one complication was 1.4% in the low-dose CT group and 1.6% in the radiography group (Table 4). A total of 0.08% of the positive screening tests in the low-dose CT group that did not result in a diagnosis of lung cancer and 11.2% of those that did result in a diagnosis of lung cancer were associated with a major complication after an invasive procedure; the corresponding percentages in the radiography group were 0.02% and 8.2%. The frequency of major complications varied according to the type of invasive procedure. A total of 16 participants in the low-dose CT group (10 of whom had lung cancer) and 10 in the radiography group (all of whom had lung cancer) died within 60 days after an invasive diagnostic procedure. Although it is not known whether the complications from the diagnostic procedure caused the deaths, the low frequency of death within 60 days after the procedure suggests that death as a result of the diagnostic evaluation of positive screening tests is a rare occurrence.

TABLE 4

Complications after the Most Invasive Screening-Related Diagnostic Evaluation Procedure, According to Lung-Cancer Status.

Incidence, Characteristics, and Treatment of Lung Cancers

A total of 1060 lung cancers (645 per 100,000 person-years) were diagnosed in the low-dose CT group, as compared with 941 (572 per 100,000 person-years) in the radiography group (rate ratio, 1.13; 95% confidence interval [CI], 1.03 to 1.23). In the low-dose CT group, 649 cancers were diagnosed after a positive screening test, 44 after a negative screening test, and 367 among participants who either missed the screening or received the diagnosis after their trial screening phase was over (Table 5). In the radiography group, 279 cancers were diagnosed after a positive screening test, 137 after a negative screening test, and 525 among participants who either missed the screening or received the diagnosis after their trial screening phase was over. Figure 1A shows the cumulative number of lung cancers through

TABLE 5

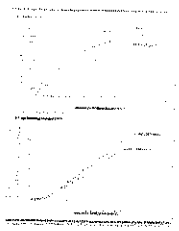
Stage and Histologic Type

December 31, 2009, according to the screening group. Detailed calculations of sensitivity, specificity, positive predictive value, and negative predictive value are not reported here.

of Lung Cancers in the Two Screening Groups, According to the Result of Screening.

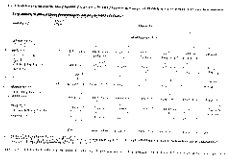
In each group, the percentage of stage IA and stage IB lung cancers was highest among cancers that were diagnosed after a positive screening test (Table 5). Fewer stage IV cancers were seen in the low-dose CT group than in the radiography group at the second and third screening rounds (Table 2 in the Supplementary Appendix). Low-dose CT screening identified a preponderance of adenocarcinomas, including bronchioloalveolar carcinomas. Although the use of the term bronchioloalveolar carcinoma is no longer recommended,[23] while the NLST was ongoing, the term was used to denote in situ, minimally invasive, or invasive adenocarcinoma, lepidic predominant (i.e., neoplastic cell growth restricted to preexisting alveolar structure). In both groups, many adenocarcinomas and squamous-cell carcinomas were detected at either stage I or stage II, although the stage distribution was more favorable in the low-dose CT group than in the radiography group (Table 6). Small-cell lung cancers were, in general, not detected at early stages by either low-dose CT or radiography. A total of 92.5% of stage IA and stage IB cancers in the low-dose CT group and 87.5% of those in the radiography group were treated with surgery alone or surgery combined with chemotherapy, radiation therapy, or both (Table 3 in the Supplementary Appendix).

FIGURE 1



Cumulative Numbers of Lung Cancers and of Deaths from Lung Cancer.

TABLE 6



Histologic Type of Lung Cancers in the Two Screening Groups, According to Tumor Stage.

Lung-Cancer–Specific Mortality

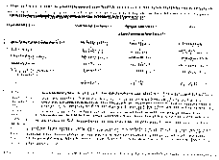
After the accrual of 144,103 person-years in the low-dose CT group and 143,368 person-years in the radiography group, 356 and 443 deaths from lung cancer in the two groups, respectively, had occurred, corresponding to rates of death from lung cancer of 247 and 309 deaths per 100,000 person-years, respectively, and a relative reduction in the rate of death from lung cancer with low-dose CT screening of 20.0% (95% CI, 6.8 to 26.7; P=0.004). Figure 1B shows the cumulative number of deaths

from lung cancer in the two screening groups through January 15, 2009. When only participants who underwent at least one screening test were included, there were 346 deaths from lung cancer among 26,455 participants in the low-dose CT group and 425 deaths among 26,232 participants in the radiography group. The number needed to screen with low-dose CT to prevent one death from lung cancer was 320.

Overall Mortality

There were 1877 deaths in the low-dose CT group, as compared with 2000 deaths in the radiography group, representing a significant reduction with low-dose CT screening of 6.7% (95% CI, 1.2 to 13.6) in the rate of death from any cause (P=0.02). We were unable to obtain the death certificates for two of the participants in the radiography group who died, but the occurrence of death was confirmed through a review by the end-point verification team. Although lung cancer accounted for 24.1% of all the deaths in the trial, 60.3% of the excess deaths in the radiography group were due to lung cancer (Table 7). When deaths from lung cancer were excluded from the comparison, the reduction in overall mortality with the use of low-dose CT dropped to 3.2% and was not significant (P=0.28).

TABLE 7



Cause of Death on the Death Certificate, According to Screening Group.

DISCUSSION

In the NLST, a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group. The rate of positive results was higher with low-dose CT screening than with radiographic screening by a factor of more than 3, and low-dose CT screening was associated with a high rate of false positive results; however, the vast majority of false positive results were probably due to the presence of benign intrapulmonary lymph nodes or noncalcified granulomas, as confirmed noninvasively by the stability of the findings on follow-up CT scans. Complications from invasive diagnostic evaluation procedures were uncommon, with death or severe complications occurring only rarely, particularly among participants who did not have lung cancer. The decrease in the rate of death from any cause with the use of low-dose CT screening suggests that such screening is not, on the whole, deleterious.

A high rate of adherence to the screening, low rates of lung-cancer screening outside the NLST, and thorough ascertainment of lung cancers and deaths contributed to the success of the NLST. Moreover, because there was no mandated diagnostic evaluation algorithm, the follow-up of positive screening tests reflected the practice patterns at the participating medical centers. A multidisciplinary team ensured that all aspects of the NLST were conducted rigorously.

There are several limitations of the NLST. First, as is possible in any clinical study, the findings may be affected by the "healthy-volunteer" effect, which can bias results such that they are more favorable than those that will be observed when the intervention is implemented in the community.[24] The role of this bias in our results cannot be ascertained at this time. Second, the scanners that are currently used are technologically more advanced than those that were used in the trial. This difference may mean that screening with today's scanners will result in a larger reduction in the rate of death from lung cancer than was observed in the NLST; however, the ability to detect more abnormalities may result only in higher rates of false positive results.[25] Third, the NLST was conducted at a variety of medical institutions, many of which are recognized for their expertise in radiology and in the diagnosis and treatment of cancer. It is possible that community facilities will be less prepared to undertake screening programs and the medical care that must be associated with them. For example, one of the most important factors determining the success of screening will be the mortality associated with surgical resection, which was much lower in the NLST than has been reported previously in the general U.S. population (1% vs. 4%).[26] Finally, the reduction in the rate of death from lung cancer associated with an ongoing low-dose CT screening program was not estimated in the NLST and may be larger than the 20% reduction observed with only three rounds of screening.

Radiographic screening rather than community care (care that a participant usually receives) was chosen as the comparator in the NLST because radiographic screening was being evaluated in the PLCO trial at the time the NLST was designed.[11] The designers of the NLST reasoned that if the PLCO trial were to show a reduction in lung-cancer mortality with radiographic screening, a trial of low-dose CT screening in which a community-care group was the control would be of less value, since the

standard of care would have become screening with chest radiography. Nevertheless, the choice of radiography precludes a direct comparison of low-dose CT with community care. Analysis of the subgroup of PLCO participants who met the NLST criteria for age and smoking history indicated that radiography, as compared with community care, does not reduce mortality from lung cancer.[27] Therefore, a similar reduction in lung-cancer mortality would probably have been observed in the NLST if community care had been chosen instead for the control group.

In addition to the high rate of false positive results, two other potentially harmful effects of low-dose CT screening must be mentioned. Overdiagnosis, a major source of controversy surrounding low-dose CT lung-cancer screening, results from the detection of cancers that never would have become symptomatic.[28] Although additional follow-up would be necessary to measure the magnitude of overdiagnosis in the NLST, a comparison of the number of cancers diagnosed in the two trial groups suggests that the magnitude of overdiagnosis with low-dose CT as compared with radiographic screening is not large. The other harmful effect, the association of low-dose CT with the development of radiation-induced cancers, could not be measured directly, is a long-term phenomenon, and must be assessed in future analyses.[29]

A number of smaller, randomized trials of low-dose CT screening are under way in Europe.[30-36] Because none of these trials have sufficient statistical power to detect a reduction in lung-cancer mortality of the magnitude seen in the NLST, it is expected that meta-analyses of the findings from these trials will be performed. The European studies are gathering types of data that were not collected by the NLST and will be able to address additional questions about low-dose CT screening, including the best strategies for the management of nodules observed with screening.[37]

The observation that low-dose CT screening can reduce the rate of death from lung cancer has generated many questions. Will populations with risk profiles that are different from those of the NLST participants benefit? Are less frequent screening regimens equally effective? For how long should screening continue? Would the use of different criteria for a positive screening result, such as a larger nodule diameter, still result in a benefit? It is unlikely that large, definitive, randomized trials will be undertaken to

answer these questions, but modeling and microsimulation can be used to address them. Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone are, in our opinion, insufficient to fully inform such important decisions.

Before public policy recommendations are crafted, the cost-effectiveness of low-dose CT screening must be rigorously analyzed. The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and overdiagnosis, as well as the costs. The cost component of low-dose CT screening includes not only the screening examination itself but also the diagnostic follow-up and treatment. The benefits, harms, and costs of screening will all depend on the way in which low-dose CT screening is implemented, specifically in regard to the eligibility criteria, screening frequency, interpretation threshold, diagnostic follow-up, and treatment. For example, although there are currently only about 7 million persons in the United States who would meet the eligibility criteria for the NLST, there are 94 million current or former smokers8 and many more with secondhand exposure to smoke or other risk factors. The cost-effectiveness of low-dose CT screening must also be considered in the context of competing interventions, particularly smoking cessation. NLST investigators are currently analyzing the quality-of-life effects, costs, and cost-effectiveness of screening in the NLST and are planning collaborations with the Cancer Intervention and Surveillance Modeling Network to investigate the potential effect of low-dose CT screening in a wide range of scenarios.

Other strategies for early detection of lung cancer — in particular, molecular markers in blood, sputum, and urine, which can be studied in specimens that were obtained as part of ACRIN's NLST activities and are available to the research community — may one day help select persons who are best suited for low-dose CT screening or identify persons with positive low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

The American College of Radiology Imaging Network component of the National Lung Screening Trial (NLST) was funded through grants (U01-CA-

80098 and U01-CA-79778) under a cooperative agreement with the Cancer Imaging Program, Division of Cancer Treatment and Diagnosis. The Lung Screening Study sites of the NLST were funded through contracts with the Early Detection Research Group and Biometry Research Group, Division of Cancer Prevention: University of Colorado Denver (N01-CN-25514), Georgetown University (N01-CN-25522), Pacific Health Research and Education Institute (N01-CN-25515), Henry Ford Health System (N01-CN-25512), University of Minnesota (N01-CN-25513), Washington University in St. Louis (N01-CN-25516), University of Pittsburgh (N01-CN-25511), University of Utah (N01-CN-25524), Marshfield Clinic Research Foundation (N01-CN-25518), University of Alabama at Birmingham (N01-CN-75022), Westat (N01-CN-25476), and Information Management Services (N02-CN-63300).

Mr. Clapp reports holding a financial interest in Human Genome Sciences; and Dr. Gatsonis, receiving consulting fees from Wilex, MELA Sciences, and Endocyte, lecture fees from Bayer HealthCare, and support from the Radiological Society of North America for developing educational presentations. No other potential conflict of interest relevant to this article was reported.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

The members of the writing team (who are listed in the Appendix) assume responsibility for the integrity of the article.

This article (10.1056/NEJMoa1102873) was published on June 29, 2011, at NEJM.org.

We thank the trial participants for their contributions in making this trial possible.

SOURCE INFORMATION

Address reprint requests to Dr. Christine D. Berg at the Early Detection Research Group, Division of Cancer Prevention, National Cancer Institute, 6130 Executive Blvd., Suite 3112, Bethesda, MD 20892-7346, or at bergc@mail.nih.gov.

A complete list of members of the National Lung Screening Trial research team is provided in the Supplementary Appendix, available at NEJM.org.

Appendix

The members of the writing team of the National Lung Screening Trial Research Team are as follows: Denise R. Aberle, M.D., University of California at Los Angeles, Los Angeles; Amanda M. Adams, M.P.H., American College of Radiology Imaging Network (ACRIN) Biostatistics Center, Brown University, Providence, RI; Christine D. Berg, M.D., Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; William C. Black, M.D., Dartmouth–Hitchcock Medical Center, Lebanon, NH; Jonathan D. Clapp, B.S., Information Management Services, Rockville, MD; Richard M. Fagerstrom, Ph.D., Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; Ilana F. Gareen, Ph.D., ACRIN Biostatistics Center, Brown University, Providence, RI; Constantine Gatsonis, Ph.D., ACRIN Biostatistics Center, Brown University, Providence, RI; Pamela M. Marcus, Ph.D., Division of Cancer Prevention, National Cancer Institute, Bethesda, MD; and JoRean D. Sicks, M.S., ACRIN Biostatistics Center, Brown University, Providence, RI.

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Exhibit C

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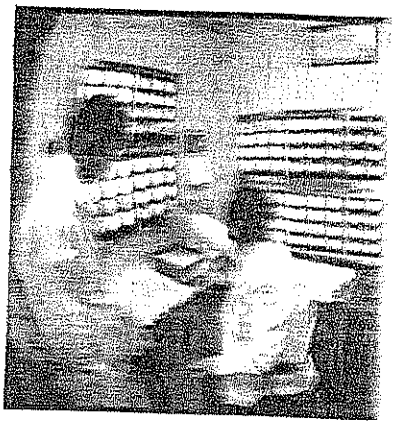
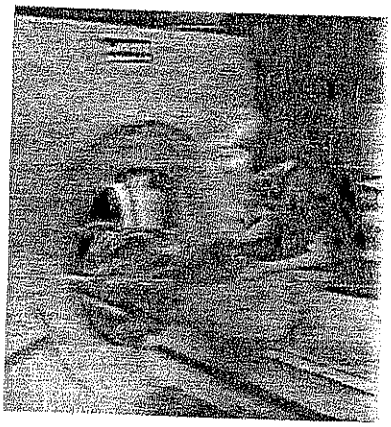
FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Home | What is CT? | What are the Radiation Risks From CT? | Should I get "whole body" CT? | How does FDA regulate CT? | Other Resources | Radiation Quantities and Units | Contact Us

Brochure: Full-Body CT Scans *What You Need to Know*







Using a technology that "takes a look" at people's insides and promises early warnings of cancer, cardiac disease, and other abnormalities, clinics and medical imaging facilities nationwide are touting a new service for health-conscious people: "Whole-body CT screening." This typically involves scanning the body from the chin to below the hips with a form of X-ray imaging that produces cross-sectional images.

The technology used is called "X-ray computed tomography" (CT), sometimes referred to as "computerized axial tomography" (CAT). A

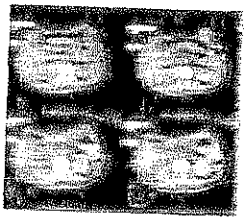
number of different types of X-ray CT systems are being promoted for various types of screening. For example, "multi-slice" CT (MSCT) and "electron beam" CT (EBCT) - also called "electron beam tomography" (EBT) - are X-ray CT systems that produce images rapidly and are often promoted for screening the buildup of calcium in arteries of the heart.

CT, MSCT and EBCT all use X-rays to produce images representing "slices" of the body - like the slices of a loaf of bread. Each image slice corresponds to a wafer-thin section which can be viewed to reveal body structures in great detail.

CT is recognized as an invaluable medical tool for the diagnosis of disease, trauma, or abnormality in patients with signs or symptoms of disease. It's also used for planning, guiding, and monitoring therapy. What's new is that CT is being marketed as a preventive or proactive health care measure to healthy individuals who have no symptoms of disease.

No Proven Benefits for Healthy People

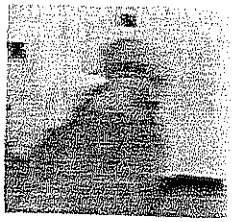
Taking preventive action, finding unsuspected disease, uncovering problems while they are treatableÑ these all sound great, almost too good to be true! In fact, at this time the Food and Drug Administration (FDA) knows of no scientific evidence demonstrating that whole-body scanning of individuals without symptoms provides more benefit than harm to people being screened. The FDA is responsible for assuring the safety and effectiveness of such medical devices, and it prohibits manufacturers of CT systems to promote their use for whole-body screening of asymptomatic people. The FDA, however, does not regulate practitioners and they may choose to use a device for any use they deem appropriate.



Compared to most other diagnostic X-ray procedures, CT scans result in relatively high radiation exposure. The risks associated with such exposure are greatly outweighed by the benefits of diagnostic and therapeutic CT. However, for whole-

body CT screening of asymptomatic people, the benefits are questionable:

- Can it effectively differentiate between healthy people and those who have a hidden disease?
- Do suspicious findings lead to additional invasive testing or treatments that produce additional risk with little benefit?
- Does a "normal" finding guarantee good health?



Many people don't realize that getting a whole body CT screening exam won't necessarily give them the "peace of mind" they are hoping for, or the information that would allow them to prevent a health problem. An abnormal finding, for example, may not be a serious one, and a normal finding may be inaccurate. CT scans, like other medical procedures, will miss some conditions, and "false" leads can prompt further, unnecessary testing.

Points to consider if you are thinking of having a whole-body screening:

- CT screening has not been demonstrated to meet generally accepted criteria for an effective screening procedure.
- Medical professional societies have not endorsed CT scanning for individuals without symptoms.
- CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available.
- The radiation from a CT scan may be associated with a very small increase in the possibility of developing cancer later in a person's life.
- The FDA provides additional information regarding whole-body CT screening on its Web site at: *www.fda.gov/cdrh/ct/*

FDA's Recommendation:

Before having a CT screening procedure, carefully investigate and

consider the potential risks and benefits and discuss them with your physician.

DHHS Publication No: (FDA) 03-0001
March 2003

Exhibit D

ACR Practice Guideline

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

Revised 2006 (Res. 46,17,35)*

ACR PRACTICE GUIDELINE FOR THE PERFORMANCE OF PEDIATRIC AND ADULT CHEST RADIOGRAPHY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

Chest radiography is a proven and useful procedure for evaluation of the airways, lungs, pulmonary vessels, mediastinum, heart, pleura, and chest wall. The common and accepted practice consists of posteroanterior (PA) and left lateral radiographs obtained in the upright position. Under certain clinical circumstances and in certain patient populations (e.g., critically ill, postoperative, trauma, newborn), portable chest radiography may be indicated and should be performed in accordance with the ACR Practice Guideline for the Performance of Pediatric and Adult Portable (Mobile Unit) Chest Radiography.

(For pediatric considerations, see section V.D.2.)

II. GOAL

The goal of the chest radiographic examination is to help establish the presence or the absence and the etiology of disease processes that involve the thorax or to follow their course.

III. INDICATIONS AND CONTRAINDICATIONS

Indications for chest radiography include, but are not limited to:

A. Evaluation of signs and symptoms potentially related to the respiratory, cardiovascular, and upper gastrointestinal systems, and the musculoskeletal system of the thorax. The chest radiograph may also help to evaluate thoracic disease processes, including systemic and extrathoracic diseases that secondarily involve the chest. Because the lungs are a frequent site of metastases, chest radiography may be useful in staging extrathoracic as well as thoracic neoplasms.

B. Follow-up of known thoracic disease processes to assess improvement, resolution, or progression.

C. Monitoring of patients with life-support devices and patients who have undergone cardiac or thoracic surgery or other interventional procedures.

D. Compliance with government regulations that may mandate chest radiography. Examples include surveillance PA chest radiographs for active tuberculosis or occupational lung disease or exposures, or other surveillance studies required by public health law.

E. Preoperative radiographic evaluation when cardiac or respiratory symptoms are present or when there is a significant potential for thoracic pathology that may compromise the surgical result or lead to increased perioperative morbidity or mortality.

For the pregnant or potentially pregnant patient, see the *ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation*.

IV. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the ACR–SPR Practice Guideline for General Radiography.

A. Physician

Additionally, physicians interpreting pediatric chest radiographs should also have had 3 months of documented formal training in pediatric radiology, including interpretation and formal reporting of pediatric chest radiographs.

Physicians whose residency or fellowship training did not include the above may still be considered qualified to interpret pediatric chest radiographs when the following are documented:

1. The physician has supervised and interpreted chest radiographs for at least 2 years.
2. An official interpretation (final report) was generated for each study.

B. Radiologic Technologist

If pediatric chest radiography is to be performed, documented training in pediatric chest radiography is required (in addition to the qualifications listed under the general radiography guideline).

V. SPECIFICATIONS OF THE EXAMINATION

A. The written or electronic request for chest radiography should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state's scope of practice requirements. (ACR Resolution 35, adopted in 2006)

B. A standard chest examination should include an erect PA and left lateral projection made during full inspiration. The examination may be modified by the physician or qualified technologist depending on the clinical circumstances (e.g., when young children are not yet able to stand, supine images are performed). Other positions that may be used occasionally include supine, oblique, decubitus, or lordotic. Views in expiration or with nipple markers may also be used. At times a single view, such as an anteroposterior (AP) or PA view is appropriate.

C. The chest radiograph should include both of the lung apices and costophrenic angles. The mid-thoracic vertebral bodies and the left retrocardiac pulmonary vessels should be appropriately defined. The scapulae should be positioned off of the lungs on the PA view, and the arms should be elevated for the lateral view. The vertebral column should be centered between the clavicles. The radiographic beam should be appropriately collimated to include the structures listed while limiting

exposure of the remainder of the patient and should not exceed the geometry of the image receptor.

D. Technical Factors

1. Adults: For a PA chest radiograph, the mean entrance skin exposure (ESE) should not exceed 0.3 mGy per exposure, and the exposure time should not exceed 40 msec. A high-kilovoltage technique (120 to 150 kVp) should be employed. An antiscatter technique (e.g., grid or air gap) should be used that reduces scatter at least as much as a 10:1 grid (preferably 12:1 grid). Technique charts should be posted for use by technologists in the radiographic room. An optimally exposed radiograph should display the lung parenchyma at a mid-gray level.

2. Newborns, infants, and children: In newborns and infants, a supine chest radiograph is preferred. For an AP or PA chest radiograph, the mean ESE should range from 0.05 to 0.3 mGy per exposure, respectively, for a 1-year-old to adult-sized patient using a 200-speed image receptor. The kVp should be selected to provide adequate contrast; it should range from as low as 60 for infants to as high as 150 for adult-sized patients.

   When using high-kVp techniques on larger patients, an antiscatter technique (e.g., grid or air gap) should be selected to reduce scatter equivalent to that of a 10:1 grid (preferably 12:1 grid). After establishing the correct kVp as a function of patient size, a tube current should be selected which makes the exposure time as short as feasible for fixed radiographic units, to minimize patient motion during the exposure. The selected mAs and kVp should produce an image that displays the lung parenchyma at a mid-gray level.

E. The following quality control (QC) procedures should be applied to chest radiography:

1. When the examination is completed, the images should be reviewed by qualified personnel, either a physician or a radiologic technologist.
2. Images of less than optimal diagnostic quality should be repeated as necessary. A repeat-rate program should be part of the QC process.
3. Each film or image should be permanently marked with the patient's name, identification number, right or left side, patient position, and the date and the time of the examination. Labeling the image with the patient's date of birth is strongly recommended.

VI. DOCUMENTATION AND REPORTING

New images should be compared with prior chest examinations and/or other pertinent studies that may be available.

An official interpretation (final report) of the examination should be included in the patient's medical record. Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

VII. EQUIPMENT SPECIFICATIONS

The equipment requirements include a diagnostic radiographic unit with a rotating anode tube and tube filtration sufficient to achieve a half-value layer (HVL) greater than 3 mm of aluminum at 100 kVp. A grid should be used for adult radiography. At least a 10:1 grid (preferably 12:1 grid) with a minimum of 103 lines per inch (stationary) or 80 lines per inch (reciprocating) is recommended.

Radiographs shall be exposed only with equipment having a beam-limiting device that provides rectangular collimation.

There should be at least a 72-inch source-image distance (SID) to minimize magnification for routine upright projections. A 40-inch SID may be used when clinically necessary (e.g., supine positioning, infants and young children, immobilized patients, etc.).

The nominal source (focal spot) shall not exceed 2.0 mm; 0.6 to 1.2 mm is the recommended range.

For analog studies, intensifying screens shall be used. Any film-screen combination with a speed of at least 200 may be used.

Automatic processing is preferable with carefully controlled temperature and maintenance. A constant time and temperature shall be employed for manual processing.

Photostimulable phosphor plates or digital imaging techniques are an acceptable alternative to film-screen radiography, but require careful quality control. Since image degradation from scattered radiation is greater with photostimulable plates than with film-screen imaging, grids may be needed for radiographs of small patients.

VIII. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary

diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

IX. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (http://www.acr.org/guidelines).

The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used particularly in pediatric examinations. Radiation doses should be determined periodically based on a reasonable sample of pediatric examinations. Technical factors should be appropriate for the size and the age of the child and should be determined with consideration of parameters such as characteristics of the imaging system, organs in the radiation field, lead shielding, etc. Guidelines concerning effective pediatric technical factors are published in the radiological literature.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web page (http://www.acr.org/guidelines) by the Guidelines and Standards Committee of the Commission on General, Small, and Rural Practice.

Principal Reviewer: Diane C. Strollo, MD

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Suggested Reading (Additional articles that are not cited in the document but that the committee recommends for further reading on this topic)

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
1993 (Resolution 2)
Amended 1995 (Resolution 24, 53)
Revised 1997 (Resolution 23)
Revised 2001 (Resolution 53
Revised 2006 (Resolution 46, 17, 35)
Amended 2009 (Resolution 11)

The American College of Radiology, with more than 30,000 members, is the principal organization of radiologists, radiation oncologists, and clinical medical physicists in the United States. The College is a nonprofit professional society whose primary purposes are to advance the science of radiology, improve radiologic services to the patient, study the socioeconomic aspects of the practice of radiology, and encourage continuing education for radiologists, radiation oncologists, medical physicists, and persons practicing in allied professional fields.

The American College of Radiology will periodically define new practice guidelines and technical standards for radiologic practice to help advance the science of radiology and to improve the quality of service to patients throughout the United States. Existing practice guidelines and technical standards will be reviewed for revision or renewal, as appropriate, on their fifth anniversary or sooner, if indicated.

Each practice guideline and technical standard, representing a policy statement by the College, has undergone a thorough consensus process in which it has been subjected to extensive review, requiring the approval of the Commission on Quality and Safety as well as the ACR Board of Chancellors, the ACR Council Steering Committee, and the ACR Council. The practice guidelines and technical standards recognize that the safe and effective use of diagnostic and therapeutic radiology requires specific training, skills, and techniques, as described in each document. Reproduction or modification of the published practice guideline and technical standard by those entities not providing these services is not authorized.

2007 (Res. 19)*

ACR PRACTICE GUIDELINE FOR PERFORMING FDG-PET/CT IN ONCOLOGY

PREAMBLE

These guidelines are an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. They are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care. For these reasons and those set forth below, the American College of Radiology cautions against the use of these guidelines in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in light of all the circumstances presented. Thus, an approach that differs from the guidelines, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in the guidelines when, in the reasonable judgment of the practitioner, such course of action is indicated by the condition of the patient, limitations of available resources, or advances in knowledge or technology subsequent to publication of the guidelines. However, a practitioner who employs an approach substantially different from these guidelines is advised to document in the patient record information sufficient to explain the approach taken.

The practice of medicine involves not only the science, but also the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment.

Therefore, it should be recognized that adherence to these guidelines will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The sole purpose of these guidelines is to assist practitioners in achieving this objective.

I. INTRODUCTION

This guideline has been developed by the American College of Radiology (ACR) to guide interpreting physicians performing positron emission tomography/computed tomography (PET/CT) with fluorine-18-2-fluoro-2-deoxy-D-glucose (FDG) for oncologic imaging in adult and pediatric patients.

FDG-PET is a scintigraphic technique that provides three-dimensional information about the rate of glucose metabolism in the body and is a sensitive method for detecting, staging, and monitoring the effects of therapy for many malignancies. CT uses an external source of radiation to provide three-dimensional images of the density of the tissues in the body. CT images provide information about the size and shape of organs and abnormalities within the body. Combined PET/CT devices [1,2] provide both the metabolic information from FDG-PET and the anatomic information from CT in a single examination. The information obtained by PET/CT has been shown to be more accurate in evaluating patients with known or suspected malignancy than either PET or CT alone or PET and CT obtained separately but interpreted together [3-10].

FDG-PET and CT are proven diagnostic procedures. The advantages of having both PET and CT in a single device have resulted in rapid dissemination of this technology in the United States. Techniques for registration and fusion of images obtained from separate PET and CT scanners have been available for several years and have been shown to improve diagnostic accuracy [11-18]. This practice guideline, however, pertains only to combined PET/CT devices.

Several issues related to PET/CT have arisen and include equipment specifications, image acquisition protocols, supervision, interpretation, professional qualifications, and safety. A discussion of these issues by representatives of the ACR, the Society of Nuclear Medicine, and the Society of Computed Body Tomography and Magnetic Resonance is available [19,20].

II. GOAL

The goal of PET/CT imaging in oncology is to enable the interpreting physician to 1) distinguish benign from malignant disease, 2) determine the extent of disease, 3) detect residual and recurrent tumors, 4) monitor the effect of therapy, and 5) guide therapy.

III. DEFINITIONS

For the purposes of this guideline, the following definitions apply:

PET/CT fusion: The simultaneous display (superimposed or not) of registered PET and CT image sets. When superimposed, the image sets are typically displayed with the PET data color-coded onto the grayscale CT data.

PET/CT registration: The process of taking PET and CT image sets that represent the same body volume and aligning them such that there is a voxel-by-voxel match for the purpose of combined image display (fusion) or image analysis.

PET/CT scanner: A device that includes a single patient table for obtaining a CT scan or PET scan, or both. If the patient stays reasonably immobile between the scans, the PET and CT data are aligned and can be accurately fused.

IV. INDICATIONS

Indications for PET/CT include, but are not limited to, the following:

1. Evaluating an abnormality detected by another imaging method to determine the level of metabolism and the likelihood of malignancy.
2. Searching for an unknown primary tumor when metastatic disease is discovered as the first manifestation of cancer.
3. Staging patients with known malignancy.
4. Monitoring the effect of therapy on known malignancies.
5. Determining if residual abnormalities on imaging studies following treatment represent tumor or post-treatment inflammation, fibrosis, or necrosis.
6. Detecting recurrence, especially in the presence of elevated tumor markers.
7. Assisting in treatment planning.

PET/CT does not work equally well for all tumors. A continuing review of the literature is recommended to determine the most effective applications.

For the pregnant or potentially pregnant patient, see the ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation.

V. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

A. Physician

1. All PET/CT examinations must be performed under the supervision of and interpreted by a physician who has the following qualifications:
   a. Certification in Radiology or Diagnostic Radiology by the American Board of Radiology, American Osteopathic Board of Radiology, the Royal College of Physicians and Surgeons of Canada, or Le College des Medecins du Quebec; and involvement with the interpretation, reporting, and/or supervised review of 300 PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT)[1], and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

[1] Should include cases that are representative of the following areas: abdomen, chest, neck, and pelvis. In meeting the requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic CT, physicians who are certified by the ABNM and have completed the ACGME approved nuclear medicine residency program, can count up to 100 hours of didactic training in CT toward satisfying the 200 hours requirement in the guideline, and 500 CT cases interpreted under the supervision of a physician qualified under the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography.

b. Completion of an Accreditation Council for Graduate Medical Education (ACGME) approved diagnostic radiology residency program or an American Osteopathic Association (AOA) approved diagnostic radiology residency program; and involvement with the interpretation, reporting, and supervised review of 500 or more PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT), and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

c. Certification in Nuclear Medicine by the ABNM or in special competence in nuclear medicine by the ABR; and involvement with the interpretation, reporting, and/or supervised review 300 PET and/or PET/CT examinations in the past 36 months; 15 hours of PET and PET/CT CME (AMA category 1), at least 8 of which are PET/CT; and meets the physician training and experience requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT), and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

or

Physicians in the certification/training categories in a, b, and c above, but without the recent PET or PET/CT involvement specified may achieve the required PET/CT training experience equivalent by completing and documenting the following:

i. Physician category a: 150 PET and/or PET/CT interpretations in a supervised situation,[2] at least 100 of which are PET/CT, and 15 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

ii. Physician category b: 200 PET and/or PET/CT interpretations in a supervised situation, at least 150 of which are PET/CT, and 25 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

iii. Physician category c: 150 PET and/or PET/CT interpretations in a supervised situation, at least 100 of which are PET/CT, and 15 hours of PET and/or PET/CT CME, at least 8 of which are PET/CT. The physician training requirements of the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the physician qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals must be met.

or

d. Physicians not board certified in radiology or nuclear medicine, or not trained in a diagnostic radiology residency or nuclear medicine program who assume the responsibilities of supervising, interpreting, and reporting PET/CT examinations, should meet the following criteria: completion of an ACGME approved residency program plus 80 hours of PET and PET/CT CME, at least 40 of which are PET/CT, and supervision, interpretation, and reporting of 500 PET/CT cases in a supervised situation. In addition, these physicians must meet the training requirements in the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the qualifications in the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

[2]Acceptable ways to have PET/CT and CT case interpretations in a supervised situation include practice-based learning locally or in a visiting fellowship, learning in an interactive live case based on conference where an interpretation is rendered and then scored or critiqued, or distance learning such as over the Internet, in an interactive case-based format where an interpretation is rendered and then scored or critiqued, under the supervision or review of physicians expert in the field.

and

2. The physician shall have documented training in the physics of nuclear medicine and diagnostic radiology. Additionally, the physician must demonstrate training in the principles of radiation protection; the hazards of radiation exposure to patients, radiological personnel and the public; handling radiopharmaceuticals; and the appropriate regulatory and monitoring requirements.

and

3. The physician should be thoroughly acquainted with the many morphologic, pathologic, and physiologic radiopharmaceutical distributions with artifacts demonstrated on PET/CT. Additionally, the supervising physician should have appropriate knowledge of alternative imaging methods, including the use and indications for general radiography and specialized studies such as angiography, ultrasonography, magnetic resonance imaging (MRI), and alternative nuclear medicine studies.

and

4. The physician should be familiar with patient preparation for the examination. The physician must have training in and knowledge of the properties of radiopharmaceuticals used as well as in the recognition and treatment of adverse effects of contrast materials that may be employed.

and

5. The physician shall have the responsibility for reviewing all indications for the examination; specifying the radiopharmaceutical dose and the type, dose, and administration rate of any contrast materials employed; specifying imaging technique and protocol; treating and documenting of any adverse reactions and relevant patient counseling; interpreting images; generating official interpretations (final reports); and maintaining the quality of the images and the interpretations.

The required qualifications set forth in section V.A above will become applicable by July 1, 2009. Until then the physician should work toward achieving these requirements in a supervised situation or where expert consultation is readily available.

Maintenance of Competence

All physicians performing PET/CT examinations should demonstrate evidence of continuing competence in the interpretation and reporting of those examinations. If competence is assured primarily based on continuing experience, a minimum of 75 examinations per year is recommended in order to maintain the physician's skills. Because a physician's practice or location may preclude this method, continued competency can also be assured through monitoring and evaluation that indicates acceptable technical success, accuracy of interpretation, and appropriateness of evaluation.

B. Qualified Medical Physicist

A Qualified Medical Physicist is an individual who is competent to practice independently one or more of the subfields in medical physics. The ACR considers certification and continuing education and experience in the appropriate subfield(s) to demonstrate that an individual is competent to practice one or more of the subfields in medical physics and is a Qualified Medical Physicist. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology (ABR), the Canadian College of Physics in Medicine, or for MRI, by the American Board of Medical Physics (ABMP) in magnetic resonance imaging physics.

The appropriate subfields of medical physics for this standard are Diagnostic Radiological Physics and Radiological Physics.

A Qualified Medical Physicist should meet the ACR Practice Guideline for Continuing Medical Education (CME). (ACR Resolution 17, 1996 – revised in 2008, Resolution 7)

The medical physicist or other qualified scientist performing services in support of nuclear medicine facilities should meet all of the following criteria:

1. Advanced training directed at the specific area of responsibility (e.g., radiopharmacy, medical physics, health physics or instrumentation).
2. Licensure, if required by state regulations.
3. Documented regular participation in continuing education in the area of specific involvement to maintain competency.
4. Knowledge of radiation safety and protection and of all rules and regulations applying to the area of practice.

C. Radiologic and Nuclear Medicine Technologist

See the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT) and the ACR Technical Standard for Diagnostic Procedures Using Radiopharmaceuticals.

Representatives of the Society of Nuclear Medicine and the American Society of Radiologic Technologists (ASRT) met in 2002 to discuss the training of technologists for PET/CT. The recommendations from that consensus conference and the plans for training technologists for PET/CT are given in [21]. As a consequence of this conference and ensuing educational

recommendations, cross-training and continuing educational programs have been developed to educate radiologic, radiation therapy, and nuclear medicine technologists in PET/CT fusion imaging.

The Nuclear Medicine Technology Certification Board (NMTCB) has developed a PET specialty examination that is open to appropriately educated and trained, certified, or registered nuclear medicine technologists, registered radiologic technologists, CT technologists, and registered radiation therapists, as defined on the NMTCB Web site (www.nmtcb.org). The American Registry of Radiologic Technologists (ARRT) offers a CT certification examination for qualified radiologic technologists and allows certified or registered nuclear medicine technologists who have met the educational and training requirements to take this examination. Eligibility criteria are located on the ARRT Web site (www.arrt.org).

VI. SPECIFICATIONS OF THE EXAMINATION

A. The written or electronic request for an FDG-PET/CT examination should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). Additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006)

See the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Extracranial Head and Neck in Adults and Children, the ACR Practice Guideline for the Performance of Pediatric and Adult Thoracic Computed Tomography (CT), and the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Abdomen and Computed Tomography (CT) of the Pelvis.

Sections VI. B, C, E, F below have been copied from an article in the *Journal of Nuclear Medicine Technology*, "Procedure Guideline for Tumor Imaging with ^{18}F-FDG PET/CT 1.0," with permission from the Society of Nuclear Medicine. [22].

B. Patient Preparation

The major goals of preparation are to minimize tracer uptake in normal tissues, such as the myocardium and skeletal muscle, while maintaining uptake in target tissues (neoplastic disease). The preparation should include, but not be limited to, the following:

1. Pregnancy testing when appropriate.
2. Fasting instruction and no oral or intravenous fluids containing sugar or dextrose (4 to 6 hours).
3. Serum glucose analysis immediately prior to FDG administration.
4. Hydration (a loop diuretic, without or with bladder) catheterization, may be used to reduce accumulated urinary tracer activity in the bladder.
5. Keeping the patient in a warm room 30 to 60 minutes prior to injection and until the time of FDG injection to help minimize brown fat uptake. Lorazepam or diazepam given prior to injection of FDG may reduce uptake by brown adipose tissue or skeletal muscle. Beta-blockers may also reduce uptake by brown fat.
6. Focused history regarding diabetes, recent exercise, dates of diagnosis and treatments, medications, and recent trauma or infections.

C. Radiopharmaceutical

For adults, the amount of radiopharmaceutical administered should be 370 to 740 MBq (10 to 20 mCi); and for children, 5.18 to 7.4 MBq/kg (0.14 to 0.20 mCi/kg). The radiopharmaceutical should be injected at a site contralateral to the site of concern. With PET/CT, the radiation dose to the patient is the combination of the dose from the PET radiopharmaceutical and the dose from the CT portion of the study.

D. Protocol for CT Imaging

The PET/CT examination can be performed either as a diagnostic PET/CT scan with the CT scan obtained for attenuation correction and anatomic correlation or as a diagnostic PET scan and an optimized CT scan, with or without contrast. If a diagnostic CT scan is requested, the CT protocol appropriate for the body region(s) requested should be used. If the CT scan is obtained for attenuation correction and anatomic correlation, the CT parameters should be set to minimize patient radiation dose, while still ensuring that the CT images are of sufficient quality to allow for accurate anatomic correlation of PET findings.

For the diagnostic CT scan of the abdomen and/or pelvis, an intraluminal gastrointestinal contrast agent may be administered to provide adequate visualization of the gastrointestinal tract unless medically contraindicated or unnecessary for the clinical indication. This may be a positive contrast agent such as dilute barium or Gastrografin, or a negative contrast agent such as water. Highly concentrated barium collections may result in an attenuation-correction artifact that leads to a significant overestimation of the regional FDG concentration [23]; dilute barium and oral iodinated agents cause less overestimation and do not impact image quality [23-26].

When indicated, the CT scan can be performed with intravenous contrast material using appropriate injection techniques. High intravascular concentrations of intravenous contrast agents may cause an attenuation-correction artifact on the PET image [27, 28], but the impact is limited [24,29].

PET and CT findings should be correlated with each other. Clinically important findings on the CT scan should be reported.

Breathing patterns during CT acquisition - for PET/CT the position of the diaphragm should match as closely as possible on the PET emission and the CT transmission images.

E. Protocol for PET Emission Imaging

Emission images are obtained at least 45 minutes following radiopharmaceutical injection. Emission image acquisition time varies from 2 to 5 minutes or longer per bed position for body imaging and is based on the administered activity, patient body weight, and the sensitivity of the PET tomograph (as determined largely by detector composition and acquisition method).

Semiquantitative estimation of tumor glucose metabolism using the standardized uptake value (SUV) is based on relative lesion radioactivity measured on images corrected for attenuation and normalized for the injected dose and body weight, lean body mass, or body surface area. The accuracy of SUV measurements depends on the accuracy of the calibration of the PET tomograph, among other factors. The reproducibility of SUV measurements depends on the reproducibility of clinical protocols, and is affected by dose infiltration, time of imaging after FDG administration, type of reconstruction algorithms, type of attenuation maps, size of the region of interest, changes in uptake by organs other than the tumor, methods of analysis (e.g., max, mean), etc. This measurement is performed on a static emission image typically acquired more than 45 minutes postinjection.

A change of intensity of uptake with semiquantitative measurements, expressed in absolute values and percent change, may be appropriate in some clinical scenarios. However, the technical protocol and analysis of images need to be more consistent in the two sets of images.

F. Interpretation

With an integrated PET/CT system, typically the software packages provide registered and aligned CT images; FDG-PET images and fusion images in the axial, coronal, and sagittal planes; and maximum-intensity-projection (MIP) images for review in the 3D-cine mode. FDG-PET images with and without attenuation correction should be available for review.

Normal and variable physiologic uptake of FDG can be seen to some extent in every viable tissue, including the brain, myocardium (where the uptake is significant in some patients despite prolonged fasting), breast, liver, spleen, stomach, intestines, kidneys and urine, muscle, lymphoid tissue (e.g., tonsils), bone marrow, salivary glands, thymus, uterus, ovaries, testes, and brown adipose tissue.

On whole-body scans, studies have shown that FDG-PET imaging of the brain is relatively insensitive for detecting cerebral metastases, partially related to the high physiologic FDG uptake in the gray matter.

Although the pattern of FDG uptake and specific CT findings as well as correlation with history, physical examination and other imaging modalities are usually the most helpful in differentiating benign from malignant lesions, semi-quantitative estimates (e.g., SUV) may also be of value, especially for evaluating changes with time or therapy.

Processes other than malignancies may cause false-positive and false-negative results. The following list, although not all-inclusive, includes the most commonly encountered causes:

1. False-positive findings
    a. Physiologic uptake that may lead to false-positive interpretations
        - Salivary glands and lymphoid tissue in the head and neck
        - Thyroid
        - Brown adipose tissue
        - Thymus, especially in children
        - Lactating breast
        - Areola
        - Skeletal and smooth muscle (more marked with hyperinsulinemia)
        - Gastrointestinal (e.g., esophagus, stomach, bowel)
        - Urinary tract structures (containing excreted FDG)
        - Female genital tract (e.g., uterus during menses, corpus luteum cyst)

b. Inflammatory processes
   - Postsurgical inflammation/infection/hematoma, biopsy site, amputation site
   - Postradiation (e.g., radiation pneumonitis)
   - Postchemotherapy
   - Local inflammatory disease, especially granulomatous processes (e.g., sarcoidosis, fungal and mycobacterial disease)
   - Ostomy site (e.g., trachea, colon) and drainage tubes
   - Injection site
   - Thyroiditis
   - Esophagitis, gastritis, inflammatory bowel disease
   - Acute and occasionally chronic pancreatitis
   - Acute cholangitis and cholecystitis
   - Osteomyelitis, recent fracture sites, joint prostheses
   - Lymphadenitis

c. Benign neoplasms
   - Pituitary adenoma
   - Adrenal adenoma
   - Thyroid follicular adenoma
   - Salivary glands tumors (e.g., Warthin's, pleomorphic adenoma)
   - Colonic adenomatous polyps and villous adenoma
   - Ovarian thecoma and cystadenoma
   - Giant cell tumor
   - Aneurysmal bone cyst
   - Leiomyoma

d. Hyperplasia/dysplasia
   - Graves' disease
   - Cushing's disease
   - Bone marrow hyperplasia (e.g., anemia, cytokine therapy)
   - Thymic rebound hyperplasia (after chemotherapy)
   - Fibrous dysplasia
   - Paget's disease

e. Ischemia
   - Hibernating myocardium

f. Artifacts
   - Misalignment between PET and CT data can cause attenuation correction artifacts. PET images without attenuation correction and fusion images can be used to help identify these artifacts.
   - Inaccuracies in converting from polychromatic CT energies to the 511 keV energy of annihilation radiation can cause artifacts around metal or dense barium, although these artifacts are less common with newer conversion algorithms.

g. False-negative findings
   - Small size (< 2 x resolution of the system)
   - Tumor necrosis
   - Recent chemotherapy or radiotherapy
   - Recent high-dose steroid therapy
   - Hyperglycemia and hyperinsulinemia
   - Some low-grade tumors (e.g., sarcoma, lymphoma, brain tumor)
   - Tumors with large mucinous components
   - Some hepatocellular carcinomas, especially well-differentiated tumors
   - Some genitourinary carcinomas, especially well-differentiated tumors
   - Prostate carcinoma, especially well-differentiated tumors
   - Some neuroendocrine tumors, especially well-differentiated tumors
   - Some thyroid carcinomas, especially well-differentiated tumors
   - Some bronchioloalveolar carcinomas
   - Some lobular carcinomas of the breast
   - Some skeletal metastases, especially osteoblastic or sclerotic tumors
   - Some osteosarcomas

VII. EQUIPMENT SPECIFICATIONS

See the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET/CT Imaging Equipment, the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Extracranial Head and Neck in Adults and Children, the ACR Practice Guideline for the Performance of Pediatric and Adult Thoracic Computed Tomography (CT), and the ACR Practice Guideline for the Performance of Computed Tomography (CT) of the Abdomen and Computed Tomography (CT) of the Pelvis.

A. Performance Guidelines

For patient imaging, the PET/CT scanner should meet or exceed the following specifications:

1. For the CT scanner
   a. Spiral scan time: <5 sec (<2 sec is preferable)
   b. Slice thickness and collimation: <5 mm (<2 mm is preferable)
   c. Limiting spatial resolution: >8 lp/cm for >32 cm display field of view (DFOV) and >10 lp/cm for <24 cm DFOV
2. For the PET scanner
   a. In-plane spatial resolution: <6.5 mm
   b. Axial resolution: <6.5 mm
   c. Sensitivity (3D): >4.0 cps/kBq

d. Sensitivity (2D): >1.0 cps/kBq
e. Uniformity: <5%

3. For the combined PET/CT scanner
   a. Maximum co-scan range (CT and PET): >160 cm
   b. Maximum patient weight: >350 lb
   c. Patient port diameter: >59 cm

B. Appropriate emergency equipment and medications must be immediately available to treat adverse reactions associated with administered medications. The equipment and medications should be monitored for inventory and drug expiration dates on a regular basis. The equipment, medications, and other emergency support must also be appropriate for the range of ages and sizes in the patient population.

C. A fusion workstation with the capability to display CT, PET, and fused images with different percentages of CT and PET blending should also be available.

D. PET/CT scanning done specifically for radiation therapy planning should be performed with a flat table top, immobilization devices as needed, and the use of appropriate positioning systems.

VIII. DOCUMENTATION

A. Reporting should be in accordance with the ACR Practice Guideline for Communication of Diagnostic Imaging Findings.

In addition, the procedure section should include the dose of radiopharmaceutical, route of administration, uptake time, field of view, patient positioning, and baseline glucose level.

The findings section should include description of location, extent, and intensity of abnormal FDG uptake in relation to normal comparable tissues and describe the relevant morphologic findings related to PET abnormalities on the CT images. An estimate of the intensity of FDG uptake can be provided with the SUV; however, the intensity of uptake may be described as mild, moderate, or intense or in relation to the background uptake in normal hepatic parenchyma (average SUV weight: 2.0 to 3.0, maximum SUV: 3.0 to 4.0). If the CT scan was requested and performed as a diagnostic examination, the CT component of the study may be reported separately, if necessary to satisfy regulatory, administrative, or reimbursement requirements. In that case, the PET/CT report can refer to the diagnostic CT scan report for findings not related to the PET/CT combined findings.

When PET/CT is performed for monitoring therapy, a comparison of extent and intensity of uptake may be summarized as metabolic progressive disease, metabolic stable disease, metabolic partial response, or metabolic complete response using published criteria for these categories [30].

IX. EQUIPMENT QUALITY CONTROL

PET performance monitoring should be in accordance with the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of Gamma Cameras and the ACR Technical Standard for Medical Nuclear Physics Performance Monitoring of PET/CT Imaging Equipment.

CT monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

The quality control (QC) procedures for PET/CT should include both the CT procedures and the PET procedures according to the ACR Technical Standards. The QC procedures for the CT should include air and water calibrations in Hounsfield units for a range of kV. The QC procedures for PET should include a calibration measurement of activity in a phantom containing a known radionuclide concentration, generally as a function of axial position within the scanner field of view. A daily check on the stability of the individual detectors should also be performed to identify detector failures and drifts.

In addition, for PET/CT, the alignment between the CT and PET scanners should be checked periodically. Such a check should determine an offset between the CT and PET scanners that is incorporated into the fused image display to ensure accurate image alignment.

X. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This concept is known as "as low as reasonably achievable (ALARA)."

Facilities, in consultation with the medical physicist should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active; if not, manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Periodically, radiation exposures should be measured and patient radiation doses estimated by a medical physicist in accordance with the appropriate ACR Technical Standard. (ACR Resolution 17, adopted in 2006 – revised in 2009, Resolution 11)

XI. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR web page (http://www.acr.org/guidelines).

In all pediatric patients, the lowest exposure factors should be chosen that would produce images of diagnostic quality.

For specific issues regarding CT quality control, see the ACR Practice Guideline for Performing and Interpreting Diagnostic Computed Tomography (CT).

For specific issues regarding PET and PET/CT quality control, see section IX on Equipment Quality Control.

Equipment performance monitoring should be in accordance with the ACR Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography (CT) Equipment.

ACKNOWLEDGEMENTS

This guideline was revised according to the process described under the heading *The Process for Developing ACR Practice Guidelines and Technical Standards* on the ACR web page (http://www.acr.org/guidelines) by the Guidelines and Standards Committee of the Commission on Nuclear Medicine.

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Edward V. Staab, MD
Julie K. Timins, MD
Fred S. Vernaccinia, MD
Jeffrey C. Weinreb, MD
Scott C. Williams, MD

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*Guidelines and standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For guidelines and standards published before 1999, the effective date was January 1 following the year in which the guideline or standard was amended, revised, or approved by the ACR Council.

Development Chronology for this Guideline
2007 (Resolution 19)
Amended 2009 (Resolution 11)

Exhibit E

American College of Radiology September 2002
Statement on CT Screening Exams

amednews.c
AMERICAN MEDICAL NEWS

HEALTH

Full-body scans: Buying peace of mind

This new trend offers patients full-body CT screens to detect serious illnesses e waiting rooms full of patients with stacks of scan reports and worried looks?

By SUSAN J. LANDERS, amednews staff. Sept. 3, 2001.

Washington -- The newspaper and magazine ads are enticing. "A simple 15-minute exan "Why take a chance?"

Radiologists who conduct the exams, which are actually full-body computed tomograph earliest stages of several conditions in asymptomatic patients. The conditions range fron wouldn't be attracted to such a marvelous procedure that can help see into a patient's me

But at the same time, this increasingly available screening practice raises tricky issues th exam room and across the health care financing system.

"It's a great concept," said Sandra Fryhofer, MD, immediate past president of the Ameri Society of Internal Medicine. "[But] I don't think we're there yet." It reminds her of a Sta care: "Quick, painless and easy."

The latest series of CT scanners do lend a sci-fi aspect to modern medicine. The machin views of all types of tissue. Targeted CT scans are frequently used to diagnose many can pancreatic cancer. CT scans also are being used to detect early heart disease.

But many physicians take a harsher view of the growing popularity of full-body scans fo the scans subject patients to unnecessary exposure to radiation or to possibly risky follo conditions that frequently turn out to be harmless.

The critics look for the large-scale studies that demonstrate the effectiveness of the body improving patient morbidity and mortality rates. But these studies haven't been done yet

In addition, some fault the expensive screening tests for siphoning off scarce health care initial scan, which ranges from about $800 to more than $1,000, but health insurance co necessary follow-up tests.

Joel Bowers, MD, is the medical director of MillenniumScan, a facility that opened its d months ago. MillenniumScan already performs about 18 full-body scans a day.

Like most such facilities, which are springing up around the country, asymptomatic pati appointments themselves. No physician referral is needed.

In its opening months, MillenniumScan has detected early lung tumors, four brain tumo cancer and a few abdominal aortic aneurysms.

With the less-than-positive news in hand, patients are referred to their family physicians by Dr. Bowers were confirmed by additional tests.

Dr. Bowers is enthusiastic about the effectiveness of the scans. "I've seen a lot of things who has 25 years experience. "And time will tell, but I think this has a lot of potential an

Bradley Jabour, MD, a neuroradiologist and CEO of Smart Heart and Health, a preventi Calif., also supports the use of whole body scans, but with provisos. "If you ensure the a no-radiation scans, thereby providing a test that is both accurate and safe, why wouldn't lives when disease is likely to rear its ugly head?" he said.

Dr. Jabour's facility has established criteria to guide patients to the most appropriate sca certain low-risk patients, such as those younger than 40, those with no family history of

Need for follow-up

The scans do present a conundrum to the primary care physician confronted by a patient frightening news.

Dr. Fryhofer had a Medicare patient who came in with a full-body scan that showed sign a gastroenterologist gave her a clean bill of health.

Even if no other signs of illness are present, a primary care physician can't ignore the sc

"You have an obligation to follow through," Dr. Fryhofer said. "As a primary care physi sure all the i's are dotted and the t's are crossed."

Paul van Gorp, MD, a family physician in Long Prairie, Minn., said the scans might hel early, and likely more curable, stage. But he sees problems.

He sees the likelihood that many of the benign conditions detected by the very sensitive use will lead to useless additional evaluations and testing that may cause the patient harr

But he agrees that the findings can't be ignored. "Now you have an objective report that obligated, because of liability issues, to chase it," Dr. van Gorp said.

Even good reports can create a false sense of security.

"There are a whole host of health risks that scans don't touch upon," Dr. van Gorp said. comprehensive health assessment that also addresses such matters as cholesterol levels, detection and such risk factors as immunizations and lifestyle issues, he noted.

But patients whose scans have not revealed any abnormality may be tempted to forgo an

Dr. Bowers argues that his facility works closely with a patient's primary care physician supplemental source of information.

Dr. Bowers also emphasizes that the body scan is a screening study and, like all such stu that will turn out to be nothing. He compares the criticisms of whole body scans to those mammography was introduced.

"There were a lot of naysayers about mammography who said, 'You're going to find all t do about it?' " Dr. Bowers said. While a significant number of breast biopsies done as a r be negative, he noted, "that does not mean that they shouldn't be done."

Studies now show that the mortality rate for breast cancer has gone down significantly, l

Dr. Bowers also said follow-up tests are not necessarily invasive. "Very often, you go fr in many cases, is either not invasive or minimally invasive," he said. For example, the n to have brain tumors was an MRI, not brain surgery.

"I don't think it is a valid argument to say that just because you're going to find many thi nonlethal, that we shouldn't do it," Dr. Bowers said. "It's up to physicians to attack what

FDA concerns

The Food and Drug Administration is keeping an eye on full-body scanning, although n made. The agency has only limited power over the use of the scanners.

"We can address improper claims being made for a particular piece of equipment," said physicist in the FDA's Center for Devices for Radiological Health. "But once a physician lot the FDA can do about how the individual physician uses that device."

FDA concerns center on the lack of scientific data or evidence that the scans are useful. the benefit to the patient?' There are really no studies that show that they help that much.

Another problem, he added, is that many of the scans are done without the use of an inje that better accentuates the difference between normal and abnormal tissue, thus raising t scan is not the best.

Meanwhile, Robert Smith, PhD, director of the American Cancer Society's screening pr issue. "It's a waste of money and a bad idea," he said.

"As cutting edge as the technique seems, we do not know whether this test is even as go tests that have been around for a long time," he said.

While CT scans hold promise for diagnosing colorectal cancer and lung cancer and dete Smith would rather see those scans performed as stand-alone tests and then only when t person is at risk for a disease.

And Robert Stanley, MD, chair of the Dept. of Radiology at the University of Alabama- mistake for radiologists to be offering the scans to asymptomatic, healthy adults.

In April, Dr. Stanley used his bully pulpit as president of the American Roentgen Ray S take responsibility for giving sound advice and for selecting the appropriate people to sc argument that people have the right to spend their money on the costly procedure.

"But guess who starts paying for biopsies and follow-ups? It's the health insurance comp said. "Once the normal, average person is told there is a nodule in their lung that could b when they were 20 years old -- and now they're 50 -- or it could be a very early cancer -- person's response? No. 1, they'd get anxious, and No. 2, they'd want something done abc

Dr. Jabour has a different view. Using the example of mammography's effectiveness wit way, it's going to prove that when people get older, they will be more likely to have dise and, rather than waiting for the symptoms of those diseases, there will be statistics that s many lives. It's pretty much common sense."

ADDITIONAL INFORMATION:

ACR votes thumbs down

The American College of Radiology's position statement on total body CT screening:

> *"The American College of Radiology (ACR), at this time, does not i scientific evidence to justify recommending total body computed to screening for patients with no symptoms or a family history sugges*
>
> *"To date there is no evidence that total body CT screening is cost-effective or is eff addition, the ACR is concerned that this procedure will lead to the discovery of nu ultimately affect patients' health, but will result in increased patient anxiety, unnec and treatments and wasted expense.*
>
> *"ACR will continue to monitor scientific studies concerning this procedure."*
>
> -- Sept. 2000

Scanning the promises

Excerpts from ads and Web sites promoting full body CT scans:

- People are taking more responsibility than ever for their own h is absolutely critical for good health.
- Bring a friend with you and receive $50 off both scans.
- As seen on "Oprah."

- Thirty minutes can save a life, your own.
- Enhances the annual physical into the 21st century.

Weblink

The American College of Radiology (http://www.acr.org/)

American Roentgen Ray Society (http://www.arrs.org/)

Society of Cardiovascular and Interventional Radiology (http://www.scvir.org/)

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Exhibit F

NIH Publications, J Bioeth. 2009 April; 9(4):3-14

NIH Public Access
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Published in final edited form as:
Am J Bioeth. 2009 April ; 9(4): 3–14. doi:10.1080/15265160902790583.

Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations

Ingrid M. Burger and
Johns Hopkins Bloomberg School of Public Health

Nancy E. Kass
Johns Hopkins Bloomberg School of Public Health, and Berman Institute of Bioethics, Johns Hopkins University

Abstract

During the past decade, screening tests using computed tomography (CT) have disseminated into practice and been marketed to patients despite neither conclusive evidence nor professional agreement about their efficacy and cost-effectiveness at the population level. This phenomenon raises questions about physicians' professional roles and responsibilities within the setting of medical innovation, as well as the appropriate scope of patient autonomy and access to unproven screening technology. This article explores how physicians ought to respond when new screening examinations that lack conclusive evidence of overall population benefit emerge in the marketplace and are requested by individual patients. To this end, the article considers the nature of evidence and how it influences decision-making for screening at both the public policy and individual patient levels. We distinguish medical and ethical differences between screening recommended for a population and screening considered on an individual patient basis. Finally, we discuss specific cases to explore how evidence, patient risk factors and preferences, and physician judgment ought to balance when making individual patient screening decisions.

Keywords

computed tomography; decision-making; evidence; ethics; professionalism; screening

During the past decade, screening tests using computed tomography (CT) have disseminated into practice despite neither conclusive evidence nor professional agreement about their efficacy and cost-effectiveness at the population level (United States Preventive Services Task Force [US PSTF] 2004a; Hillman 2003a; Ilies et al. 2003; Kalish et al. 2004; Lee and Brennan 2002; American College of Radiology [ACR] 2004). These screening tests often involve CT scans that aim to detect specific diseases, such as chest CT to detect lung cancer

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Address correspondence to Ingrid M. Burger, University of California, San Francisco, Department of Radiology, 505 Parnassus Ave., M-391, San Francisco, CA 94143-0628. ingrid.burger@gmail.com.

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in smokers or CT angiography to detect cerebral aneurysms. Additionally, whole-body CT screening examinations aim to search for a wide range of possible diseases. Screening CT tests are directed at apparently healthy adults, who may have risk factors such as smoking or family history, to detect disease that has not yet produced symptoms. The hope is that by detecting such diseases at earlier stages, patient outcomes will improve and treatment will be less costly than if detected at a later stage.

The primary goal of population-based screening is to decrease disease-specific mortality (Black & Welch 1997; Kopans et al. 2003; Morrison 1992). Most CT screening tests lack sufficient evidence demonstrating reduction in population mortality and are not recommended by professional societies as population-based screening tools (Administration 2002; Council on Scientific Affairs 2003; Force 2004a; Radiology 2004). Nevertheless, many individual physicians and physician groups offer a variety of screening tests, at times marketing screening services directly to consumers (Ilies et al. 2004). Indeed, patients generally seek these tests themselves and, in certain instances, obtain screening tests without a physician's referral ("patient self-referral").

In an era that promotes evidence-based medicine and cost effectiveness, the marketing and diffusion of these CT screening examinations into current practice before rigorous empirical evaluation raises concern. Image-based screening tests carry important risks for patients: CT exposes patients to radiation, and high false positive rates may lead to invasive, risky, and costly follow-up procedures. Further, the detection of pseudo-disease—that is, cancers that grow so slowly that they never produce symptoms or impact a patient's health—leads to interventions and treatments that provide no medical benefit and may pose significant risk (Black and Welch 1993; Malm 1999; Welch 1996, 2001, 2004). Those supporting widely available CT screening, however, argue that the benefits of early detection outweigh these risks. Supporters also consider that patients ought to have access to new screening technology in the pursuit of preventive healthcare, either with or without a physician's referral, and should be able to decide for themselves if the benefits outweigh the risks without waiting several years for the results of rigorous efficacy studies (Brant-Zawadzki 2000, 2002a; Henschke et al. 2006; Siedt 2004).

The early diffusion of CT screening tests into practice raises questions about physicians' professional roles and responsibilities within the setting of medical innovation, as well as the appropriate scope of patient autonomy and access to unproven medical technology. The purpose of this article is to explore how physicians ought to respond when new screening examinations that lack conclusive evidence of overall population benefit emerge in the marketplace and are requested by individual patients. To this end, the article begins by considering the nature of evidence and how it influences decision-making for screening at both the public policy level and at the level of the individual physician and patient. We distinguish important medical and ethical differences between screening that is recommended for a population, and screening that may be considered on an individual-patient basis when population screening is not yet recommended. Finally, we discuss several specific cases in order to explore how evidence, patient risk factors and preferences, and physician judgment ought to balance when making individual patient screening decisions. We shall argue that under most circumstances, physicians should discourage individual patient access to screening examinations prior to conclusive evidence and professional society endorsement of population-based screening. However, there may be certain circumstances under which it could be appropriate to screen patients, provided that well-controlled observational studies have established the possibility of early detection, patients have well-defined risk factors for the screened disease, patients greatly value screening information, and physicians believe the benefits may outweigh the risks for particular patients.

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While our discussion will focus on the diffusion of CT screening tests, many of the issues raised by these particular tests can be generalized to other areas of medicine where new technology is introduced and marketed to patients before conclusive evidence and professional agreement exist about its benefit to populations.

THE ROLES AND LIMITATIONS OF EVIDENCE IN GUIDING DECISION-MAKING

Traditional principles of medical ethics, including beneficence, autonomy, and justice (Beauchamp and Childress 2000), help articulate the moral force of grounding treatment decisions in evidence. Ashcroft (2004) writes that advocates of evidence-based medicine (EBM):

> can generally be characterized as having a strong ethical sense of the importance of avoiding unnecessary harms to patients and improving health care in the interests of the general good … This approach had a strong ethical imperative behind it, rooted in concern to do no harm, to do one's best for one's patient, and to do so justly by eliminating waste (131).

Physicians are entrusted with promoting the well-being of patients by recommending treatments that are on balance beneficial. Proponents of EBM assert that only well-designed clinical trials can quantify the risks and benefits of certain treatments to a level of sufficient accuracy, enabling physicians and patients to understand and choose the best course of treatment. Further, evidence regarding the outcomes of treatments applied to well-defined groups of patients can guide policy makers in their efforts to optimally allocate resources, in turn improving distributive justice in the healthcare system.

While there are strong ethical reasons to ground both health policy decisions and individual patient care decisions in evidence, great variability exists in the strength of evidence for tests and therapies in medicine. The traditional "levels of evidence" in EBM, ranging lowest to highest, include expert opinion, single case reports, uncontrolled case series, case series using historical controls, controlled observational studies, and finally randomized controlled trials (RCTs) (Cochrane.org; Meakins 2002). For screening tests, the level of evidence produced by particular study designs has important implications for screening decisions. For example, observational studies, namely case-control or cohort studies, that control for relevant variables in the screened and non-screened groups may reliably demonstrate that a screening test detects disease at an earlier stage. Importantly, however, increased detection of early-stage cancers and prolonged survival represent intermediate endpoints that may not translate into improved morbidity and mortality for the screened population.[1] Observational designs are subject to the effects of lead time, length time, and overdiagnosis biases, and cannot answer the question of whether or not screening improves overall population outcomes, such as disease-specific mortality, considered to be a more important endpoint. (Black and Welch 1997).

RCTs are considered the highest level of clinical evidence (Pocock 1983), and are of particular importance for evaluating screening tests; RCT designs avoid important biases and can provide valid information about whether improves disease-specific mortality in the screened population (Black and Welch 1997) The value of RCTs has been demonstrated via numerous examples in recent history of procedures and devices that were developed and disseminated into practice, only later to be shown in randomized clinical trials to be

[1] *Disease-specific survival* and *disease-specific mortality* are distinct ideas, measured in different ways. Survival statistics are better suited to measuring patient outcomes after treatment of known disease, whereas mortality is better suited to measuring the outcomes of population screening; unlike survival statistics, mortality measurements are resistant to the biases described previously in text.

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ineffective or harmful (Cobb et al. 1959; Dimond et al. 1960; Group 1985; Mello and Brennan 2001). Unfortunately, RCTs of screening tests can require thousands of patients, years of follow-up, and high cost to complete. A recent example is the National Lung Screening Trial (NLST), sponsored by the National Cancer Institute (Bethesda, MD), to evaluate the benefit of screening smokers for lung cancer with chest CT. The NLST has enrolled 50,000 patients, will take a total of 8 years to complete, and costs approximately $200 million (Black et al. 2006; Hillman 2003b; Sunshine and Applegate 2004; Swensen et al. 2005). As such, it is not practically feasible to conduct an RCT to evaluate every new screening test.

The level of evidence for various tests or therapies influences the strength and nature of policy recommendations, including population-screening guidelines. For example, the US PSTF and the Physician's Data Query (PDQ) database program have both developed methods for evaluating the scientific evidence behind various preventive medical services, such as screening tests (Franco et al. 2002). The US PTF formulates recommendations of variable strengths depending on the grade, or quality, of evidence, and its recommendations are considered the "gold standard" for preventive services such as screening (Harris et al. 2001; Woloshin et al. 2005; Woolf et al. 1996). According to the US PSTF model, a screening test for which well-designed RCTs demonstrate population benefit, i.e., "level I evidence," may translate to a "grade A" recommendation that there is strong evidence to support screening. Similarly, a screening test for which there are well-designed observational studies, such as a non-randomized cohort or case-control studies, i.e., "level II evidence," may translate into a "grade B" or "grade I" recommendation that there is either fair or insufficient evidence, respectively, to support the test (US PST 2007a; Harris et al. 2001).

While these formalized connections between evidence and clinical guidelines/health policy exist, a subset of physicians and entrepreneurs have marketed CT screening tests directly to consumers before higher-level evidence and professional endorsement exist. This phenomenon raises deeper questions about how evidence ought to play a role in two types of decision-making regarding screening: 1) public policy decisions and practice guidelines to recommend screening for a particular population, and 2) individual decisions between a physician and patient regarding screening. To this end, we shall explore the medical and moral differences between screening activities that are recommended for specific populations, such as mammography for women older than 50 years, and those that have not been recommended for populations but are nonetheless marketed to or requested by individual patients, such as lung CT screening in smokers. The following paragraphs articulate these differences and explain why they may allow different evidence requirements.

Population-Based Screening: Epidemiological Characteristics, Ethical Foundations, Evidence Requirements

Population-based screening is a public health activity. Morrison (1992) has defined population screening as:

> a systematic testing of asymptomatic individuals for preclinical disease. The purpose is to prevent or delay the development of advanced disease in the subset of patients with preclinical disease through early detection and treatment (4).

Cole and Morrison (1980) further specified the objective of cancer screening as "to reduce morbidity and mortality from that cancer among persons screened at a reasonable cost" (1263). Most population-based screening tests possess certain defining features: a disease or risk factor to be detected, a specific population screened, a recommended time interval between screening tests, the sensitivity and specificity of the screening test, and the body of

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research evidence concerning the medical benefit and cost-effectiveness of screening (Black and Welch 1997; Morrison 1992). Obuchowski and colleagues (2001) have outlined ten criteria for effective screening that can be used to evaluate the utility and appropriateness of an image-based screening test for a population (Table 1).

Population-based screening tests are typically endorsed by professional societies and governmental bodies, such as the American Cancer Society (Atlanta, GA), the American College of Radiology (Reston, VA), and the US PSTF among others, based upon evidence suggesting that the overall benefits to the target population outweigh the risks (US PSTF 2004; Hillman 2003b). Pap smears, mammograms, and colonoscopies are current examples of screening tests recommended for particular target populations. Given the great investment of public resources for promoting a population-based screening examination and its widespread impact on the public's health, the level of evidence required to support population-based screening should be high, ideally based upon RCT data.[2] Furthermore, Woolf and colleagues (1996) has noted,

> the burden of proof [to demonstrate that interventions result in more good than harm before recommending them to the public] is even more appropriate for preventive services [including screening examinations], which are offered to essentially healthy persons as something "good for them" (514).

Once a screening test is recommended, patient and professional groups advocate for insurance coverage in order to provide broader access to screening, based upon the understanding that all in the target population are entitled to the benefits of screening.

Individually-Requested Screening: Epidemiological Characteristics, Ethical Foundations, Evidence Requirements

We define "individually requested" screening tests as those which have not been recommended at the population level, but which are nonetheless sought by patients or offered by physicians on an ad-hoc basis when either party is concerned about latent disease and believes that early detection may provide life-saving benefits. Individually requested screening tests lack high-level evidence of population benefit from RCTs, and most CT screening tests fit into this category. Examples include lung screening CT in smokers, brain CT angiography (CTA) or magnetic resonance angiography (MRA) screening for cerebral aneurysms, and whole-body screening CT.

The state of evidence for individually requested screening tests varies greatly, from screening examinations with no trial data (as for whole-body screening CT) to examinations for which trials have established that screening detects disease earlier in its course but have not yet concluded that screening improves population outcomes (as for lung CT screening in smokers) (Black et al. 2006; Henschke et al. 2006). Most CT screening examinations are not considered by professional societies, governmental bodies, or insurers to have sufficient levels of evidence of population benefit to recommend population screening. In some cases, such as for cerebral aneurysm screening, professional societies are largely silent and strong guidelines do not exist. In other cases, such as for whole-body CT screening, professional societies actively discourage screening. In the case of lung cancer screening, professional guidelines state that current evidence is insufficient to recommend for or against routine lung cancer CT screening in people older 60 years who have smoked for more than 20 years (US PSTF 2006; Strauss et al. 2005).

[2] It should be noted that groups such as the US PSTF does not always require RCT-type evidence before recommending a screening test: Pap smears, for example, are supported by evidence from multiple observational studies (Woolf et al. 1996).

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Despite the lack of endorsement, CT screening tests are readily available for use and direct-to-consumer marketing efforts have encouraged patients to seek screening. Under such circumstances, individual physicians and patients need to consider whether screening is appropriate. This leads to a more fundamental question about how to incorporate existing evidence—specifically, evidence at a level lower than RCT-type evidence—into individual patient care decisions. While the "evidence" of evidence-based medicine is often defined in terms of outcomes-based research on *populations*, applying EBM to *individual* cases is a complex problem. Sacket and colleagues (1996) has stated that:

> EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients, taking into account individual patients' predicaments, rights, and preferences using best evidence from clinically relevant research (71).

Using this concept of EBM, Ashby and colleagues have argued that Bayesian decision-making is a useful model for incorporating evidence from clinical trials into individual patient care decisions (Ashby and Smith 2000). Bayesian models consider the best available evidence based upon population studies, as well as individual patient risk factors, characteristics, values, and the clinician's insights. This approach can be helpful for individual decision-making in light of uncertain or inconclusive evidence. Bayesian belief networks are already being developed to aid in the interpretation and management decisions for patients undergoing mammography (Burnside et al. 2000, 2006). Further, Bayesian decision-making may be particularly useful for individual screening decisions when practice guidelines conclude that there is insufficient evidence to either support or oppose a screening test for a population.

The differences between population-based screening and individually requested screening imply, in our view, that the two types of decision-making may require different levels of evidence. Promoting the good of the population is the main objective of public health policy decisions, which affect large numbers of people and require substantial investment of public resources. Decisions to recommend screening for a population, therefore, should be based upon the highest possible level of evidence of population benefit from clinical trials. Promoting the good of the individual patient is the main objective of individual patient care decisions. Decisions to recommend screening for an individual, therefore, should be based upon an individual's risk profile and preferences in addition to the best available evidence. These individually based decisions, we believe, may not require the higher levels of evidence, such as RCTs, that are desirable for population-based decisions. Rather, individual patient and physician characteristics and values may be given more weight in the decision-making process regarding individually requested screening.

The next section focuses on how physicians ought to respond to patient requests for screening examinations when the population risks and benefits are still uncertain. We examine various combinations of scientific evidence, professional guidelines, patient risk factors and preferences, and physician beliefs in order to more precisely demarcate when an individually requested screening examination is and is not appropriate. Indeed, we suggest that it may be appropriate in certain cases to allow patients access to screening even before RCT-level evidence and professional guidelines support population screening. We include a description of the particular safeguards we feel should be in place when individually requested screening is considered.

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ROLES AND RESPONSIBILITIES OF PHYSICIANS REGARDING INDIVIDUALLY REQUESTED SCREENING

Given that many new screening examinations lack the level of evidence to be recommended as population-based screening tools, how should individual physicians respond when their patients express interest in obtaining such examinations? There may be a great deal of pressure from worried patients, industry, medical—legal concerns about missing latent disease, and the technological imperative in medicine to provide new tests, particularly image-based screening tests that visualize the anatomy in spectacular detail.

All physicians who consider adopting new screening technology, in our view, have a minimum set of basic responsibilities to protect the welfare of their patients. First, physicians ought to understand the epidemiological basis for evaluating and recommending screening tests for populations. This includes understanding the pitfalls of length time, lead time, and overdiagnosis biases that compromise the validity of certain study designs, as well as understanding the potential for false-positive and false-negative results and the risks, costs, and psychological stress for patients associated with follow-up tests and procedures. Second, physicians should evaluate the existing literature and consult professional society guidelines regarding screening tests that their patients may request. Such awareness of the state of evidence and professional recommendations is essential in order for physicians to better evaluate whether screening may be in their patients' best interests. This will also help them explain to patients the potential risks, benefits, and uncertainties of the screening examination.

The third basic responsibility for physicians is to advocate or, when possible, be involved in early, formal evaluation of new screening tests for which there is a poor evidence base. We believe that all physicians have a professional duty to incorporate evidence into their decision-making and the field should encourage research to formally evaluate innovative practices. While it is unlikely to be financially or practically feasible to conduct an RCT for each screening test that emerges in practice, other study designs and forms of evidence—well-controlled observational studies and computer-based decision analysis (Gazelle et al. 2005), for example—are more easily produced and may inform screening practices. When feasible, physicians should consider becoming involved in such studies that, when begun early in the application of a new screening test, can gather valuable information about the sensitivity and specificity of the test and provide the initial "proof of concept" that screening can at least detect disease early in its progression (Woolf et al. 1996).

The fourth basic responsibility for physicians is to refrain from engaging in direct-to-consumer advertising of screening services to patients before they are recommended for the population. Research suggests that people often overestimate the benefits and underestimate the risks from various cancer screening tests (Katapodi et al. 2004; Marcus 1999; Schwartz et al. 2004; Vernon 1999; Woloshin et al. 2000). Further, research on direct-to-consumer advertising of pharmaceuticals suggests that many consumers assume that all advertised drugs are safe and/or effective (Bell et al. 1999). It is possible that consumers may falsely infer that any screening examination advertised by physicians offers more benefits than risks and/or is recommended by physicians as a whole. Given the high likelihood of misleading patients, consumer advertising before screening is endorsed for a population, in our view, is unprofessional.

After fulfilling these basic responsibilities, individual physicians will still need to decide whether a new screening test is appropriate for specific patients in their care. Making the decision to screen a patient in light of inconclusive evidence of population benefit is difficult and involves weighing several different factors. We suggest physicians and patients consider

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four primary factors, based on the Bayesian approach described earlier, to address these decisions: 1) the strength of evidence and nature of professional recommendations for a particular screening examination, 2) the patient's risk factors for the screened disease, 3) the patient's valuation of screening information, and 4) the clinician's own experience and intuitions. The following paragraphs explore three specific scenarios with variable evidence-based professional recommendations, using the US PSTF language and levels of evidence as a guide when possible. The US PSTF grades the strength of its evidence-based recommendations from "A" (*strongly recommends*), "B" (*recommends*), "C" (*no recommendation for or against*), "D" (*recommends against*), or "I" (*insufficient evidence to recommend for or against*) (Harris et al. 2001). We focus on screening tests with D- and I-type level recommendations, as these are the categories under which most CT screening examinations currently fall, examining how patient characteristics and values and physician preferences ought to weigh and balance at each of these levels. Importantly, we acknowledge that screening decisions will be highly context-dependent, as the nature of disease, risks inherent to the screening test, and invasiveness and costs of follow-up studies will vary greatly among screening tests. Nevertheless, we outline the important considerations for several common CT screening scenarios that physicians and patients may face.

Case 1: Professional Society Guidelines Discourage the Screening Examination. ("Class D"-Type Recommendations)

The first case we consider involves a screening examination that is explicitly discouraged by professional society guidelines, or has a "class D"-type level recommendation. Such screening examinations may have either no or low-quality evidence of benefit for populations or may have sufficiently strong evidence of patient harm. Low-quality evidence includes evidence from uncontrolled case series or poorly controlled observational studies. An example of such a situation would be a whole-body CT scan requested by an asymptomatic, healthy 55-year-old individual with no risk factors except age, who wants to gain peace of mind. There have been no clinical trials to evaluate the benefit of whole-body CT screening, and many professional societies explicitly discourage this examination (US Food and Administration [US FDA] 2002; American Medical Association [AMA] Council on Scientific Affairs 2003; US PSTF 2004a; ACR 2004).

Physicians should generally discourage individual patients from screening when there is no or poor evidence and professional society discouragement, regardless of their personal beliefs about the utility of the examination, the patients' risk profile, and patient beliefs and preferences for screening. There are several reasons for this position. First, in this case, the potential risks and benefits of screening are poorly understood, making it quite difficult for a physician to estimate whether the test will be on balance beneficial. Discouraging screening in such cases coheres with a physician's professional duties to protect patients from tests that may cause more harms than benefits, including diagnostic screening tests of great uncertainty. Further, we agree with Doukas and colleagues (1997) that, by educating their patients about the risks and benefits of the screening test, physicians may "articulate the boundaries of their own professional integrity, for patients cannot compel physicians to render services that run counter to their best professional and ethical judgment" (486).

A secondary concern in this case has to do with the judicious use of shared healthcare resources. It has been argued that a just health system should not tolerate the proliferation of expensive, unproven therapies that lead to spiraling costs and shift resources away from more urgent healthcare needs, even if the market would support this (Sox 2001). As care provided to one patient will most likely affect the care available to others, denying patient requests for screening in this case coheres with a physician's duty to act as a prudent

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steward of shared healthcare resources by discouraging costly tests with poorly understood likelihood of medical benefit.

Some have argued that as long as informed consent explains the risks, benefits, and uncertainties, patients should be able to access screening services that they believe will benefit them, particularly if they are willing to assume the costs (Amis 2003; Brant-Zawadzki 2002a, 2002b). We disagree with this view, however, particularly for screening tests of class D-type level recommendation. While physicians should generally take into account patient preferences in medical decision-making, screening decisions are particularly complex and challenging. Previous research on screening with mammography, prostate-specific antigen (PSA), and colonoscopy suggests that patients generally tend to overestimate the benefits and underestimate the risks of screening tests (Schwartz et al. 2000, 2004; Silverman et al. 2001; Volk et al. 1999, 2003; Woloshin et al. 2000). Importantly, the recent increase of direct-to-consumer marketing of screening puts patients at risk of making harmful choices in the absence of adequate guidance and constraints. That is, the context has changed such that some information coming from health professionals (i.e. screening advertisements) is not based on a clear, balanced presentation of existing evidence.

Even if the individual requesting the whole-body CT had a good understanding of the uncertainties of the test and believed he would derive great psychological benefit from screening, these potential psychological benefits are inadequate, in our view, to outweigh the potential medical risks, including radiation exposure, false-positive results leading to invasive, risky, and costly follow-up procedures, false negatives, and the detection of pseudo-disease. The primary goal of medicine, including the administration of medical services, is to benefit patients' health (Beauchamp and Childress 2000; Pellegrino 2001). As such, patients should not have free access to any medical test or treatment they desire and can pay for, as they would for other types of goods and services. Indeed, constraining patient autonomy under the conditions of Case 1 is appropriate, in our view, as physicians should actively protect them from medical products of poorly quantified risks and benefits.

A variation on this case includes a situation in which a physician actually believes the benefits of screening could outweigh the harms for a particular patient, despite no or low quality evidence of its benefit and professional societies discouragement. A physician may encounter particular patients with strong risk factors for disease who place great value on the knowledge derived from screening. One example could be a patient with a family history of pancreatic cancer who would like a whole-body CT screen to rule out this aggressive cancer for reassurance. The US PSTF (2004b) recommendations explicitly discourage whole-body CT screening for this purpose. Initial, small prospective studies suggest that screening patients with a strong family history can detect disease early, while the impact of screening on long-term morality remains unknown (Canto et al. 2006). While cases like these are difficult, were commend a conservative approach that gives more weight to the low level of evidence and to professional society guidelines than to individual patient and physician preferences; clinicians should generally not provide screening examinations that have low level or no evidence and are discouraged by professional societies.

Case 2: Professional Society Guidelines are Neutral or Non-Existent

The second case we consider involves a screening examination for which professional recommendations are either neutral or non-existent. The evidence for such screening examinations may be of low quality, sparse, or in the early stages of production. One current example of this situation could include using magnetic resonance imaging (MRI) and/or MRA of the brain to screen for cerebral aneurysms in patients with a positive family history. The US PSTF does not have specific guidelines for cerebral aneurysm screening. The only

official guideline comes from the Stroke Council of the American Heart Association (Dallas, TX), stating that while current evidence argues neither for nor against population screening, clinicians may consider it for particular patients on an individualbasis. (Bederson et al. 2000). Currently, few studies have evaluated the use of MRI/MRA as screening tests, and there is no evidence that cerebral aneurysm screening benefits population morbidity or mortality (Crawley et al. 1999; The Magnetic Resonance Angiography in Relatives of Patients with Subarachnoid Hemorrhage Study Group 1999). Scenarios such as these are common, and the lack of directive guidelines implies that physicians and patients need to draw upon factors other than evidence to make decisions about screening (Woolf et al. 1996).

Similar to Case 1, physicians and patients should be aware that screening under these circumstances may expose patients to poorly quantified risks and benefits. And, although neutral professional society guidelines may appear an invitation for physicians to engage in screening as they like, there is another reason to be cautious about granting patients access to screening tests that have a poor evidence base: this may slow the progression of research that aims to better characterize the risks and benefits of the test. If physicians were to commonly grant patient requests for unproven screening test when there is no or low quality evidence and neutral guidelines, the motivation to conduct or participate in research trials to formally evaluate the test may diminish. Indeed, granting patients access to such screening tests may lead to their gradual diffusion into practice, potentially becoming understood as standard of care and further delaying our ability to characterize the risks and benefits of a screening examination. As mentioned previously, there are numerous examples of medical treatments that have diffused into practice in such a manner, only later to be proven ineffective or harmful to patients after more formal evaluation. These include internal mammary artery ligation for angina (Cobb et al. 1959; Dimond et al. 1960), internal carotid artery bypass to prevent the recurrence of stroke (Group 1985), and bone marrow transplantation for breast cancer (Mello and Brennan 2001). The delay in rigorous evaluation of these treatments caused thousands of patients to suffer harms from unnecessary and non-beneficial interventions. Thus, commonly allowing patients access to a screening test at a stage when there is no or low-quality evidence of benefit poses a threat to the research enterprise and, ultimately, to patient welfare.

The best approach, in our view, would be for physicians to discourage screening in most cases with neutral or non-existent recommendations and advocate better evaluation of screening. For patients with well-defined risk factors who would greatly value information from a particular screening examination, such as a patient with cardiovascular risk factors and first-degree relatives who have died from cerebral aneurysm rupture, physicians should consider encouraging enrollment in research trials that will bolster the evidence base for a screening test. This may constrain both patient and physician autonomy. However, in general these constraints are justified for all of the reasons given in Case 1: protecting patients from poorly quantified harms, protecting them from possible overestimated expectation of benefits, and curbing waste in the healthcare system. An additional justification is the desire to move research forward in an expedient manner so that the results can benefit individual and population-level decision-making as soon as possible, particularly when professional society guidelines are non-directive.

Case 3: Professional Society Guidelines State Evidence is Insufficient to Recommend For or Against a Screening Test ("Class I" Recommendation)

The last case we consider involves a screening examination with class I-type level recommendations. According to the US PSTF, class-I recommendations state that evidence is insufficient to recommend for or against routine population screening because evidence that the screening test is effective does not exist, is of low quality, or conflicting (US PSTF

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2007b). We wish to focus on situations in which the screening test has undergone substantial evaluation and there is valid evidence from properly controlled observational studies suggesting that a screening test detects disease at earlier stages, but data from RCTs has not yet emerged to establish the benefit (or "effectiveness") for population outcomes. These cases, in our view, may be the most complex and controversial. Lung CT screening in smokers is a current example of this situation (USPSTF 2004c). There is great debate in the medical literature about whether it is appropriate to offer smokers chest CT screening, either on an individual basis or at the population level. Smoking is a well-established risk factor for lung cancer. (Samet 1993) and controlled observational trials have established that lung CT in smokers detects lung cancer at earlier stages. Several RCTs are currently underway to determine whether screening smokers will decrease lung-cancer related mortality (Gohagan et al. 2004; NLST 2007; Swensen et al. 2005; Xu et al. 2006) Those in favor of screening worry that patients are being deprived of a life-extending test while we wait for RCT-level data to arrive (Henschke et al. 2006). Others counter that there is no guarantee that early detection will lead to a reduction in population-based mortality, and the relatively great risks and costs associated with the follow-up of asymptomatic lung lesions must be balanced against higher-level proof of population benefit (Patz et al. 2001; Swensen et al. 2005).

Under such circumstances, in light of a class I-type level recommendation, we argue that it may be appropriate for physicians and patients who greatly value potential information from screening to engage in screening provided certain conditions are met. First, the patient should have well-defined risk factors for the disease to be screened. Importantly, these risk factors should be specified by either a group of clinical experts or clinical research collaborators as helpful in defining which patients are likely to benefit from screening. For example, the NLST has used pack-year smoking history and age to demarcate the high-risk population that may benefit from lung cancer screening with chest CT. In order to minimize the risks and maximize the potential benefits from individually based screening, therefore, defined risk factors for the screened disease should exist in order to place a patient within or outside of the potential target population. The second condition for screening under class I-type recommendations is that well-controlled observational trial data should have already established that a screening test increases early detection rates in the target population and that RCTs are well underway. Lung cancer screening with chest CT could meet these two conditions for certain patients.

Under these two conditions, it is reasonable to believe that the benefits of screening could outweigh the harms for an individual patient, even when clinical trials have not yet established a mortality benefit at the population level. While offering screening in this scenario may expose patients to the risks and unknowns of screening and compromise the expediency of research, these drawbacks may be attenuated in certain circumstances; specifically, if previous research and preliminary data from ongoing clinical trials point strongly toward a potential benefit and have well characterized aspects such as sensitivity and specificity of screening, concerns about exposing patients to the harms of screening without any benefit are reduced. Further, for screening tests in which RCTs are ongoing, there is less of a concern that offering patients screening outside of trials jeopardizes the research enterprise. Thus, the threats to patient welfare and research expediency in Case 3 may be at a level low enough to allow for patient and physician preferences to weigh more heavily in the decision of whether or not to screen.

As Maim (1999) has argued, while it is important to ground population-based screening recommendations in the best possible evidence rather than upon assumptions about the value of early detection, "a screening recommendation is ethically justified only if the test reasonably can be expected to be beneficial on balance to the person taking it" (33). Under the two conditions described previously, we believe that individual physicians and patients

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may have adequate information to expect a screening test to be beneficial on balance. Indeed, denying all individual requests for any screening examination until the completion of RCTs is too rigid, absolute, and unrealistic a position for several reasons. First, performing RCTs for every potential screening test will never be practically feasible; the quality of evidence exists on a continuous spectrum, and thinking intelligently about where we are on that spectrum is more important than designating absolute "cutoffs" of evidence below which any screening is unacceptable. Second, it is important to allow some space for individual patient desires and physician judgment to enter the decision-making process under conditions of uncertainty. As we have noted, one option might be to encourage physicians who screen patients before RCT-level evidence is available to contribute their patients' information to a national database that would collect observational data on screening.

We consider briefly the analogy between early access to new screening tests and early access to new pharmaceuticals for severely ill patients who have exhausted standard treatment options. The conflict between conducting thorough research and accommodating individual patient access to promising, potentially life-saving therapies gained unprecedented attention in the midst of the AIDS epidemic in the late 1980s. Severely ill patients who could not gain entry to clinical trials fought for access to those unproven therapies off-label, arguing the risk-benefit analysis made sense given that they were facing certain death. This debate has evolved to the point where many pharmaceutical companies and the US FDA have provisions for granting patients with a variety of severe diseases off-label access ("compassionate use") to investigational new drugs, provided early phase clinical trials have shown promise and certain safeguards are systems are in place to track patient outcomes. (Pfizer 2008; Thompson 2000). Important lessons for screening can be drawn from the history of off-label pharmaceutical use. Yet, while similar ethical tensions arise in both settings—respecting patient autonomy, protecting against unknown risks, promoting population benefits via research—important differences between the nature of screening and treating life-threatening illness may imply a different threshold for access. Certainly, novel pharmaceuticals pose more immediate and potentially more severe harms than do diagnostic screening tests. Likewise, such interventions potentially offer more immediate benefits for severely ill patients than do screening tests for apparently healthy ones. In our view, the more urgent situation of patients without standard treatment options provides a more compelling reason to provide early access, assuming there is adequate surveillance and treatment of adverse events and outcomes, and that clinical trials are already adequately populated to produce population-level evidence.

While it may be appropriate for individual physicians to refer eager patients with defined, specific risk factors for screening in certain cases, it is important that safeguards and quality assurance mechanisms are in place to maximize the benefit of screening under these conditions. The appropriateness of screening also depends upon, we argue, the quality of the informed consent process, quality of screening equipment, and thoroughness of follow-up of screening results with patients and their physicians. Because all of these factors are provided in the controlled setting of a research trial, the option to offer eligible patients trial enrolment is even more attractive. The following paragraphs articulate why these particular features can make screening individual patients appropriate, despite lack of conclusive evidence about population benefit.

Criteria and Safeguards for Granting Patient Access to Unproven Screening Examinations, Outside the Research Context

A critical safeguard for screening patients with an unproven examination is a thorough informed consent process to ensure patients understand the potential risks, benefits, and uncertainties of the screening test. This is particularly crucial given ample evidence to

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suggest that people often misperceive the goals or effects of cancer screening, are poor estimators of their personal cancer risk, and are generally enthusiastic about cancer screening (Katapodi et al. 2004; Kreuter 1999; Marcus 1999; Schwartz et al. 2004; Vernon 1999; Woloshin et al. 2000). For example, in a study of the general population's attitudes toward cancer screening, Schwartz and colleagues (2004) found that patients had a strong enthusiasm for cancer screening, both for specific cancers and whole-body screening, even despite past personal experience with false positives and unnecessary work-up. When asked about whole-body CT screening, 86% of respondents wanted a free scan. Of these, 73% would rather have a scan than $1000 and only 27% mentioned there may be a downside to a body CT scan: 14% mentioned false-positive results and 3% unnecessary work-up (Schwartz et al. 2004) Other studies reveal that people are quite tolerant of false positive screening results, have a poor understanding of pseudo-disease, overestimate the benefits from screening, and perceive screening as a primary rather than secondary prevention tool. (Aiken et al. 1995; Domenighetti et al. 2003; Schwartz et al. 2000) As Schwartz and colleagues (2004) have noted, public misperceptions about the benefits and burdens from screening, combined with a "cultural enthusiasm for screening create an environment ripe for the premature diffusion of screening technologies, placing the public at risk of overtesting and overtreatment" (71).

Given evidence that people often misestimate the risks and benefits from both proven and unproven screening examinations, the appropriateness of screening will hinge heavily upon the quality of the informed consent process. For some patients, such a process may dissuade them from screening despite their initial eagerness. For example several studies indicate that men are less likely to be interested in screening for prostate cancer with PSA testing if they are made aware of the 'pros,' 'cons,' and uncertainties during informed consent. (Flood et al. 1996; Volk et al. 1999; 2003; Wolf et al. 1996) The population benefit of routine PSA screening in men older than age 50 years has not been established, and professional society guidelines do not currently recommend routine screening (US PSTF 2002). Many have advocated that risk communication for PSA screening should aim at more neutral informed consent or shared decision-making to help ensure that patients make screening decisions that are in their best interests (Chan and Sulmasy 1998; Chan et al. 2003; Vernon 1999) After patients have an adequate understanding of the risks, benefits, and uncertainties of the screening examination, they can better decide whether such risks and unknowns are acceptable to them.

While we agree that physicians should strive to provide information about risks, benefits, and uncertainties, there will remain disputes in the field about what sort and how much information to provide patients. For example, research suggests that physicians have different notions of what patients should be told about PSA screening during informed consent. A study by Chan and colleagues (2003) revealed that, despite professional guidelines supporting informed decision making, non-urologists were more likely than urologists to rate facts reflecting uncertainty as highly important for men to know, including statements about prostate cancer risk, screening with PSA, and treatment. Individual physicians could be better guided in their approach to consent by more explicit guidelines from professional societies regarding the specific types of risks, benefits, and uncertainties that should be stressed to patients. One interesting model is provided by a recent outline of information for patients about the risks, benefits, uncertainties, and state of evidence associated with lung cancer CT screening. (Strauss et al. 2005).

Another safeguard for screening patients before population screening is recommended involves using screening equipment of adequate quality. Some have expressed concern that the use of older scanners, lack of intravenous contrast, or lack of adequate radiologist training in a particular modality or organ system compromises the sensitivity and specificity

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of screening examinations, producing results that are difficult to interpret and may lead to more diagnostic testing (Berlin 2003; Fishman and Horton 2002) For screening tests that have already been validated and considered standard of care, it is likely that guidelines will already exist regarding equipment quality, technical standards, and required physician training. Radiologists reading mammograms, for example, must be certified and are required to read a minimum number of studies per year. Such technical and training guidelines will not exist for screening tests of unproven value, opening the door to variations in techniques and competency potentially harmful to test validation and patient well being. One example of this situation is provided by MRA for cerebral aneurysm detection, where there is preliminary evidence to suggest that the detection rate depends upon the quality of the equipment and the training of the radiologist in three-dimensional imaging of the cerebral vasculature (Schwab et al. 2008).

The final safeguard to providing appropriate screening is to establish routine mechanisms to ensure timely communication of the results to the primary care physician, adequate counseling of patients about the meaning of results, and timely follow-up of any positive findings. Patients should be referred for screening from their primary care physician, who has discussed their understanding of and expectations for screening. The physician's referral, combined with thorough follow-up of results, is particularly important in light of recent data from Illes and colleagues indicating great variability in the manner and extent to which results of self-referred CT screening examinations were communicated with physicians and patients (Illes et al. 2003).

CONCLUSION

Engaging in individual-based screening before population-based screening is endorsed by evidence and professional guidelines raises timeless questions about physicians' duties in the setting of innovation and the scope of patient autonomy to access new technology. We hope that the issues and cases presented here may help guide individual physicians as they consider how to respond to patient requests for new screening examinations.

To best balance the goals of consumer protection, patient autonomy, and prudent innovation, we believe it generally inappropriate for physicians and patients to engage in individually requested screening. There may be a few exceptions, however: when rigorously-designed clinical trials are underway and good evidence already exists to suggest potential population benefit from screening, when well-defined, specific patient risk factors for disease have been articulated, and when patients and clinicians both value screening information. Such screening activities should employ specific safeguards, including careful informed consent, high-quality equipment, and thorough follow-up of results. Despite these individual exceptions, referring physicians and the field as a whole should be vigilant in the appraisal of evidence, and continue to support formal evaluation of new screening examinations. This will better ensure that the best evidence is available for patients and their physicians to make good choices about screening.

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Table 1

Ten Criteria for Effective Screening

1	The disease screened has serious consequences.
2	The screening population has a high prevalence of detectable preclinical disease.
3	The screening test detects little pseudo-disease.
4	The screening test has high accuracy for detecting the detectable preclinical disease.
5	The screening test detects disease at a point in which intervention improves outcome.
6	The screening test causes little morbidity.
7	The screening test is affordable and available.
8	Treatment exists.
9	Treatment is more effective when applied before symptoms begin.
10	Treatment is not too risky or toxic.

Criteria from Obuchowski and colleagues (2001).

Exhibit G

Early Lung Cancer Program Protocol dated July 1, 2011

July 1, 2011

International Early Lung Cancer Action Program: Enrollment and Screening Protocol

PI: Claudia I. Henschke, PhD, MD
New York, New York

Overview 2
Admissibility for collaboration 2
Indications for screening..... 3
Regimen of screening..... 3

- Image production
- Image reading
- Screening frequency
- Baseline screening
- Repeat screening
- Assessment of growth
- Biopsy

Classification and characterization of diagnosed cancers..... 8
Intervention policy..... 9
ELCAP Management System..... 10
Quality assurance..... 10
Outcome determination..... 11
Workup of ancillary findings 12

Overview

The International Early Lung Cancer Action Program (I-ELCAP) has as its broad research objective the advancement of knowledge for early diagnosis and treatment of lung cancer. Details of the specific aims and the theoretical basis for the research are given elsewhere (1-15).

The participating institutions need to commit themselves to performing baseline and at least one repeat screening (while more are desirable for precision), and follow-up of at least 10 years of all diagnosed lung cancer cases. It is critical for validity of the I-ELCAP database that each institution is committed to fully document the initial and all subsequent screenings for as long as the screenings on that person continue, and to transmit the documentation to the I-ELCAP database. It is also critical to identify and document all instances of interim diagnosis of lung cancer among the screenees, as well as reasons for instances of discontinuation of the screenings.

The treatment interventions of diagnosed cancers can be selected by each institution. However, each participating institution must be committed to document, for each diagnosed case of lung cancer, not only the timing and nature of the intervention(s) (if any) but also the prospective course in respect to manifestations of metastases.

The development of a protocol has been a concern of the ELCAP (Early Lung Cancer Action Project) Group for more than a decade (1-5), and updatings have been made in the framework of the International Conferences (4) organized by this Group and in their resultant international consortium on screening for lung cancer, I-ELCAP. The research program of I-ELCAP is guided by a common protocol (5, 6) and its approach to long-term follow-up (7, 8). The most recently updated version of the protocol is presented below – with the understanding that the pathology aspects of the screening in the I-ELCAP are guided by a separate protocol specific to its process (9, 10).

In the framework of the I-ELCAP protocol, there is opportunity for the conduct of related *ancillary studies*: various non-CT (e.g., sputum, blood, urine) tests can be deployed parallel with the low-dose CT test. This provides an opportunity for studying their relative merits for one and their value as add-ons for another. Similarly, various treatment options for early lung cancer can be studied.

Admissibility for collaboration

The admissibility criteria for an institution to collaborate in the I-ELCAP are as follows:

1. It is committed to implement the protocol's regimen of early diagnosis specified below, including at least one repeat screening.

2. It submits to the I-ELCAP database the institutional documents which approve the screening and participation in the I-ELCAP; that the institution is committed to conform to the stated requirements, and is amenable to auditing of the data for compliance with those requirements.

3. It is committed to provide the I-ELCAP database with each successive instance of baseline screening, and to fully documenting this and also all repeat screenings.

4. It is committed to identify, and to document, each instance of interim diagnosis of lung cancer, including its symptoms/signs.

5. It is committed to document the reason(s) for discontinuation of screening.

6. It is committed to document the timing and nature of the intervention(s), if any, in each instance of diagnosed lung cancer, including in interim-diagnosed cases.

7. It is committed to follow and document each diagnosed case of lung cancer, interim-diagnosed cases included, until manifestations of metastases, death (its cause), or otherwise, for at least 10 years.

8. It is committed to deploy the ELCAP web-based management system for CT screening for lung cancer, and in this framework to submit all the research data – and images as well as pathology specimens (their digital counterparts) – to the I-ELCAP database.

9. It is committed to conform to all other policies of the I-ELCAP, notably those concerned with quality assurance (below).

It deserves note that among the contributors to I-ELCAP could very well be those studies performing randomized controlled trials (RCTs) contrasting CT screening with either no screening or some other type of screening. Here the relevant contributions would derive from the CT screening arm of such a trial, provided that all of the requirements above would be satisfied.

Indications for screening

As screening is for asymptomatic persons, needed is documentation of the symptom profile, specifically current presence/absence of potential manifestations of lung cancer which include worsening cough, hoarseness, hemoptysis, and unexplained loss of weight. Symptomatic persons are ineligible for enrollment.

Indications for subject participation may vary somewhat, notably as to age and smoking history as these can be set by each participating institution, and those indications must be specified. The person must also be willing to undergo at least one repeat screening on schedule.

Regimen of screening

In this protocol, 'screening' refers to the entire process of the pursuit of early, rule-in diagnosis of lung cancer. It begins with the initial low-dose CT scan. A positive result of this test is followed by further diagnostics, possibly including biopsy and pathologic assessment of the specimen.

It is understood that there may need to be occasional exceptions to the protocol. Each site is fully responsible for performance of the CT scans and the interpretation, and workup recommendations. In those cases for which protocol recommendations are not followed, it is important to document the reasons for this and to record all results of the alternative workup.

Image production

In this regimen, the initial imaging is the same in baseline and repeat screenings. As there are a large variety of CT manufacturers and models, the following are general guidelines for the image production. Scans should be acquired on multi-detector-row scanners with 4 or more rows. Scans should be acquired so that images can be reconstructed at 1.25 mm or less. There is no specific definition of "low-dose," although historically most screening protocols have used scan parameters of

120-140 kVp and 30-100 mAs. **We suggest that scans be obtained at 120 kVp or lower and 40 mAs or lower.** Collimation and pitch also affect dose, and these should be set to allow for the lowest dose, while maintaining acceptable image quality. It may be useful to reconstruct the images using both a standard and high-resolution kernel. Scan parameters may also be adjusted to allow for higher doses on large patients. In addition, new dose reduction techniques are being made available by scan manufacturers, and these may also be used, providing that acceptable image quality is maintained.

Images should be acquired in a single breath from the lung apices through the lung bases. The use of contrast material is not involved. For the workup of lung abnormalities that have been identified, typically the same low dose parameters can be used.

Reading of images

The resulting images are read by a radiologist at the site. The reader is aware that the images derive from the initial CT for early diagnosis of lung cancer, and also is informed of whether they are from baseline or repeat screening. The reader views the images as they are displayed in a high-resolution monitor at their typical window and level settings, scrolling through the images one at a time. For the purposes of assessing the size of a nodule or that of a mediastinal abnormality, however, the following settings are used: lung window width 1500 and lung window level -650, and mediastinal window width 350 and mediastinal window level 25.

For a number of screenings, a second, 'central' reading is done for quality assurance and teaching purposes, without knowledge of the results of the first, site reading. The site radiologist receives the 'central' reading report, with discrepancies, if any, highlighted. In case of a discrepancy, the site radiologist may find it necessary to change the site report; and in this event, the updated report is also submitted to the central facility, where a record is kept. The site radiologist sends the final report to the subject and to his/her referring physician. The quality of the scan and its interpretation is solely the responsibility of the site.

In both baseline and repeat screening, the reader's first concern with the images from the first, low-dose test is to identify all *non-calcified* nodules visible in them. A nodule is manifest as a focal non-linear opacity, whether the nodule be solid, part-solid, or nonsolid (the latter two corresponding to 'ground-glass opacity'), located in the parenchyma or endobronchially. A nodule is classified as non-calcified if it fails to meet the usual criteria for benign, calcified nodules. Thus, a nodule less than 5 mm in diameter is non-calcified if all of it appears less dense than the ribs (on bone and lung windows); a nodule 5-20 mm in diameter is non-calcified if most of it is non-calcified (by that criterion) and/or the calcification does not correspond to a classical benign pattern (complete, central, lamellated, popcorn) and/or the edge is spiculated (to any extent); and a nodule over 20 mm in diameter is non-calcified if any part of it is non-calcified (by the criterion above).

The reader documents each of the nodules that even alone would have made the result positive. Specifically, as for each of these nodules, the reader documents the location, size, consistency ('solid,' 'part-solid' or 'nonsolid'), presence of calcifications, edge and presence of spiculations. A nodule is classified as part-solid if it has patches within it that completely obscure the lung parenchyma, and non-solid if none of the lung parenchyma in it is completely obscured (11). In making the distinction between part-solid and nonsolid nodule, blood vessels within the nodule, despite their appearance as solid components, are not regarded as solid components.

Nodule diameter is the average of length and width. Length is measured on a single CT image that shows the maximum length; width, defined as the longest perpendicular to the length, is measured on

the same CT image. In I-ELCAP research these measures will be replaced by computer-based assessments of volume when there is sufficient evidence of their validity.

The reader also documents other findings in the chest, including those in the mediastinum, heart, soft tissues, and bones.

Mediastinal masses can occur anywhere in the mediastinum, including in the thymus, heart, and esophagus; and a mass in the neck, such as the thyroid, may extend into the mediastinum. Such mediastinal and soft tissues masses are documented as to location and size. The reader also documents findings in the visualized upper abdomen as to location and size.

Each coronary artery is identified (main, left anterior descending, circumflex, and right). Evidence of calcification in each artery is documented as none, minimal, moderate, or severe, scored as 0, 1, 2, and 3, respectively. Minimal calcification was defined if less than 1/3 of the length of the entire artery, moderate as 1/3-2/3, and severe as more than 2/3 shows calcification. With 4 arteries thus scored, each subject received a CAC score in the range from 0 to 12.

The extent of emphysema is identified and classified as none, mild, moderate, or severe, each being scored 0 to 3, respectively. Mild emphysema is defined by having no discrete areas of decreased CT attenuation but splaying of blood vessels suggesting parenchymal expansion or having occasional discrete areas of decreased attenuation; moderate emphysema if discrete areas of decreased attentuation can be identified involving less than half of the lung parenchyma; and, severe emphysema if discrete areas of decreased attenuation can be identified involving more than half of the lung parenchyma. Each subject receives an emphysema score in the range from 0 to 3.

Screening frequency

When application of the regimen at baseline does not lead to the diagnosis of malignancy, repeat screening is scheduled for a preset time subsequent to the initial, low-dose test at baseline. Whereas the protocol calls for annual repeat screening, each institution is free to choose the timing of the repeat screening. In reality, however, practicality leads to variation in this preset interval. Such variations do not threaten the validity of the study, so long as they arise from compelling circumstantial matters (and thereby are as though randomly assigned) and these would provide an opportunity to study the implications of different intervals to repeat screening (in the regimen) as for the resultant diagnostic distribution.

If Stage I, II or IIIA lung cancer is diagnosed, screening may be continued with the original schedule after the intervention is completed.

Baseline screening

At *baseline* the result of the initial CT is positive if at least one solid nodule, part-solid nodule, or solid endobronchial nodule 5.0 mm or more in diameter is identified (11-15). When non-calcified nodules are identified but all of them are too small to imply a positive result, including a nonsolid nodule of any size, the result is semi-positive and calls for CT 12 months after the initial one at baseline. If no nodules are identified, the test is negative, a repeat CT is to be performed 12 months later.

When the result is positive, further diagnostic work-up concerns all nodules which even alone would

have made the result positive. However, the work-up is different according to the size of the largest nodule.

For solid and part-solid nodules 5 mm but less than 15 mm, there are two options. The preferred option (A) is to perform another low-dose non contrast CT 3 months later; if it shows growth at a malignant rate (see growth assessment), biopsy is recommended; if there is no growth or partial or complete resolution, the workup stops. If the nodule is solid and greater than 10 mm in diameter or the solid component of a part-solid nodule is greater than 10 mm in diameter, then another option (B) is to perform PET scan and if the result is positive, biopsy is recommended, while if negative or indeterminate a low-dose CT 3 months later is performed and acted on as specified in option A. When multiple nodules are present and occult infection or inflammation is a possibility, an added option (C) is a course of a broad-spectrum antibiotic with anaerobic coverage followed by low-dose CT 3 months later (13) and the result is acted on as specified in option A.

For solid and part-solid nodules 15 mm or larger in diameter two additional options are available. If the nodule appearance is highly suggestive of lung cancer, immediate biopsy is one option (D). As occult infection is a possibility, option (E) is a course of an antibiotic with anaerobic coverage followed by low-dose CT 1 month later (13); if the CT shows no resolution or growth at a malignant rate (see growth assessment), biopsy is recommended. If there is partial or complete resolution on CT, the workup stops.

If a solid endobronchial nodule 5.0 mm or more is identified, a low-dose non-contrast CT scan is performed within 1 month. At the time of the follow-up CT scan, the participant is asked to cough vigorously several times. If the nodule is still present, the participant is referred for pulmonary consultation, and if necessary, bronchoscopy.

For all individuals in whom the diagnostic work-up was stopped or the biopsy did not lead to a diagnosis of lung cancer, repeat CT 12 months after the initial baseline CT is to be performed.

Repeat screening

On *repeat* screenings, again, the reader's first concern with the initial CT is to identify all non-calcified nodules, but now *regardless of size*, and with special regard for the nodules(s), if any, that produced a semi-positive result on the initial CT at baseline. The focus, among these, is on those nodules that are showing *growth* since the previous screen, of overall size or the size of the solid component if previously part-solid, or appearance of a solid component if previously nonsolid. To determine whether growth has occurred, the reader compares the current images with the corresponding previous ones, displayed side-by-side.

On repeat screening, the result of the initial, low-dose CT test is positive if at least one non-calcified solid or part-solid nodule 3 mm or larger, or a solid endobronchial nodule 5.0 mm or larger in diameter with interim growth is identified, whether newly seen or seen in retrospect but not previously identified. If a new solid or part-solid nodule less than 3 mm or nonsolid nodule of any size is identified, the result is semi-positive and calls for CT 12 months later. If the test is negative, a repeat CT is to be performed 12 months later.

The documentation of the repeat-screen nodules of record -- ones that even alone would have made the test result positive -- is analogous to that at baseline, except that this documentation is supplemented by the corresponding characterization of the nodule in the previous screen. The further diagnostic workup depends on the size and consistency (solid or part-solid) of the nodule(s) of

record.

If all the non-calcified newly identified solid or part-solid nodules are more than 3.0 mm but less than 5.0 mm in diameter, low-dose non contrast CT at 6 months after the prior one is to be performed; any nodule with further growth at a malignant rate (see growth assessment) is recommended for biopsy; if growth is not at a malignant rate or no growth is seen in any of the nodules or they have completely or partially resolved the workup stops.

If at least one of the newly identified noncalcified nodules, either solid or part-solid, is 5 mm in diameter or larger, the preferred option (A) is an immediate course of a broad-spectrum antibiotic with anaerobic coverage followed by low-dose CT 1 month after the prior low-dose test. If it shows growth (see growth assessment), biopsy is recommended; if there is complete or partial resolution, the workup stops. If the nodule is unchanged, then there are two options (B) and (C). Option (B) is to perform a low-dose CT 3 months after the initial CT and if it shows growth, biopsy is recommended, otherwise the workup stops. Option (C), preferably for solid nodules 10 mm or larger and part-solid nodules whose solid component is 10 mm or larger, is to perform PET scan and if it is positive, immediate biopsy is recommended while if it is indeterminate or negative, low-dose CT 3 months after the initial CT is performed. If the nodule shows growth on this follow-up CT, biopsy is recommended, otherwise the workup stops.

If a solid endobronchial nodule 5.0 mm or more is identified, a low-dose non-contrast CT scan is performed within 1 month. At the time of the follow-up CT scan, the participant is asked to cough vigorously several times. If the nodule is still present, the participant is referred for pulmonary consultation, and if needed, bronchoscopy.

For all individuals in whom the work-up was stopped or the biopsy did not lead to a diagnosis of lung cancer, repeat CT 12 months after the prior baseline or repeat CT is to be performed.

Assessment of growth

Growth of a nodule is defined as enlargement of the entire nodule and/or of the solid component of a part-solid nodule and/or the development of a solid component in a nonsolid nodule on the follow-up CT after the initial annual repeat CT. Short-term assessment of growth, based on CT images, includes consideration of the measurement error and whether nodule volume doubling rate is consistent with malignancy. Volume doubling rates are based on measuring the change in nodule volume from two time separated scans. The time between these two scans must be sufficiently long for a significant detectable change in volume to occur.

The initial low-dose CT scan is used for the initial nodule measurement. All subsequent CTs of the nodule(s) are again performed at low-dose, ideally with the same scanning parameters that were used to acquire the initial images. The use of contrast material is not involved.

Conservative criteria for a significant percent change in the nodule diameter or growth of the solid component in part-solid nodules are: a) for nodules < 5 mm in diameter, it should be at least 50%; b) for nodules 5 - 9 mm in diameter, it should be at least 30%; c) for nodules ≥ 10 mm in diameter, it should be at least 20%. The time between the serial CT scans to observe these changes is given in the baseline and repeat screening sections of this protocol. A very rapid growth rate in the relevant time period is more suggestive of an infection than a malignancy and in this case a course of antibiotics followed by CT 1 month later is to be performed.

Computer assisted growth rate is still a topic of research, and there is variation among the different software that is currently available. These guidelines have been developed as a result of the evaluation of our in house software, and may differ from others, including those that are commercially available. With careful technical and clinical quality review as outlined below, the results of computer analysis are useful in guiding the workup. In this assessment, the screening site has access to having an analysis performed using the ELCAP web-based research tools (16-20). When using any computer assisted software, the radiologist must be satisfied with the quality of the CT images and the computer segmentation results as ultimately it is clinical judgment that determines whether growth has occurred. The computer scans and the segmentation should be inspected for image quality (e.g., motion artifacts) and for the quality of the segmentation. The radiologist should visually inspect both nodule image sets side-by-side to verify the quality of the computer segmentation for each image that contains a portion of the nodule. The segmentations should also be examined for extreme errors such as when a vessel is segmented as part of a nodule in one scan but not in the other. Scan slice thickness should not exceed one-third of the nodule size. Also, use of automated algorithms when there is variation in the scanning parameters, in particular, different collimation, should be interpreted with caution.

Communication of results

The results of the interpretation of the initial, low-dose CT scan are sent to the referring physician and the participant. Early-diagnosis regimen is described in the consent form and is to be communicated by the physician to each subject. If, however, the subject or his/her physician refuses to follow the recommended regimen, the actual work-up must be carefully documented using the web-based management system.

Biopsy

For the biopsy procedure, CT-guided percutaneous transthoracic fine-needle aspiration is preferred, as this is a 1-hour, minimally invasive, outpatient procedure performed with local anesthesia at the needle puncture site. If this is not feasible, ultrasound or other guided bronchoscopic biopsy is an option. Video-assisted thoracoscopic (VAT) biopsy can be used; however, use of this procedure requires a very strong suspicion of malignancy. It is recommended that prior to VAT, growth assessment at a malignant rate be performed as well as a PET scan when feasible. The images of the cytology and histology specimens are entered into the web-based management system.

The biopsy specimens are described and classified into standard diagnostic categories. Digital images of the cytology and histology slides are submitted for independent reading by the I-ELCAP Cytology and Pathology Panels. The diagnosis of these panels is used as the final diagnosis for study purposes, and it is documented on the study forms in the I-ELCAP database.

Classification and characterization of diagnosed cancers

A diagnosis (rule-in) of lung cancer is classified as a baseline screen-diagnosis if it results from work-up prompted by a positive result of the initial CT on baseline, regardless of when the diagnosis actually is achieved. It is classified in this way also if the result was 'semi-positive' in the sense of calling for a repeat CT 12 months later -- on the grounds that at least one non-calcified nodule was identified but none met the size criteria for a positive result. If the result of the initial CT at baseline is negative and diagnostic work-up is prompted by suspicion-raising symptoms (or an incidental

finding) before the scheduled first annual repeat screening, it is classified as an interim-diagnosis in the baseline cycle, again regardless of when the diagnosis is achieved. Analogous attributions are applied in the context of repeat-screening cycles.

Each diagnosed cancer is characterized according to indicators of how early and otherwise significant the cancer is – all of this bearing on the prognostic issues. Initially the descriptors are defined on a-priori grounds, as specified in the section below. Ultimately, once enough outcome information is available, the descriptors of prognostic relevance can be selected on the basis of the accrued data.

Principal among these descriptors/indicators is the *clinical stage* of the disease at diagnosis. Clinical Stage I, for purposes of I-ELCAP research, is defined by no manifestations of lymph node metastases in the hila, mediastinum, supraclavicular or axillary regions, nor distant metastases in adrenals, liver, spleen, bones, or soft tissues visible in the chest CT and no signs of metastases on PET scan, if performed. The presence/absence of lymph-node and distant metastases (N and M status) is assessed on the most recent CT scan at the time of diagnosis, and also from a PET scan, if available. The person is still classified as being of clinical Stage I as long as these imaging studies do not demonstrate evidence of lymph node or distant metasases (N0M0) even when there is more than 1 adenocarcinoma, all less than 30 mm in diameter (6, 21, 22). Monitoring and quality assurance is directed to this aspect of the Program.

Closely related to the clinical stage of the disease is the *size* of the tumor, notably within Stage I (23). Quality assurance in respect to this descriptor of the diagnosed malignancies is internal to the I-ELCAP database, as the study data from the images are available for central measurement. Two measurements of size can be used. One of these is the 'diameter' involved in the present regimen of early diagnosis presented above: the 'diameter' is the average of the nodule's length and width. In the analyses, however, an alternative to this may also be used: the nodule volume determined automatically using available software.

Important also is the tumor's *volume doubling rate*. This rate is critical to the early-diagnostic regimen, particularly for tumors less than 15 mm in diameter, and is also presumably quite significant prognostically. This doubling rate can also be derived centrally – and on the basis of automated volumetry (16-20).

Eminently important are the pathology data, especially for the distinction between cell types, most notably small-cell and non-small-cell types (21-25). Further differentiation of adenocarcinoma subtypes are being made (22). Other descriptors of prognostic significance may be added, if data-analysis affirms their relevance. The study data for analysis are, again, derived centrally.

It is hoped that prognostic characterization of the diagnosed cancers can also, in the not too distant future, be in part based on 'biomarkers' of the cancer's degree of aggressiveness. Pursuit of this goal is part of the research aims of I-ELCAP.

Intervention policy

When lung cancer has been diagnosed by the experimental regimen of early diagnosis, that diagnosis creates a situation not inherently one of medical research but of medical practice. The I-ELCAP protocol (of research) naturally does not dictate decisions of practice. However, since the concern in the Program is to learn from the treatment intervention practices, close documentation of the intervention(s) is required. Also important to carefully document is the occurrence of any

complications of the intervention(s), notably surgical death (within 30 days) and other serious complications.

The pathologic stage of the cancer in terms of presence/absence of lymph-node involvement and respective station (N and M status) and intrathoracic extension (M) is based on the surgical findings which are documented. Representative pathology slides are sent for review by the Pathology Panel *according to the pathology protocol (10).*

Embedded in the framework of the I-ELCAP, there is opportunity to study the relative merits of *alternative interventions*. With select subtypes of lung cancer diagnoses, some institutions may wish to participate in randomized controlled trials (RCTs) designed to address the relative merits of different therapeutic interventions. RCTs on prevention options are also possible, studies directed, for example, to chemoprevention of recurrence.

The choice of intervention, including the decision whether to intervene, naturally is dependent on individualized prognosis under whatever action is considered. To develop new knowledge for the individualization of prognosis, ancillary studies on the role of biomarkers are encouraged among I-ELCAP participants.

The ELCAP Management System

For the purposes of I-ELCAP, there is a web-based interactive system to guide the actions, and to document these actions and various findings, from the initial contact to schedule the baseline screening to the end of the follow-up of at least 10 years of a diagnosed case of lung cancer (26). The system is accessed from any computer connected to the Internet at the participating institution. It presents the context-relevant data form and thereby provides for immediate data entry, at the initial contact and at each subsequent encounter. Not only does it guide the actions in any given encounter, but it also schedules the next one. All of the information is automatically transmitted to the institution's data repository. The system monitors protocol conformity as well as completeness and consistency of the data at the time of its entry.

The system also provides for electronic transmission of CT images (using standard DICOM protocols) and digital pathology 'slides' to the institution's repository. This allows for central reading, including the automatic assessment of nodule volumes and rate of growth. At the same time, each participating institution has high-speed computer access to its own data.

The system assures confidentiality and reliability. In the transmission, secure scripts are used. Unique passwords are required for access to particular segments of the central database. Accessing the data from each institution involves built-in encryption to maintain security over the Internet (ssh2 and SSL for web access). Identification of the subject is available only to the participating institution, as only the system-assigned code-identifier is available in the I-ELCAP database.

Quality assurance

In I-ELCAP, quality assurance is a central concern. It begins with application of the criteria for data-contributing institutions' admissibility for collaboration (above), and it is served by the built-in management system described above. Additional elements are an integral part of the I-ELCAP database. These include, but are not limited to: central reading of images for teaching purposes, the training of site coordinators as to the I-ELCAP database, and monitoring of their performance – and

recommending corrective actions, as needed.

A team of professionals consisting of radiologists, pulmonologists, thoracic surgeons, oncologists, and pathologists working together and meeting regularly has proven to be the most important contribution to assurance of quality in implementing the protocol with efficiency and safety. Such a multi-disciplinary team should be formed and serve at every I-ELCAP site.

Qualifications of the radiologists in the participating institutions consist in board-certification and if possible subspecialization in chest imaging. They have continual access to the electronic teaching files imbedded in the management system and are encouraged to visit the I-ELCAP database center for training sessions provided by its chest radiologists who are highly experienced in the use of CT in the various phases and situations involved in early diagnosis of lung cancer (cf. Regimen of Early Diagnosis, above). This training is concentrated in the time before an institution begins its subject enrollment and it is also available subsequently as needed. The first 100 baseline CTs submitted by a site are also read at the I-ELCAP database. The site receives each central report together with a discrepancy report and is asked to prepare the final report using the central input. After completion of the first 100 baseline CT scans, a report of the results are sent to the site and a conference call is scheduled to discuss the results and any other questions and concerns. A similar process occurs after the next 100 and after 500 baseline CTs are completed. For the radiologists, review of I-ELCAP teaching files (electronically available by the web-based management system) and participation in the International Conferences on Screening for Lung Cancer are required.

As for the pathologists in the participating centers, information regarding the preparation and reading of cytology and histology specimens is provided by the pathology protocol (10). In addition, an outside panel of pathology experts, the Pathology Panel and Cytology Panel, review the pathology specimens (below).

Qualifications of the site pathologist consist of board-certification in pathology and, if possible, subspecialization in chest pathology. These qualifications are supplemented, as needed by on-site training at the I-ELCAP database with pathologists who are experienced in the pathology readings of specimens obtained in the context of the I-ELCAP protocol. They can also participate in the reviews that are held by the Pathology and Cytology Panels. Quality assurance is provided by comparisons of the site readings with those of the Expert Cytology Panel and Expert Pathology Panel. For the pathologists, review of I-ELCAP teaching files (electronically available by the web-based management system) and participation in the International Conferences on Screening for Lung Cancer are recommended.

The study coordinators of the participating institutions are trained by the senior supervisor of the coordinators as to the I-ELCAP database.

If issues arise that cannot be resolved by conference calls, site visits to the participating institution are made to better assess the issue. The site will be provided a reasonable period of time to accomplish any remedial actions.

Outcome determination

Every effort will be made by the I-ELCAP sites to assure complete 10-year follow-up of all diagnosed cases of lung cancer. The beginning of this is documentation of all information that serves to identify the patient over time including the Social Security number in the US (or equivalent

internationally). And where the local efforts fail, assistance in locating the person or identifying his/her death will be given, as well as in documenting whether manifestations of metastases have occurred and the cause of death.

Embedded in this protocol is the opportunity to pursue the analysis of those data in the database that provide new information related to the diagnosis and prognosis of lung cancer, according to its diagnostic distribution and treatment interventions.

Smoking cessation

Smoking cessation efforts need to be built into the program, particularly for current smokers but also for former smokers. CT screening provides "a teachable moment" for smoking cessation advice (27) and has been shown not to cause former smokers to start smoking (28). However, personalized counseling or referral to quit lines and other support groups is useful.

Workup of ancillary findings

The following recommendations for thymic masses, cardiac calcifications and emphysema may be modified as additional data accrue in I-ELCAP.

1. **Thymic masses**

Based on the frequency and natural course of thymic masses identified in baseline and annual repeat screenings for lung cancer (29), the following work-up recommendations are made: If the mass is less than 3.0 cm in diameter on baseline CT, follow-up CT one year later is recommended. If the thymic mass is greater than 3.0 cm or shows growth on the follow-up CT, then further workup according to standard practice is recommended.

2. **Cardiac calcifications**

If the cardiac calcification score is 4 or more, a referral to a cardiologist, with special focus on preventive cardiology is recommended (30, 31).

3. **Emphysema**

If emphysema is present and previously unrecognized, pulmonary function testing and consultation with a pulmonologist are recommended (32).

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Exhibit H

August 30, 2011, Memorandum Re
DuPont: CT Scans and Medicare

MEMORANDUM

TO: Edgar C. Gentle, Esq.

FROM: Diandra S. Debrosse, Esq.

DATE: August 30, 2011

RE: DuPont:CT Scans and Medicare; Our File No. 4609-1{I}

It is of no consequence for Medicare purposes whether the QSF or DuPont pays for CT Scans as it does not involve medical treatment for which billing will be sent to Medicare or Medicaid. The only issue which arises is with regard to any intermediary testing which may be required by the physician to make a determination as to whether the CT Scan is medically necessary.

The Medicare Secondary Payer Statute (the "MSP Statute") allows Medicare to recover "payments that have been made, or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance." 42 U.S.C. 1395y(b)(2)(A) (2010). The MSP Statute applies where Medicare is a secondary payer, that is to say, only liable to pay the remainder of medical bills that some other person or entity is not responsible to pay. 42 U.S.C. 1395y(b)(2)(A) (2010).

Future Medical Testing

Medicare and Medicaid is not being asked to pay for any test incidental to medical care in the Settlement's medical monitoring program. It is our understanding that all Parties are in agreement that DuPont is the primary payor with regard to medical testing.

The only potential Medicare or Medicaid issue which may arise is where a physician may

determine that additional tests (e.g., a chest x-ray) or services are necessary to determine whether he or she should recommend a CT Scan for an eligible claimant. Arguably, these tests and/or services are part of the medical monitoring program and should be covered by DuPont. In the event that DuPont were to disagree with this position, and Medicare and/or Medicaid were to cover the preliminary exam or other preliminary services necessary to make a CT Scan recommendation, there would potentially be room for Medicare or Medicaid to seek reimbursement for these services.

Payment by DuPont v. The QSF

Whether the QSF or DuPont pays for the CT Scan has no bearing on the above analysis and means nothing to Medicare or Medicaid. CMS's main focus is to ensure that they do not pay for services that should be paid by another party. In this matter, whether the QSF or DuPont pays, the main focus is to ensure that Medicare or Medicaid is not billed for any services which can be seen as part of the medical monitoring program.

As part of the guidelines, physicians should be emphatically reminded to solely bill the QSF for any testing covered under the medical monitoring program.

IV.
B. Proposed Final CT Rule

October 10, 2011
Claims Administrator
Revised CT Guidelines In Response to
Comments to September 1, 2011 Submitted CT Guidelines

THE PERRINE MEDICAL MONITORING PROGRAM,
A PRODUCT OF THE PERRINE DUPONT SETTLEMENT

CT SCAN UTILIZATION GUIDELINES

FOR MEDICAL MONITORING BEGINNING NOVEMBER 1, 2011

These CT Scan Utilization Guidelines, which will be updated every 2 years based upon the state of scientific research respecting radiology and input from the Program's Medical Advisory Committee, is to be utilized by the examining physician in carrying out Step 3 of the CT Scan Utilization Protocols in Exhibit A for a Medical Monitoring participating Claimant who is CT Scan eligible, with eligibility to be determined in accordance with Dr. Brookshire's Report.

To ensure that we do not burden the court with repetition, we refer to and have attached our September 1, 2011 preliminary proposed CT Scan guidelines (without the Exhibits thereto) as Exhibit B.

I. There is No Scientific Data to Suggest that Asymptomatic Screening is Appropriate For CT Scan Eligible Claimants

The proposed guidelines address the position that CT Scans should be allowed for any and all claimants due to their exposure. These guidelines to the rule also incorporate the Responses of Plaintiffs, Defendant and the Guardian Ad Litem to the September 1, 2011 Submission to the Court of the Proposed CT Scan guidelines. These CT guidelines serve to complement the CT Scan Rule which was approved by this Honorable Court on August 31, 2011.

As noted in the Claim's Administrator's September 1, 2011 preliminary proposed guidelines for the attending physician to consider in determining whether to diagnose a CT Scan for CT Scan eligible Medical Monitoring participating claimants, and as stated in the Expert Opinion provided by Dr. Jubal Watts, a cardiopulmonary radiologist at the University of Alabama at Birmingham (the second largest participating site in the National Lung Cancer Screening Trial (NLST)), in Exhibit C, [t]here are no professional societies...that recommend lung cancer screening for populations with risk profiles outside of those of the NLST population". *See* Expert Watts Opinion in Exhibit C.

In Class Counsel's Response to DuPont's Submission in Connection with Proposed CT Guidelines and Preliminary Medical Monitoring Budget, dated October 3, 2011 (hereinafter "Class Counsel Response"), Class Counsel asserts that asymptomatic patients should be screened based solely on their exposure to heavy metals. Class Counsel Response at p. 2. As clearly set forth by Dr. Watts, a cardiopulmonary radiologist, as well as the USFDA Center for Devices and Radiological

Health[1], medical professional societies have not endorsed CT scanning for individuals without symptoms, and CT screening of high-risk individuals for specific diseases such as lung cancer are currently being studied. The Food and Drug Administration maintains the position that CT Scans and radiography imaging are to be used *in the diagnosis of symptomatic people*.

Furthermore, despite the Guardian Ad Litem's assertion on page 5 of the Submission of Guardian Ad Litem Regarding the Preliminary CT Rule and Preliminary Medical Monitoring Budget of September 21, 2011, that the NLST supports the proposition that asymptomatic eligible CT Scan claimants should be screened, the very language of the NLST report belies said assumption.

In the NLST[2], a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group[3]. Despite this finding, the National Lung Screening Trial Research team went on to say:

> Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone, are in our opinion, insufficient to fully inform such important decisions.... Emphasis Added.
>
> The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and over[-]diagnosis, as well as costs...
>
> Other strategies for early detection of cancer... may one day help select persons who are best suited for low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

In sum, Dr. Watts addresses the GAL's comparison of the NLST and the risk to claimants as follows:

> **I think the incremental risks associated with the heavy metal exposure are 2 to 3 orders lower... than the risks faced by 55+ older smokers with a 30+ pack history**... Just the radiation induced lung cancer mortality from the low dose NLST screening protocol [3 to 5 per 10,000 in a 42 year old woman) appears to me greater than the incremental risk of the majority of the class area [as provided for in Dr. Werntz's report and referred to throughout Dr. Watts Opinion]. Adding the breast cancer risk in women... and downstream risk of higher dose exams required to work-up false positives leads me to believe that **CT screening based solely on heavy**

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[1] See Publication of USFDA in **Exhibit D**; http://www.pueblo.gsa.gov/cic_text/health/fullbody-ctscan/

[2] Another large ongoing study is the Ducth-Belgian randomized lung cancer screening trial (NELSON). The NELSON trial is investigating whether the 16-detector multislice computed tomography screening will decrease lung cancer mortality compared to no screening. This trial started in August 2003 and is expected to be completed in December 2015. It is expected to include 15, 600 participants. The participants will receive CT screenings or usual care.

[3] *Id.*

metal exposures for zones 2 and 3 may create more cancers than it would detect and cure. Emphasis Added.

In sum, based upon the statement of the NLST trial team, medical societies and professionals (as discussed ad nauseam in the Claims Administrator's September 1, 2011 submission), and as found in Dr. Watts expert opinion (as a cardiopulmonary radiologist employed by the second largest participating site in the NLST), the NLST results **do not** establish that asymptomatic screening is appropriate in this population because they have been exposed to heavy metals.

Rather, the NLST trial team, medical societies and professionals, and Dr. Watts uniformly state that these decisions are to be made on a case by case basis by a qualified health professional.

II. The Claims Administrator Has No Issue With Removing Signs and Symptoms from the Guidelines to the CT Scan Rule and Is Focused on Ensuring that the Physician Makes the Final Determination Regarding "Medical Necessity"

As noted by Dr. Watts and in line with the assertions advanced by the Guardian Ad Litem and Class Counsel, the presence of any specific signs or symptoms should not be a perquisite to obtaining a lung cancer screening CT. As such, and as reflected in the Final CT Scan Guidelines set forth below, all mention of signs and symptoms as a precursor to CT chest scans have been removed.

III. Linking Putative Disease with Cadmium, Arsenic, Zinc, and Lead Prior To Having a CT Scan is Not Feasible or Provided for by the Settlement Agreement

As noted on page 3, paragraph 4 of Defendant's Reply In Connection with Preliminary CT Scan Guidelines and Preliminary Medical Monitoring Budget dated October 3, 2011 (hereinafter "Defendant's Reply"), Defendants seek that the physician verify that the CT scans may"**only be ordered as related to the alleged heavy metal contamination**." Emphasis Added.

Despite Defendant's contention in paragraph five (5) of Defendant's Reply that the Claims Administrator is in agreement, the Claims Administrator is not in agreement. Specifically, the Preliminary Physician CT Scan Verification Form submitted on September 20, 2011 provides that the physician verifies that a "CT scan for the patient [is] medically necessary and relevant to **possible** exposure...".

Often, the etiology (cause) of disease is unknown and debatable. See, for example, respecting cancer, The Emperor of All Maladies, by Siddhartha Mukherjee. To apply a more wooden exposure rule, other than the agreed "relevant to possible exposure to heavy metal contamination" term in the November 19, 2011, Settlement Memorandum of Understanding (the "MOU") by removing the term "possible", as apparently suggested by Defendant, may remove the very "physician decisions" Defendant advocates in Defendant's Reply, and is therefore rejected by your Claims Administrator as possibly medically ethically improper.

IV. Lung Cancer Screening Should Be Performed At Institutions Similar to the Ones Involved in the NLST

According to the Hammer L. Krille, MD, many physicians underestimate the radiation risks associated with lung cancer screening. Krille L, Hammer GP, Merzenich H., and Zeeb H., "Systematic review of physician's knowledge about radiation doses and radiation risks of computed tomography." Eur J Radiol. 2010 Oct; 76[1]:36-41. The majority of physicians (60 to 70%) in trials underestimated CT doses. Id.

For these reasons, Dr. Watts strongly urges that lung cancer screening be performed at institutions similar to the ones involved in the NLST, as the NLST had low diagnostic procedure rates.

V. CT Scan Guidelines

In light of the above, the briefing of the parties, and the expert opinion of Dr. Watts, the below guidelines are recommended:

1. These rules shall be re-evaluated every two years based upon scientific developments in radiology, and following consultation with the Medical Advisory Committee.

2. CT Scan eligible Claimants are described in Dr. Brookshire's Report.

3. During the CT-Scan eligible Claimant's initial medical monitoring visit with the examining physician, the examining physician will:

    a. Take the Claimant's vital signs;
    b. Conduct a general health interview which shall include the number of years the Claimant has lived in the Class Area in Exhibit 2, with greater weight being given to:
        i. Zone 1 Claimants who have lived in the Class Area for 2 years or more;
        ii. Zone 2 Claimants who have lived in Class Area for 6 years or more; and
        iii. Zone 3 Claimants who have lived in the Class Area of concern for 10 years or more);

    c. Review the Claimant's prior medical record (necessary to determine propensity for cancer); and

    d. Ensure that all female Claimants receive a pregnancy exam.

4. The Claimant will have paragraph C on page 2 of the Memorandum of Understanding in Exhibit A read to him or her by the examining physician or will be provided a copy to read.

5. The examining physician will ensure informed consent. Specifically, the examining physician will explain the nature of the radiological imaging, that the results may not be definitive, there may be false outcomes, and that there is a risk associated with radiological imaging and CT Scans specifically.

6. After a review of the Claimant's vital signs, general health interview, and prior medical history, the examining physician will, in his discretion, make a determination on whether to recommend a CT Scan for the Claimant as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination (which will be documented by the examining physician with the execution of the Perrine Medical Monitoring Program CT Scan Physician Verification Form to which no objection has been made).

7. The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used.

8. The care provider shall not bill Medicaid, Medicare and/or any other third party for the services outlined in these guidelines under any circumstances.

EXHIBIT A

CT SCAN UTILIZATION PROTOCOLS

1. CT Scan eligible claimants are described in Dr. Brookshire's report.

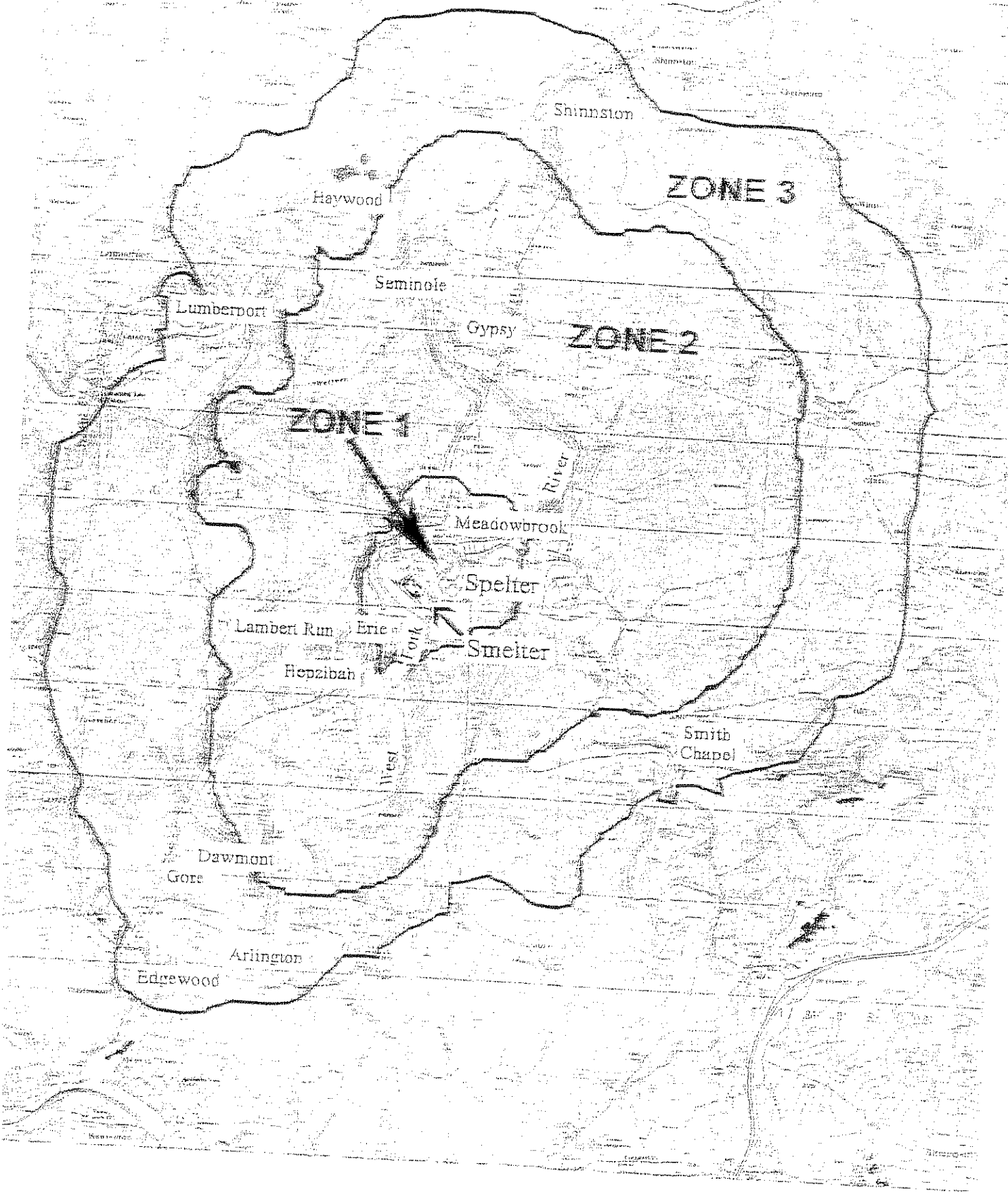
2. At the initial medical monitoring testing visit, the attending physician will take the CT scan eligible claimant's vital signs and conduct a general health interview of the claimant.

3. After examining the claimant, the examining physician will make a determination on whether to recommend a CT scan for the claimant as being diagnostically medically necessary based on the CT Scan Utilization Guidelines to be developed by the Claims Administrator and to be ultimately determined by the Court.

4. The claimant can accept or decline the recommendation for a CT scan.

5. Prior to agreeing to a CT scan, a claimant will be told by the physician the benefits and risks of a CT scan.

6. Claimants agreeing to a CT scan shall sign a standard CT scan release.


Shinnston
ZONE 3
Haywood
Seminole
Lumberport
Gypsy
ZONE 2
ZONE 1
River
Meadowbrook
Spelter
Lambert Run
Erie
Smelter
Hepzibah
Smith
Chapel
West Fork
Dawmont
Gore
Arlington
Edgewood

5. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

EXHIBIT B

September 1, 2011
Claims Administrator
Preliminary CT Rule for Briefing

THE PERRINE MEDICAL MONITORING PROGRAM, A PRODUCT OF THE PERRINE DUPONT SETTLEMENT

CT SCAN UTILIZATION GUIDELINES

FOR MEDICAL MONITORING BEGINNING NOVEMBER 1, 2011

These CT Scan Utilization Guidelines, which will be updated every 2 years based upon the state of scientific research respecting radiology and input from the Program's Medical Advisory Committee, is to be utilized by the examining physician in carrying out Step 3 of the CT Scan Utilization Protocols in Exhibit 1 for a Medical Monitoring participating Claimant who is CT Scan eligible, with eligibility to be determined in accordance with Dr. Brookshire's Report.

I. PREFACE

The proposed guidelines address the position that CT Scans should be allowed for any and all claimants due to their exposure. Furthermore, they address prior suggestions that we attempt to quantify the approximate number of CT Scans which may occur as a result of Medical Monitoring.

The most recent scientific trial involving the benefit of CT Scans in the early detection of lung cancer[1] qualifies its finding of a 20% decrease in mortality by stating that the current data alone is insufficient to fully inform a decision to unilaterally recommend CT Scans to a high risk population. Similarly, the Lung Cancer Alliance states that all "...those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening...".

As suggested in the below guidelines, after a review of the Claimant's history and exposure, the examining physician will determine whether to recommend a CT Scan for the Claimant as being medically necessary. No definitive determination is recommended for all CT Scan eligible Medical Monitoring Participating Claimants at this time. The NCI Division of Cancer Prevention, the Lung Cancer Alliance, the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and Prevention, and the National Institute of Health appear to agree with this approach.

We note that DuPont is in agreement with our position. Specifically, in the Memorandum of James B. Lees, Jr., Esq., Counsel for DuPont, of August 29, 2011, which is in Exhibit A, DuPont states:

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[1]National Lung Screening Trial Research Team; Reduced Lung Cancer Mortality with Low-Dose Computed Tomographic Screening, N Engl J Med 2011; 365:395-409, August 4, 2011, in Exhibit B.

"The words "medically necessary" were inserted to preclude the lawyers and the Court from attempting to interfere with the medical judgments made by competent physicians. The words "medically necessary" were used to make absolutely sure that decisions in the future are being made by physicians and not pursuant to some lawyer-created criteria."

We agree. In sum, the examining physician is to decide whether to recommend a CT Scan for a given claimant, as reflected in the guidelines recommended below.

We understand that Mr. Lees has also suggested linking putative disease with cadmium, arsenic, zinc and lead exposure resulting from the former zinc smelter, prior to having a CT scan. To the extent contemplated in the Settlement, we try to accommodate this suggestion in Section 3b of the below guidelines, giving weight to additional exposure, and in Paragraph 6, as described below. However, medical screening is just that, an examination for disease. Often, the etiology (cause) of disease is unknown and debatable. See, for example, respecting cancer, The Emperor of All Maladies, by Siddhartha Mukherjee. To apply a more wooden exposure rule, other than the agreed "relevant to possible exposure to heavy metal contamination" term in the November 19, 2011, Settlement Memorandum of Understanding (the "MOU") by removing the term "possible", as apparently suggested by Mr. Lees, may remove the very "physician decisions" he advocates in the above quote, and was therefore rejected by your Claims Administrator as possibly medically ethically improper.

On September 1, 2011, we received a second Memorandum from Mr. Lees in Exhibit A, which suggests edits to the guidelines in paragraphs 2 and 3 of the Memorandum.

We agree with the substance of paragraph 2, that there should be CT Scan diagnosis and consent documentation. As to consent documentation, the Court on August 31, 2011, has already ordered it. See August 19, 2011 CT Scan Protocols approved by the Court at paragraph 6 that are Exhibit 1 hereto. We have added language to CT Scan Guidelines paragraph 6 stating that the diagnosis will also be documented. However, DuPont's suggestion in the Memo that these forms be collected by the Claims Office before a CT Scan is authorized as opposed to carrying out the CT Scan as soon as practicable, may have a chilling effect on this component of Medical Monitoring.

We do not agree with Memo paragraph 3 suggesting that the physician find the disease to be "related to" and not "relevant to possible exposure to heavy metal contamination" (the MOU standard), for the reasons stated above. We do agree to include the specific MOU standard on this issue. See revised Paragraph 6 of the CT Scan Guidelines.

We also received an August 19, 2011 letter, also in Exhibit A, from Dr. Andrea H. McGuire, who was asked by CTIA, the Medical Monitoring Plan's Third Party Administrator, to critique an earlier draft of these guidelines, which are not materially different from these guidelines. In response to Dr. McGuire's comments which are critical of the guidelines, and recommend that all eligible Claimants be provided a CT Scan, we note that although Dr. McGuire correctly notes that the reports cited in the guidelines describe Scans other than chest CT Scans, the following issues remain: (1) exposure to CT Scan radiation must be justified and weighted against a benefit to the Claimant; and

(2) we are unaware of evidence that CT scanning of all Claimants would result in a decrease in cancer mortality rates. Furthermore, as noted in these guidelines, recent publications from leading medical authorities establish that no medical authority recommends CT chest scanning of an entire at risk population absent additional research.

A revised protocol is in Section IV of this memorandum and follows an analysis of where current medical and research organizations stand with regard to CT chest scans.

II. SCIENTIFIC BACKGROUND

According to the USFDA Center for Devices and Radiological Health[2], medical professional societies have not endorsed CT scanning for individuals without symptoms, and CT screening of high-risk individuals for specific diseases such as lung cancer are currently being studied. The FDA maintains the position that CT Scans and radiography imaging are to be used *in the diagnosis of syptomatic people*.

As discussed in the American College of Radiology Practice Guideline for the Performance of Pediatric and Adult Chest Radiography[3], the "ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the physician or medical physicist in the light of the circumstances presented." That said, the below CT Scan Guidelines provide that the proper indications and contraindications that are relevant to this matter, which may establish a need for a CT Scan, and which are:

1. Evaluation of signs and symptoms potentially related to the respiratory and cardiovascular system; and
2. Compliance with governmental regulations that may indicate chest radiography (e.g., surveillance PA x-rays for active TB or occupational lung disease).

With regard to total-body CT scanning, the American College of Radiology Board of Chancellors issued the following statement[4]:

> The American College of Radiology (ACR), at this time, does not believe there is sufficient evidence to justify recommending total body computed (CT) screening for patients with no symptoms or a family history suggesting disease.

Robert Smith, Director of cancer screening at the American Cancer Society, says that his organization also discourages full-body scanning CT exams[5].

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[2]See Publication of USFDA in **Exhibit C**; http://www.pueblo.gsa.gov/cic_text/health/fullbody-ctscan/

[3]ACR Practice Guideline, attached as **Exhibit D**.

[4]American College of Radiology (2002, September). Statement on CT Screening Exams. Retrieved March 6, 2006 from http://www.acr.org/s_acr/doc.asp?TrackID=&SID=a&DID=16014&CID, attached as **Exhibit E**.

[5]Please see American Medical News article of September 3, 2011 in **Exhibit E**.

III. CT SCANS IN HIGH RISK POPULATIONS: THE MOST RECENT STUDY AND WHAT IT MEANS

The National Lung Screening Trial (NLST) described in Exhibit B was a randomized trial of screening with the use of low-dose CT as compared screening with the use of chest radiography, and was an effort of the Lung Screening Study (LSS), administered by the NCI Division of Cancer Prevention, and the American College of Radiology Imaging Network (ACRIN), and sponsored by the NCI Division of Cancer Treatment and Diagnosis, Cancer Imaging Program.

The NCI Division of Cancer Prevention conducted the NLST, a randomized controlled trial designed to determine whether screening with LDCT can reduce lung cancer mortality among persons at elevated risks for cancer. The study consisted of more than 50,000 individuals, ages 55 to 74 years with a history of smoking at least 30-pack years. Participants were randomly assigned to receive either three annual Cat Scans or three annual chest x-rays.

In the NLST[6], a 20.0% decrease in mortality from lung cancer was observed in the low-dose CT group as compared with the radiography group[7]. Despite this finding, the National Lung Screening Trial Research team went on to say:

> Although some agencies and organizations are contemplating the establishment of lung-cancer screening recommendations on the basis of the findings of the NLST, the current NLST data alone, are in our opinion, insufficient to fully inform such important decisions....
>
> The reduction in lung-cancer mortality must be weighed against the harms from positive screening results and over[-]diagnosis, as well as costs...
>
> Other strategies for early detection of cancer... may one day help select persons who are best suited for low-dose CT screening tests who should undergo more rigorous diagnostic evaluation.

As further noted by Dr. Simome Tramma, MD, MS, Eileen Storey, MD, MPH, Douglas B. Trout, MD, MHS, and Marie Haring Sweeney, Ph, MPH of the National Institute for Occupational Safety and Health of the Department of Health and Human Services Centers for Disease Control and

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[6] Another large ongoing study is the Ducth-Belgian randomized lung cancer screening trial (NELSON). The NELSON trial is investigating whether the 16-detector multislice computed tomography screening will decrease lung cancer morality compared to no screening. This trial started in August 2003 and is expected to be completed in December 2015. It is expected to include 15, 600 participants. The participants will receive CT screenings or usual care.

[7] *Id.*

Prevention in their NIOSH Science Blog (discussing the breadth of the NLST), attached hereto as Exhibit F[8]:

> "In the occupational setting, there are a number of agents associated with lung cancer. However, the excess risks for lung cancer associated with these occupational exposures vary depending on the actual exposures. Consideration of the use of any screening test in occupationally exposed groups requires a careful assessment of the risk of a given condition. The risk of lung cancer from a specific exposure will directly affect the likelihood that a positive screening test for lung cancer will actually be evidence that the cancer exists. In other words, high risk for lung cancer in the NSLT trial due to a long history of heavy smoking made it more likely that a "positive" funding on a low-dose CT Scan was in fact a lung cancer. The benefit of screening for lung cancer with low-dose CT cannot be easily estimated for populations with risk profiles that are different from those of the NLST participants."

The National Institute for Health states that "[d]ecisions to recommend screening for a population should be based upon the highest possible level of evidence of population benefit from clinical trials."

The Lung Cancer Alliance states its position with regard to lung cancer screening as follows:

> "Lung Cancer Alliance (LCA) has consistently maintained that those at high risk for lung cancer should speak with their doctors about the risks and benefits of screening. Those at risk include smokers and former smokers, first degree relatives of people diagnosed with lung cancer and those with prolonged exposure to radon, asbestos, Agent Orange, radioactive materials and other lung carcinogens. If the decision is made to undergo screening by computed tomography (CT), the scan should only be done at a site which has experience in screening for lung cancer and which follows a lung cancer screening protocol based on best published practices, such as the International Early Lung Cancer Action Program (I-ELCAP) protocol[9]." Emphases Added.

LCA Position on Lung Cancer Screening is attached as Exhibit E.

As noted in the conclusion of the LCA's position statement "[t]hose at high risk for lung cancer and their primary care doctors need to be fully informed in order to reach a decision on screening appropriate to each individual case."

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[8]National Institute of Health, Screening in the Dark: Ethical Considerations of Providing Screening Tests to Individuals When Evidence is Insufficient to Support Screening Populations, A. J Bioeth. 2009 April; 9(4):3-14. in Exhibit F.

[9] The above mentioned International Early Lung Cancer Action Program protocol, dated July 1, 2011, is attached hereto as Exhibit G, and was pioneered and developed over the past 17 years by the International Lung Cancer Action Program, and deals with research concerning the efficacy of CT scans in asymptomatic high risk individuals.

See also Radiation Dose Associated with Common Completed Tomography Examinations and the Associated Lifetime Attributable Risk of Cancer, Rebecca Smith-Bindman, MD, Archives of Internal Medicine, Vol. 169 No. 22., Dec 14/28, 2009 in Exhibit F; Lung CT scan for cancer: Should you be screened?, Mayo Clinic, mayoclinic.com/health/lung-ct-scan/CA0086/MET in Exhibit G.

In designing the guidelines and carrying out the CT Scan portion of the Medical Monitoring Program, Medicare and Medicaid issues should be considered. Please refer to the Memorandum in Exhibit H, expressing the opinion that these issues should not impact how the Medical Monitoring Program is funded.

Footnote 66 to the West Virginia Supreme Court of Appeals March 26, 2010 Decision might also be considered.

IV. THE CT SCAN GUIDELINES (THE "CT RULE")

In light of the above, and current research regarding the signs and symptoms associated with cancer, the below guidelines are recommended:

1. These rules shall be re-evaluated every two years based upon scientific developments in radiology, and following consultation with the Medical Advisory Committee.

2. CT Scan eligible Claimants are described in Dr. Brookshire's Report.

3. During the CT-Scan eligible Claimant's initial medical monitoring visit with the examining physician, the examining physician will:

    a. Take the Claimant's vital signs;
    b. Conduct a general health interview which shall include the number of years the Claimant has lived in the Class Area in Exhibit 2, with greater weight being given to:
        i. Zone 1 Claimants who have lived in the Class Area for 2 years or more;
        ii. Zone 2 Claimants who have lived in Class Area for 6 years or more; and
        iii. Zone 3 Claimants who have lived in the Class Area of concern for 10 years or more);

    c. Review the Claimant's prior medical record (necessary to determine propensity for cancer); and

    d. Ensure that all female Claimants receive a pregnancy exam.

4. The Claimant will have paragraph C on page 2 of the Memorandum of Understanding in Exhibit 3 read to him or her by the examining physician or will be provided a copy to read.

5. The examining physician will ensure informed consent. Specifically, the examining physician will explain the nature of the radiological imaging, that the results may not be definitive, there may be false outcomes, and that there is a risk associated with radiological imaging and CT Scans specifically.

6. After a review of the Claimant's vital signs, general health interview, and prior medical history, the examining physician will, in his discretion, make a determination on whether to recommend a CT Scan for the Claimant as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination (which will be documented by the examining physician with a signed form provided).

7. Factors which satisfy medical necessity include:

   (1) **Signs and Symptoms**, including but not limited to, paraneoplastic syndromes (production of hormone like symptoms from the tumor cells), unexplained weight loss, fever, fatigue, pain, persistent coughing or hoarseness, hemoptysis, unusual bleeding or discharge, dysphagia, persistent shortness of breath, thickening or lumps in the body, hyper pigmentation, jaundice, shoulder pain (Pancoast's Syndrome), pneumonia, persistent headaches, and/or other medical signs and symptoms which are widely accepted in the medical community as potential indicators of cancer.

   AND/OR

   (2) **Medical history** (including known diagnoses).

8. The lowest possible radiation dose consistent with acceptable diagnostic image quality should be used.

9. The care provider shall not bill Medicaid, Medicare and/or any other third party for the services outlined in these guidelines under any circumstances.

EXHIBIT C

I am a cardiopulmonary radiologist at University of Alabama at Birmingham, the second largest participating site in the National Lung Cancer Screening Trial (NLST). While I was not a primary investigator during the trial (I was a resident physician until the screening portion of the trial was nearly complete), I am familiar with the NLST and my participation was requested by the radiology primary investigator, Dr. Hrudaya Nath, as he could not participate due to a scheduling conflict. I am board certified in diagnostic radiology and have worked as an academic cardiopulmonary radiologist for just over four years. I am currently involved in research projects using data from the NLST.

There are no major professional societies that I am aware of that recommend lung cancer screening for populations with risk profiles outside of those of the NLST population. The data is very preliminary and will require further subset analysis and hopefully better risk stratification with biochemical markers collected at some of the participating sites, before reasonable recommendations can be made.

A few points about the NLST that need to be considered when determining the CT scan guidelines or rules that are being contested.

Over 96% of the positive screens in the CT arm of the NLST were false positives.[1]

The rate of positive screens in the CT arm of the NLST ranged from 16.8% to 27.9% per year with just over 39% of participants in the CT arm having at least one positive screen.[1]

Of these positive screens (the overwhelming majority being false positives) just under 50% subsequently required a diagnostic (typically full dose) chest CT (73% for the baseline T-0 exam). A substantial minority also had a PET or PET-CT (8.3% total and 10.3% for the baseline T-0 exam).[1]

Radiation induced malignancies have a typical lag time in excess of ten years and were not included in the NLST analysis (which had six to seven year follow-up).

Reviewing the report of Dr. Werntz (who is obviously an expert epidemiologist and I am not), if I understand correctly on page 3, he describes the time in each zone of involvement necessary to expose an individual to a 1 in 100,000 risk of developing lung and/or skin cancer. For an example, I will use zone 2, where someone living on the peripheral contour of this area would require 3 years of exposure to these heavy metals to increase the risk of developing lung cancer by 1 in 100,000. Assuming they were exposed for 30 years (one order of magnitude) then the incremental risk of developing lung cancer would be 1:10,000. If I am incorrectly understanding or am mischaracterizing these estimates I hope Dr. Werntz will correct me.

Ignoring the cumulative radiation dose from the additional diagnostic chest CT's (estimated effective dose of roughly 8 mSv per diagnostic chest CT, described in the

NLST paper[1]) or additional PET-CT's (typically substantially higher effective doses than diagnostic chest CT's) required in the work-up of these large number of false positives, the cancer risk from only the radiation involved in the low dose screening exam protocols used in the NLST has been estimated.[2] For an example, a 42 year old female would have an expected radiation induced lung cancer mortality risk of 3 to 5 per 10,000 people screened.[2] Again, if I am understanding Dr. Werntz's report correctly, then screening a 42 year old patient (with the NLST low dose protocol) would increase the risk of lung cancer mortality 3 to 5 times greater than that of a 30 year exposure at the periphery of zone 2 (1:10,000).

Radiation induced breast cancer estimates in women from the NLST protocol also range from 3-6 cases per 10,000 screened.[2]

These risks would increase substantially if the effective radiation dose from the downstream diagnostic exams generated by the false positive screens (roughly 39% in the CT arm of the NLST) were included.

Now I am a proponent of lung cancer screening in high risk populations, like the NLST population with lung cancer mortality risks in excess of 1% (1 in 100). These patients are older and the radiation risks are substantially less than for younger populations. I think the incremental risks associated with the heavy metal exposure are 2 to 3 orders of magnitude lower (1 in 100,000 for 3 years at the periphery of zone 2) than the risks faced by 55+ year old smokers with a 30+ pack year history (the population invited to screen in the NLST). Just the radiation induced lung cancer mortality from the low dose NLST screening protocol (3 to 5 per 10,000 in a 42 year old woman) appears to me greater than the incremental risk of the majority of the population in the class area. Adding the breast cancer risk in women (3-6 cases per 10,000 screened) and downstream risk of higher dose exams required to work-up the false positives leads me to believe that CT screening based solely on the heavy metal exposure for zones 2 and 3 may create more cancers than it would detect and cure.

If you take the zone 1 inner estimates of Dr. Werntz with a 1 in 100,000 risk for an exposure of 0.3 years, living 3 years in the periphery of zone 1 inner is a risk of 1 in 10,000, and living 10 years in the peripheral contour of zone 1 inner would be a risk between 3 and 4 per 10,000 (approximately the risk of inducing lung cancer solely from the radiation dose using the NLST low dose screening regimen in a 42 year old woman - 3 to 5 per 10,000).

These radiation dose risk estimates are based on the National Academy of Sciences 2005 report[3] and are the best data we have to date. While many physicians feel this data overestimates risk, being based on Japanese atomic bomb survivors and not diagnostic medical radiation, there is no better data to my knowledge. The FDA also acknowledges the potential risk in medical radiation.

Excerpts taken from the FDA website on radiation risks from CT

"A CT examination with an effective dose of 10 millisieverts (abbreviated mSv; 1 mSv = 1 mGy in the case of x rays.) may be associated with an increase in the possibility of fatal cancer of approximately 1 chance in 2000. . ."

"It must be noted that there is uncertainty regarding the risk estimates for low levels of radiation exposure as commonly experienced in diagnostic radiology procedures. There are some that question whether there is adequate evidence for a risk of cancer induction at low doses. However, this position has not been adopted by most authoritative bodies in the radiation protection and medical arenas. . ."

"The effective doses from diagnostic CT procedures are typically estimated to be in the range of 1 to 10 mSv. This range is not much less than the lowest doses of 5 to 20 mSv received by some of the Japanese survivors of the atomic bombs. These survivors, who are estimated to have experienced doses only slightly larger than those encountered in CT, have demonstrated a small but increased radiation-related excess relative risk for cancer mortality. . . "[4]

The linear no threshold model used by the National Academy of Sciences is generally accepted and I do not believe deviating from it to discount the radiation risks in lung cancer screening is reasonable with no better validated risk prediction model to date. Future analysis of NLST and other large screening populations may give us more accurate models but we do not have them currently.

The FDA estimates the increase risk in the possibility of a fatal cancer from a CT effective dose of 10 mSv at 1 in 2000. A single diagnostic chest CT (performed in large numbers in the NLST CT screening arm for the 96% false positives) has an effective dose of 8 mSv. Additional tests that were frequently performed, such as PET-CT, would increase the incremental cancer risks well above the risks of living in the peripheral contour of zone 1 inner for 10 years (between 3 and 4 in 10,000). Absent a significant smoking history, I am not certain of more benefit than harm to the patients living in the peripheral contour of zone 1 inner.

I think many physicians are underestimating the radiation risks with lung cancer screening. Physicians' knowledge of radiation risks and radiation doses with medical imaging exams is poor overall, with only a minority of physicians found to be well informed on radiation doses and risks in a recent meta-analysis.[5] The majority of physicians (60 to 87%) in the included trials underestimated CT doses.[5]

Regarding the frequency of screening, any recommendations outside the annual screening as performed in the NLST is not likely to be as beneficial. Clinically significant lung cancers are typically biologically aggressive tumors. Over the three years of screening in the NLST the numbers of lung cancers detected in the T0-baseline scan were 270, compared with 168 in the T1 (second annual screening

exam) and 211 in the T2 exam (third annual screening exam).[1] The prevalence and incidence rates are fairly similar for clinically significant lung cancers and wide screening intervals may miss most significant cancers while detecting most insignificant cancers - overdiagnosis - with resultant unnecessary morbidity. Even with annual screening, there was no real benefit for one of the most aggressive histologic types of lung cancer, small cell carcinoma.[1] It may be that semi-annual screening is necessary to detect the very aggressive type of lung cancers. No one knows the optimum screening intervals at this time and varying from the NLST trial design is unwarranted. We will have a much better idea on appropriate screening intervals in three years and I believe that high risk patients (similar to risk profiles in the NLST), should be screened aggressively, with annual screenings performed as it was in the NLST for three years. After the three annual screens more data will be available and adjustments can be made.

Lung cancer screening is medically justifiable/necessary in high risk populations and, as with any screening exam, is done based on the presence of risk factors alone and not specific signs and symptoms. Accordingly, I do not think the presence of any specific sign or symptom should be a prerequisite to obtaining a lung cancer screening CT.

In summary, we know that lung cancer screening benefits individuals at high risk for lung cancer, patients 55+ years and with 30+ pack year smoking history, and it is reasonable to screen patients with similar risk profiles. Interpreting Dr. Werntz's report to the best of my ability, I am doubtful that the incremental risks of lung cancer in the class area from the exposure to heavy metals would independently elevate an individuals cancer risk to approximate that of the NLST cohort. It would be hard to justify screening any 35 year old (the lower age limit of the involved population eligible for CT screening in the medical monitoring program) with any exposure history or risk factors, based on the radiation risks of screening alone and I do not think that screening people this young is a reasonable extrapolation of the NLST.

That being said, I agree that until more data becomes available it should be up to the patients physician to decide if lung cancer screening is medically necessary based on knowledge of cumulative risk factors, e.g. smoking history as well as duration and degree of exposure to heavy metals. The involved physicians will likely need specific education regarding radiation risks in CT screening, as current understanding of radiation dose and risk by physicians is poor. Specific physician education regarding other aspects of lung cancer screening, including the 39% positive screen rate and the 96+% false positive rate, would also allow physicians to more accurately weigh the risks and benefits.

Lastly, I also would recommend lung cancer screening be performed at institutions similar to the ones involved in the NLST, as the NLST had low diagnostic procedure rates and very low surgical mortality (1% vs 4% previously reported for the general community)[1]. I am not certain how effectively the benefits of lung cancer screening

will translate to the general medical community for the same reasons described in the NLST paper[1].

Sincerely,

Jubal R. Watts Jr. M.D.

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[1] The National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med 2011;365:395-409

[2] Berrington DE Gonzalez A, Kim KP, Berg CD. Low- Dose Lung Computed Tomography Screening Before Age 55: Estimates of the Mortality Reduction Required to Outweigh the Radiation-Induced Cancer Risk. *J Med Screen* 2008;15:153-158.

[3] National Research Council. Committee to assess health risks from exposure to low levels of ionizing radiation. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII. Washington DC: National Academy of Sciences, 2005

[4] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmitting ProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm

[5] Krille L, Hammer GP, Merzenich H, and Zeeb H. "Systematic review of physician's knowledge about radiation doses and radiation risks of computed tomography. Eur J Radiol. 2010 Oct;76(1):36-41

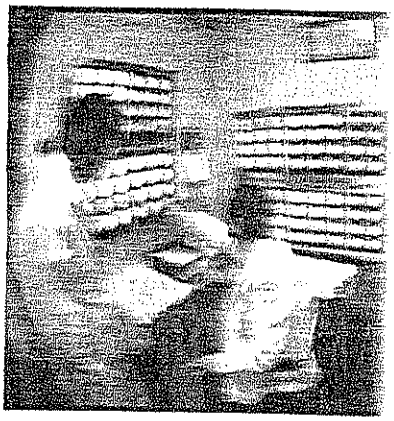
EXHIBIT D

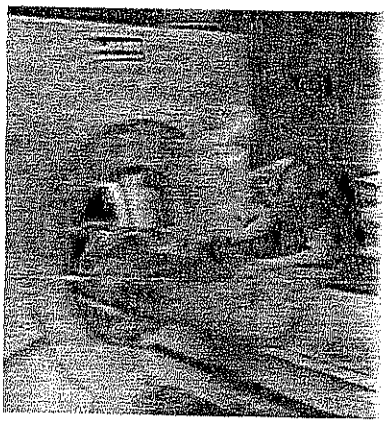
FDA U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Home | What is CT? | What are the Radiation Risks From CT? | Should I get "whole body" CT? | How does FDA regulate CT? | Other Resources | Radiation Quantities and Units | Contact Us

Brochure: Full-Body CT Scans *What You Need to Know*







Using a technology that "takes a look" at people's insides and promises early warnings of cancer, cardiac disease, and other abnormalities, clinics and medical imaging facilities nationwide are touting a new service for health-conscious people: "Whole-body CT screening." This typically involves scanning the body from the chin to below the hips with a form of X-ray imaging that produces cross-sectional images.

The technology used is called "X-ray computed tomography" (CT), sometimes referred to as "computerized axial tomography" (CAT). A

number of different types of X-ray CT systems are being promoted for various types of screening. For example, "multi-slice" CT (MSCT) and "electron beam" CT (EBCT) - also called "electron beam tomography" (EBT) - are X-ray CT systems that produce images rapidly and are often promoted for screening the buildup of calcium in arteries of the heart.

CT, MSCT and EBCT all use X-rays to produce images representing "slices" of the body - like the slices of a loaf of bread. Each image slice corresponds to a wafer-thin section which can be viewed to reveal body structures in great detail.

CT is recognized as an invaluable medical tool for the diagnosis of disease, trauma, or abnormality in patients with signs or symptoms of disease. It's also used for planning, guiding, and monitoring therapy. What's new is that CT is being marketed as a preventive or proactive health care measure to healthy individuals who have no symptoms of disease.

No Proven Benefits for Healthy People

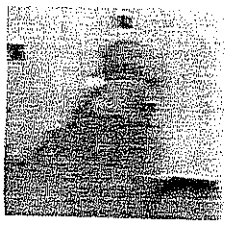
Taking preventive action, finding unsuspected disease, uncovering problems while they are treatableÑ these all sound great, almost too good to be true! In fact, at this time the Food and Drug Administration (FDA) knows of no scientific evidence demonstrating that whole-body scanning of individuals without symptoms provides more benefit than harm to people being screened. The FDA is responsible for assuring the safety and effectiveness of such medical devices, and it prohibits manufacturers of CT systems to promote their use for whole-body screening of asymptomatic people. The FDA, however, does not regulate practitioners and they may choose to use a device for any use they deem appropriate.



Compared to most other diagnostic X-ray procedures, CT scans result in relatively high radiation exposure. The risks associated with such exposure are greatly outweighed by the benefits of diagnostic and therapeutic CT. However, for whole-

body CT screening of asymptomatic people, the benefits are questionable:

- Can it effectively differentiate between healthy people and those who have a hidden disease?
- Do suspicious findings lead to additional invasive testing or treatments that produce additional risk with little benefit?
- Does a "normal" finding guarantee good health?



Many people don't realize that getting a whole body CT screening exam won't necessarily give them the "peace of mind" they are hoping for, or the information that would allow them to prevent a health problem. An abnormal finding, for example, may not be a serious one, and a normal finding may be inaccurate. CT scans, like other medical procedures, will miss some conditions, and "false" leads can prompt further, unnecessary testing.

Points to consider if you are thinking of having a whole-body screening:

- CT screening has not been demonstrated to meet generally accepted criteria for an effective screening procedure.
- Medical professional societies have not endorsed CT scanning for individuals without symptoms.
- CT screening of high-risk individuals for specific diseases such as lung cancer or colon cancer is currently being studied, but results are not yet available.
- The radiation from a CT scan may be associated with a very small increase in the possibility of developing cancer later in a person's life.
- The FDA provides additional information regarding whole-body CT screening on its Web site at: www.fda.gov/cdrh/ct/

FDA's Recommendation:

Before having a CT screening procedure, carefully investigate and

consider the potential risks and benefits and discuss them with your physician.

DHHS Publication No: (FDA) 03-0001
March 2003

V.

A. Preliminary CT Scan Verification Form; and

PERRINE MEDICAL MONITORING PROGRAM
CT SCAN PHYSICIAN VERIFICATION FORM TO BE COMPLETED BY THE HEALTH CARE PROVIDER TO BE COMPLETED FOR EACH MEDICAL MONITORING CT SCAN ELIGIBLE PATIENT

I, a licensed physician, in good standing with the West Virginia Board of Medicine, do hereby certify the following:

1. I, a qualified healthcare professional, have personally examined _____ _____ (name of claimant/patient), referred to below as the "patient," in accordance with the protocols in Exhibit 1.

2. In examining the patient, I have:

   a. Taken the patient's vital signs and reviewed the patient's blood and urine test results;

   b. Conducted a general health interview which shall include the number of years the patient has lived in the Class Area in Exhibit 2, with greater weight being given to:
      i. Zone 1 patients who have lived in the Class Area for 2 years or more;
      ii. Zone 2 patients who have lived in Class Area for 6 years or more; and
      iii. Zone 3 patients who have lived in the Class Area of concern for 10 years or more);

   c. Reviewed the patient's prior medical record (necessary to determine propensity for cancer); and

   d. Ensured that all female patients receive a pregnancy exam.

3. The patient had paragraph C on page 2 of the Memorandum of Understanding in Exhibit 3 read to him or her by me or was provided a copy to read.

4. As the examining physician, I have ensured informed consent by the patient. Specifically, as the examining physician, I explained the nature of the radiological imaging, that the results may not be definitive, there may be false outcomes, and that there is a risk associated with radiological imaging and CT Scans specifically.

5. After a review of the patient's vital signs, the blood and urine test results, general health interview, and prior medical history, I, the examining physician, have, in my discretion, made a determination on whether to recommend a CT Scan for the patient as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination.

MY RECOMMENDATION IS AS FOLLOWS (CHECK ONLY ONE):

☐ YES, I RECOMMEND A CT SCAN.

☐ NO, I DO NOT RECOMMEND A CT SCAN.

6. The decision to recommend a CT Scan or not to recommend a CT Scan rests with me, the examining qualified healthcare professional.

7. As the health care provider, I shall not bill Medicaid, Medicare and/or any other third party for the services outlined in this verification form consent under any circumstances.

Physician's Signature: _____

Printed Name of Physician: _____

Date: _____

Exhibit 1

CT Scan Utilization Protocols

CT SCAN UTILIZATION PROTOCOLS

1. CT Scan eligible claimants are described in Dr. Brookshire's report.

2. At the initial medical monitoring testing visit, the attending physician will take the CT scan eligible claimant's vital signs and conduct a general health interview of the claimant.

3. After examining the claimant, the examining physician will make a determination on whether to recommend a CT scan for the claimant as being diagnostically medically necessary based on the CT Scan Utilization Guidelines to be developed by the Claims Administrator and to be ultimately determined by the Court.

4. The claimant can accept or decline the recommendation for a CT scan.

5. Prior to agreeing to a CT scan, a claimant will be told by the physician the benefits and risks of a CT scan.

6. Claimants agreeing to a CT scan shall sign a standard CT scan release.

Exhibit 2

Class Area Map

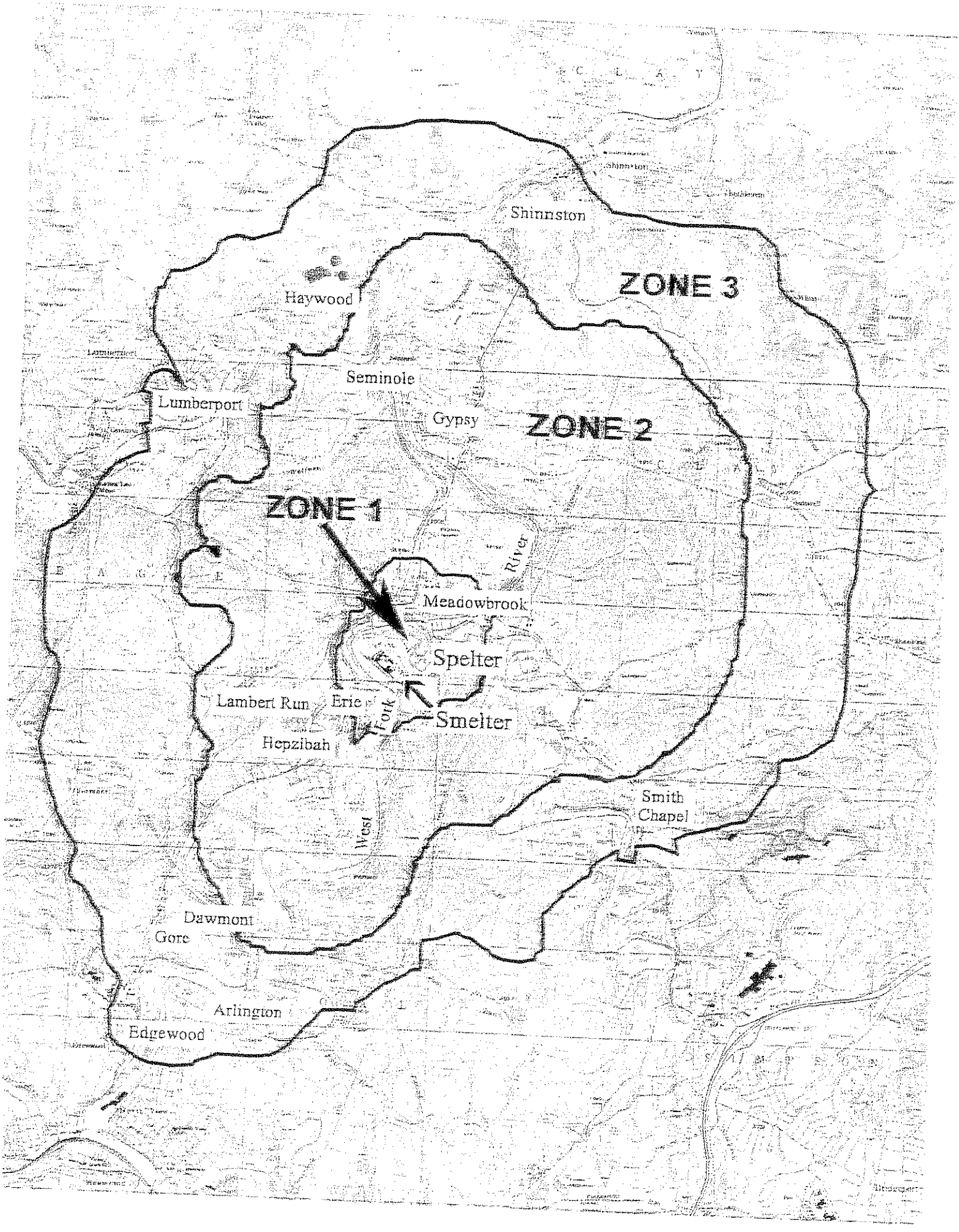

ZONE 3
ZONE 2
ZONE 1
Shinnston
Haywood
Seminole
Lumberport
Gypsy
Meadowbrook
Spelter
Smelter
Lambert Run
Erie
Fork
Hepzibah
West
River
Smith
Chapel
Dawmont
Gore
Arlington
Edgewood

Exhibit 3

Paragraph C, page 2, of Memorandum of Understanding

5. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

V.

B. Red-line Revisions Recommended by the Guardian Ad Litem; and

PERRINE MEDICAL MONITORING PROGRAM
CT SCAN PHYSICIAN VERIFICATION FORM TO BE COMPLETED BY THE HEALTH CARE PROVIDER TO BE COMPLETED FOR EACH MEDICAL MONITORING CT SCAN ELIGIBLE PATIENT

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5. After a consideration of my total exam, inclusive of all test results in Paragraph 2, including, but not limited to, a review of the patient's vital signs, the blood and urine test results, general health interview, and prior medical history, I, the examining physician, have, in my discretion, made a determination on whether to recommend a CT Scan for the patient as being medically necessary and relevant to possible

exposure to heavy metals (cadmium, arsenic, lead or zinc) contamination.

MY RECOMMENDATION IS AS FOLLOWS (CHECK ONLY ONE):

☐ YES, I RECOMMEND A CT SCAN.

☐ NO, I DO NOT RECOMMEND A CT SCAN.

6. The decision to recommend a CT Scan or not to recommend a CT Scan rests with me, the examining qualified healthcare professional.

7. As the health care provider, I shall not bill Medicaid, Medicare and/or any other third party for the services outlined in this verification form consent under any circumstances.

Physician's Signature: _____

Printed Name of Physician: _____

Date: _____

V.

C. Proposed Final CT Scan Verification Form

PERRINE MEDICAL MONITORING PROGRAM
CT SCAN PHYSICIAN VERIFICATION FORM TO BE COMPLETED BY THE HEALTH CARE PROVIDER TO BE COMPLETED FOR EACH MEDICAL MONITORING CT SCAN ELIGIBLE PATIENT

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☐ YES, I RECOMMEND A CT SCAN.

☐ NO, I DO NOT RECOMMEND A CT SCAN.

6. The decision to recommend a CT Scan or not to recommend a CT Scan rests with me, the examining qualified healthcare professional.

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Physician's Signature: _____

Printed Name of Physician: _____

Date: _____

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2. At the initial medical monitoring testing visit, the attending physician will take the CT scan eligible claimant's vital signs and conduct a general health interview of the claimant.

3. After examining the claimant, the examining physician will make a determination on whether to recommend a CT scan for the claimant as being diagnostically medically necessary based on the CT Scan Utilization Guidelines to be developed by the Claims Administrator and to be ultimately determined by the Court.

4. The claimant can accept or decline the recommendation for a CT scan.

5. Prior to agreeing to a CT scan, a claimant will be told by the physician the benefits and risks of a CT scan.

6. Claimants agreeing to a CT scan shall sign a standard CT scan release.

Exhibit 2

Class Area Map

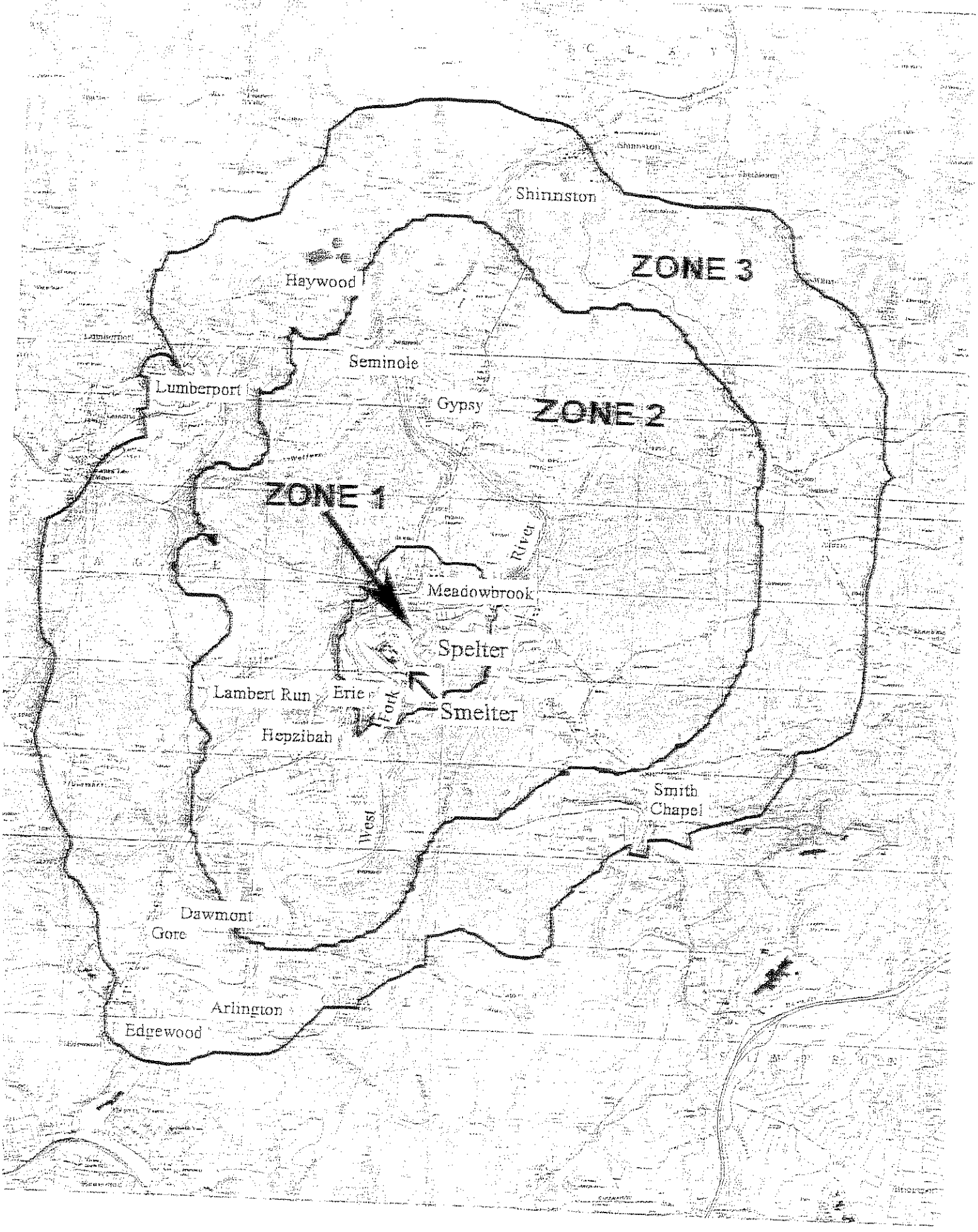

ZONE 3
ZONE 2
ZONE 1
Shinnston
Haywood
Seminole
Lumberport
Gypsy
River
Meadowbrook
Spelter
Lambert Run
Erie
Fork
Smelter
Hepzibah
Smith
Chapel
West
Dawmont
Gore
Arlington
Edgewood

Exhibit 3

Paragraph C, page 2, of Memorandum of Understanding

5. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

VI. October 3, 2011 Materially Accurate Projection of 4,000 Total Medical Monitoring Participants

PERRINE DUPONT SETTLEMENT CLAIMS OFFICE
ATTN: EDGAR C. GENTLE, CLAIMS ADMINISTRATOR
C/O SPELTER VOLUNTEER FIRE DEPARTMENT OFFICE
55 B Street
P. O. BOX 257
Spelter, West Virginia 26438
(304) 622-7443
(800) 345-0837
www.perrinedupont.com
perrinedupont@gtandslaw.com

MEMORANDUM

BY E-MAIL
CONFIDENTIAL

TO: **Virginia Buchanan, Esq.**
Stephanie D. Thacker, Esq.

FROM: **Edgar C. Gentle, III, Esq.**

DATE: **October 3, 2011**

RE: **Perrine v. DuPont Settlement - Weekly Medical Monitoring Form Status Report and Projection of Final Number of "Yes" Claimants and Final Number of Minor "No" Claimants; Our File No. 4609-1 {GG-2}**

Dear Virginia and Stephanie:

Attached, please find our weekly report, which now includes the above two projections.

Thank you for the opportunity to help administer this very interesting Settlement.

Yours very truly,

Ed Gentle,
Claims Administrator

ECGIII/kjm

cc: (via e-mail)(confidential)
Diandra S. Debrosse, Esq.
Katherine A. Harbison, Esq.
Katherine "A. Harbison, Esq.
Paige F. Osborn, Esq.
Michael A. Jacks, Esq.
William S. ("Buddy") Cox, Esq.

J. Keith Givens, Esq.
McDavid Flowers, Esq.
Farrest Taylor, Esq.
Ned McWilliams, Esq.
Perry B. Jones, Esq.
Angela Mason, Esq.
Meredith McCarthy, Esq.

PERRINE DUPONT SETTLEMENT WEEKLY MEDICAL MONITORING REGISTRATION FORMS STATUS REPORT AND PROJECTION OF "YES" CLAIMANTS AND MINOR "NO" CLAIMANTS OCTOBER 3, 2011

			"Yes" Claimants	Minor "No" Claimants	Projected "Yes" Claimants	Projected Minor "No" Claimants
A.	Total Forms Received	6,644	4,566	197	---	---
B.	Verified Registrants	(4,225)	3,079	92	(100%) 3,079	(100%) 92
C.	Verified But Personal Injury Exception	(0)				
D.	Submitted to Finance Committee as Ripe and Waiting Audit Results	(696)	441	13	(95%) 419	(95%) 12
E.	Incomplete					
	a. Claimant Sent Deficiency Letter	(552)	337	26	(50%) 169	(50%) 13
	b. Claims Office Trying to Complete	(284)	181	14	(50%) 90	(50%) 7
	c. Claimant Has Not Been Sent Deficiency Letter	(619)	401	33	(50%) 200	(50%) 16
	d. Claims Office Considered Complete Pending Claims Administrator Review	(7)	5	1	(95%) 5	(95%) 1
F.	Claim Not Reviewed	(0)				
G.	Claimant Ineligible and Has Been Notified	(223)	122	18	(10%) 12	(10%) 2
H.	Late Registrants	(38)				
I.	Reconciliation	0				
J.	Projected Final Number	N/A			3,974 (4,000)	143

VII. Proposed Final Medical Monitoring Budget for November 1, 2011 to August 31, 2012, Inclusive, to be Funded by New Money Deposit of DuPont, with Detailed Memorandum and Footnotes of Explanation with Attachments

VII.

A. Detailed Memorandum of Explanation;

MEMORANDUM

TO: **Edgar C. Gentle, III, Esq.**

FROM: **Terry D. Turner, Jr., Esq.**

DATE: **October 7, 2011**

RE: **Perrine-DuPont Settlement - Perrine DuPont Medical Monitoring Fund Post September 1, 2011 Implementation Date Budget (the "Budget"); Our File Nos. 4609-1 {R} and {NN}**

The purpose of this memorandum is to provide a critique of DuPont's initial Submission of September 21, 2011 and Reply Submission of October 3, 2011 (attached) concerning the Budget[1].

The main objections discussed in DuPont's submissions is that the Budget is not based on (1) actual claimant numbers, and (2) actual negotiated testing costs.

These two items are now materially resolved, as described below.

1. Actual Claimant Numbers: Since the August 31, 2011 Medical Monitoring registration deadline and DuPont's submissions, the Claims Administrator's office has determined that a materially accurate estimate of the number of Medical Monitoring Claimants is 4,000. See the attached projection dated October 3, 2011, that provides a materially accurate estimate of 4,000 claimants participating in the Medical Monitoring Program. In fact, utilizing the Medical Monitoring registration data, the Claims Administrator's office has projected that approximately 67%[2] of all Medical Monitoring Program Claimants are age 35 and older, allowing the Claims

---

[1] In its September 21, 2011 Submission, DuPont states that, to the extent they remain applicable, it incorporates its Objections to the Claims Administrator's August 19, 2011 Proposed Second Budget and Order. Also to the extent they remain applicable, I have attached our August 31, 2011 memorandum critiquing the same.

[2] The basis for the 67% computation is attached. DuPont's Reply Submission, in Paragraph 9 on Page 5, appears to assert that the September 1, 2011 draft of the Preliminary Budget failed to take into account that only adults 35 or older are candidates for CT scans. The revised October 7, 2011 draft of the Preliminary Budget in Exhibit C contains the Third Party Administrator's (the "TPA") projected Medical Provider costs, which recognizes that only adults 35 or older are candidates for CT scans. DuPont raises an additional concern in Paragraph 9 in its Reply Submission that the TPA, the Claims Administrator and the Finance Committee cannot reasonably estimate the number of Medical Monitoring Program participants who are candidates for a CT scan until the Court rules on the circumstances under which a CT scan will be available. Of course, all claimants 35 and older are eligible. To assist in projecting the amount reasonably necessary to fund the Medical Monitoring Program, we have provided two October 7, 2011 versions of the Budget - one with CT scans provided to 50% of adults 35 and older who participate in the Medical Monitoring Program, based upon the Court's implementation of our recommended CT Rule, and another with CT scans provided to 75% of the same adults based on routine CT scans, which we do not recommend.

Administer to further refine the Medical Monitoring Medical Provider costs provided in the revised October 7, 2011 draft of the Preliminary Budget (and discussed further below).

In addition, please note that the Medical Monitoring Program Time Line submitted on January 28, 2011 to the Court (attached), and agreed to by the Finance Committee (including DuPont), anticipated that the Court would consider approving the Medical Monitoring Program budget (on August 15, 2011) prior to testing (on September 8, 2011), with the actual number of claimants participating in the Medical Monitoring Program not being known until after testing (on November 15, 2011).

2. Actual Negotiated Medical Provider Rates: DuPont also objects to the proposed Preliminary Budget due to the fact that the TPA has not completed its negotiation with all Medical Providers to provide the actual negotiated testing costs for the Medical Monitoring Program. The revised October 7, 2011 draft of the Preliminary Budget, in Exhibit C, provides the TPA's projection of Medical Provider "targeted" fees, which we believe is an expert opinion on projected Medical Provider costs and provides for a financially sound budget amount for this expense line item. These figures have been vetted by CTIA with the participating Medical Providers, and are reflected in the attached (i) September 30, 2011 updated CTIA budget previously shared with the Parties; (ii) the October 6, 2011 follow-up letter that CTIA sent the Participating Providers; and (iii) the Participating Provider Contracts CTIA submitted for review and possible signature on October 7, 2011. Thus, not only are the estimates materially accurate, but they are becoming actuals.

3. DuPont Medical Monitoring Program New Contribution: After revising the Budget based upon targeted Medical Provider fees, the materially accurate estimate of 4,000 Medical Monitoring Claimants, and that approximately 67% of the Medical Monitoring Claimants are age 35 or older based on the attached written documentation, the DuPont Medical Monitoring Program new contribution amount significantly decreased. If CT scans are provided to 75%* of Medical Monitoring Plan participating adults 35 and older (assuming that 75% actually participate so it's 75% x 75% = 56.25%), the DuPont Medical Monitoring Program new contribution amount equals $3,143,097.77. If CT scans are provided to 50%* of Medical Monitoring Plan participating adults age 35 and older (assuming that 75% actually participate so its 75% x 50% = 37.5%), the DuPont Medical Monitoring Program new contribution amount would equal $2,789,984.94.

4. Estimated Number of Adults 35 and Older Eligible for CT Scans: Our draft October 7, 2011 Budgets provide Medical Provider costs based on Medical Monitoring Program adults that are age 35 and older receiving CT scans at two different eligibility levels - one assuming 50%* of such adults will receive a CT scan, and the other draft budget assuming 75%* of these adults will have a CT scan. For your information, please find the following table illustrating the estimated number of Medical Monitoring Program adults that may receive a CT scan under these two budget assumptions:

---

* 50% if recommended CT Rule is implemented and 75% if CT scans are routine, which we do not recommend.

	50% CT Scan Participation*	75% CT Scan Participation*
Number of Claimants	4,000	4,000
75% Medical Monitoring Program Participation Rate (other 25% don't show up)	3,000	3,000
67% Are Adults 35 and Older	2,010	2,010
50%* or 75%* CT Scan Participation Rate	1,005	1,508

5. Conclusion: In conclusion, a Budget is simply a projection of expected revenue and expenditures over a period of time utilizing reasonable data and assumptions of anticipated financial activity. As shown above, we assert that the Medical Monitoring Budget for November 1, 2011 through August 31, 2012 is financially sound, and is in accordance with the Court's January 18, 2011 Order (attached), as it will "reasonably secure such expenditures as are reasonably necessary to execute the Medical Monitoring Program."

Should you need anything further, please let me know.

TDTjr/
Attachments

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, CAROLYN HOLBERT, WAUNONA MESSINGER, REBECCAH MORLOCK, ANTHONY BEEZEL, MARY ELLEN MONTGOMERY, MARY LUZADER, TRUMAN R. DESIST, LARRY BEEZEL, and JOSEPH BRADSHAW, individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

CIVIL ACTION NO. 04-C-296-2
(Judge Thomas A. Bedell)

E.I. DU PONT DE NEMOURS AND COMPANY, a Delaware corporation doing business in West Virginia, MEADOWBROOK CORPORATION, a dissolved West Virginia corporation, MATTHEISSEN & HEGELER ZINC COMPANY, INC., a dissolved Illinois corporation formerly doing business in West Virginia, NUZUM TRUCKING COMPANY, a West Virginia corporation, T. L. DIAMOND & COMPANY, INC., a New York corporation doing business in West Virginia, and JOSEPH PAUSHEL, an individual residing in West Virginia,

Defendants.

REPLY SUBMISSION OF E. I. DU PONT DE NEMOURS AND COMPANY IN CONNECTION WITH PRELIMINARY CT SCAN GUIDELINES AND PRELIMINARY MEDICAL MONITORING BUDGET

Now comes Defendant E.I. du Pont de Nemours and Company ("DuPont"), by counsel, and pursuant to the Court's August 31, 2011 Order submits this further pleading relative to the September 1 and September 20, 2011 submissions of the Claims Administrator. (See, September 1, 2001 and September 20, 2011 Submissions of Claims Administrator, attached as Exhibits 1 and 10, respectively, to DuPont's September 21, 2011 Submission). Through ongoing discussion

and this briefing process, the Claims Administrator and the Parties are now in accord with respect to the CT Scan Guidelines. Per the November 19, 2010 Memorandum of Understanding ("MOU") between the Parties and the September 1 and September 20, 2011 Submissions of the Claims Administrator, CT Scans will not be a routine part of the Medical Monitoring program. Rather, the decision as to whether or not any particular Claimant will receive a CT scan will be made solely by the physicians participating in the Medical Monitoring program on a case by case basis. This decision will be made consistent with the dictate of the MOU:

> The program shall provide those examination and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT scans shall be performed as part of the medical monitoring program. The Defendant does agree to provide CT scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation.

As to the preliminary Medical Monitoring budget, although the Parties may ultimately achieve agreement on this as well, the budget continues to be in a state of flux. DuPont received a revised budget, including participation rates and certain cost estimates, today October 1, 2011. DuPont's preliminary comment on the received budget is set forth below at page 5.[1]

Preliminary CT Scan Guidelines

1. CT scans are to be non-routine, having been negotiated out of the Medical Monitoring program by the Parties via the settlement. (See, MOU at par. 3(c), attached as Exhibit 3 to DuPont's September 21, 2011 Submission).

2. As set forth in the MOU, only competent physicians – not the lawyers or the Claims Administrator – may make the decision regarding the diagnostic medical necessity of CT scans. *Id.*

[1] DuPont preserves all objections and argument relative to the preliminary budget previously set forth in DuPont's September 21, 2011 Submission.

3. The September 20, 2011 Preliminary CT Scan Guidelines submitted by the Claims Administrator are in accord. (See, Preliminary Physicians CT Scan Verification Form, attached as Exhibit 10 to DuPont's September 21, 2011 Submission, at pars. 1 and 6)("The decision to recommend a CT scan or not to recommend a CT scan rests with . . . the examining qualified health care professional.") The Guardian *Ad Litem* ("GAL") is in agreement that the examining physician alone should determine whether to recommend a CT scan for a Claimant . . . ." (See, September 21, 2011 Submission of the GAL at p. 1). Class counsel is likewise in agreement, stating, "[t]he only requirements expressed in the Settlement MOU were that a competent physician must make the determination that the CT scans were diagnostically and medically necessary related to the participant's exposure to heavy metals in the class area." (See, September 21, 2011 Submission of Class Counsel, at p. 1).

4. Moreover, as reflected in the MOU as well as in the above-quoted statement of Class Counsel, any CT scans may only be ordered as related to the alleged heavy metal contamination that was at issue in this litigation, that is, arsenic, cadmium, zinc, and lead. (See, MOU at par. 3(c), attached as Exhibit 3 to DuPont's September 21, 2011 Submission).

5. Again, the Claims Administrator and the Parties are in agreement. The September 20, 2011 Preliminary Physician CT Scan Verification Form submitted by the Claims Administrator specifically states, "I, the examining physician, have, in my discretion, made a determination on whether to recommend a CT scan for the patient as being medically necessary and relevant to possible exposure to heavy metals (cadmium, arsenic, lead, or zinc) contamination." (See, Exhibit 10 attached to DuPont's September 21, 2011 Submission, at par. 5).

6. The GAL supports this language, noting "Paragraph 6[2] of the proposed CT Scan Guidelines allows that an examining physician will, in his discretion, decide whether to recommend a CT scan for the Claimant as being medically necessary and relevant to possible exposure to heavy metals . . . contamination . . . ." Paragraph 6 conforms to the Parties' MOU." (See, September 21, 2011 Submission of the GAL, at p. 3).

7. The arguments set forth in the September 21, 2011 submissions of both the GAL and Class Counsel focus instead on the fact that the Claims Administrator's initial September 1, 2011 proposed Preliminary Physician CT Scan Verification Form included a listing of signs and symptoms which could satisfy medical necessity. (See, DuPont's September 21, 2011 Submission, Exhibit 1, at par. 7). Both the GAL and Class Counsel objected to inclusion of this listing of signs and symptoms in the CT Scan Guidelines. (See, September 21, 2011 Submissions of the GAL (pp. 3-8) and Class Counsel (pp. 2-4)). DuPont agrees with the GAL and Class Counsel. The Claims Administrator does as well. Indeed, in the *current* proposed CT Scan Guidelines submitted by the Claims Administrator on September 20, 2011, paragraph 7 of the initial September 1, 2011 Submission of the Claims Administrator--which was the paragraph that included the signs and symptoms listing--has been deleted and is no longer part of the criteria to be used by physicians in prescribing CT scans under the Medical Monitoring program. (See, September 20, 2011 Preliminary Physician CT Scan Verification Form, attached as Exhibit 10 to DuPont's September 21, 2011 Submission).

---

[2] This paragraph reference is with respect to the September 1, 2011 submission of the Claims Administrator. As of September 20, 2011, the Claim Administrator revised certain portions of the Preliminary Physicians CT Scan Verification Form. Although the language of this paragraph was left intact, the paragraph number is now 5 in the revised September 20, 2011 form.

8. The GAL and Class Counsel apparently drafted and filed their initial September 21, 2011 briefs prior to receiving or reviewing the Claims Administrator's September 20, 2011 Submission. In any event, all Parties and the Claims Administrator are now in apparent agreement.

Preliminary Medical Monitoring Budget

9. DuPont recently received a revised budget for the initial implementation of the Medical Monitoring program. The proposed budget assumes that 86% of the 4000 claimants are adults. The proposed budget further assumes that 75% of these adults will show up for initial testing under the Medical Monitoring program and that 50% of the adults who show up for testing will be referred for a CT Scan. Thus, the proposed budget assumes that one out of every two adults that participate in the Medical Monitoring Program will be eligible for a CT Scan. Such a high eligibility rate fails to consider that only those adults age 35 or older are considered candidates for CT scans. Until the Court issues a ruling on the circumstances under which a CT scan will be available under the Medical Monitoring program, the settlement administrator, the third party administrator and the Finance Committee are not in a position to provide a reasonable estimate of the number of Medical Monitoring participants for whom a CT scan is available and the budget necessary to cover the costs of such tests.

The "Inactive" Claimant Procedures are Unnecessary and Wasteful

10. As to the Claims Administrator's proposed rule regarding the classification and handling of "inactive" Claimants, DuPont objects. The Claims Administrator proposes to expend the resources of the Medical Monitoring program to provide Claimants with **three** separate reminders before finally declaring them to be "inactive." (See September 1, 2011 Claims Administrator's Submission, Exhibit B). DuPont objects inasmuch as it is a waste of resources to

repeatedly remind adults about their medical appointments. DuPont submits that one reminder is sufficient.

11. In any event, assuming this "three reminder" rule is approved, following what could only be described as a clear expression of intent not to further participate in the Medical Monitoring program (after failing to show after the three proposed reminders), the Claims Administrator then proposes to further expend resources of the Medical Monitoring program by sending biennial correspondence to these "inactive" Claimants inviting them to again participate. Again, DuPont objects to this waste of resources. It is perfectly reasonable for a Claimant whose initial blood and urine testing via the Medical Monitoring program does not show any heavy metal exposure to make the decision to cease further participation. It is unreasonable, however, for the Medical Monitoring program to continue to expend resources wooing such "inactive" Claimants.

The Non-Medical Monitoring Minor Procedures are Unreasonable

12. The Claims Administrator also proposes a rule to govern those Claimants who were minors during the Medical Monitoring program registration period, but whose parents/guardians chose not to register them to participate in the Medical Monitoring program. The proposed rule regarding the "minor-no" Claimants, provides that upon turning 18, the Claimant will be notified by the Claims Administrator of the program and afforded an opportunity to participate by responding affirmatively. It is further proposed that the "minor-no" Claimants continue to receive biennial correspondence regarding the program availability for the duration of the thirty years. (See August 19, 2011 Claims Administrator's Submission, Exhibit B). DuPont does not object to the Claims Administrator contacting such minor Claimants once upon their

reaching the age of majority. However, for the reasons detailed above in connection with the "inactive" Claimant proposal, DuPont objects to continued biennial contact.

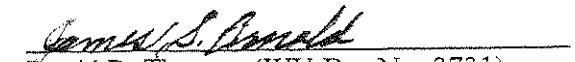
Upon the foregoing, DuPont requests this Court (i) to adopt the *current* CT Scan Guidelines which were proposed by the Claims Administrator and are consistent with the MOU and the agreement of the Parties, and (ii) to reject the recommended procedures for repeated communications with "inactive" Claimants and those Claimants who become adults.

Dated: October 3, 2011.

E.I. DU PONT DE NEMOURS AND CO.,

Defendant,

BY COUNSEL:



David B. Thomas (WV Bar No. 3731)
James S. Arnold (WV Bar No. 0162)
Stephanie D. Thacker (WV Bar No. 5898)
Guthrie & Thomas, PLLC
500 Lee Street East, Suite 800
Post Office Box 3394
Charleston, West Virginia 25333-3394
(304) 345-7250

Counsel for E.I. du Pont de Nemours and Company

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated, **Plaintiffs,** **v.** **E.I. DU PONT DE NEMOURS AND COMPANY, et al.,** **Defendants.**	CIVIL ACTION NO. 04-C-296-2 **Honorable Thomas A. Bedell**

CERTIFICATE OF SERVICE

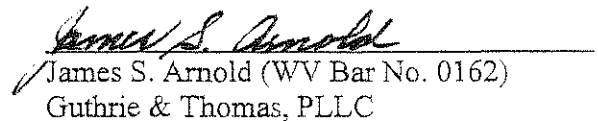
I, James S. Arnold, counsel for Defendant E.I. du Pont de Nemours, hereby certify that service of the foregoing "Reply Submission of E. I. du Pont de Nemours and Company in Connection with Preliminary CT Scan Guidelines and Preliminary Medical Monitoring Budget" has been made upon the parties herein by placing a true copy in the U. S. Mail, postage prepaid, this 3rd day of October, 2011, addressed as follows:

Virginia M. Buchanan
Levin, Papantonio, Thomas, Mitchell,
Echsner, Rafferty & Proctor, P.A.
316 S. Baylen St., Suite 400
Pensacola, FL 32502

Edgar C. Gentle, Claims Administrator
C/O Spelter Volunteer Fire Department Office
55 B Street
P.O. Box 257
Spelter, WV 26438

Meredith McCarthy, Esq.
901 W. Main Street
Suite 201
Bridgeport, WV 26330

Perry B. Jones
West & Jones
360 Washington Avenue
Clarksburg, WV 26301



James S. Arnold (WV Bar No. 0162)
Guthrie & Thomas, PLLC
500 Lee Street East, Suite 800
Post Office Box 3394
Charleston, West Virginia 25333-3394
(304) 345-7250
Counsel for E.I. du Pont de Nemours and Company

LAW OFFICES
GUTHRIE & THOMAS, PLLC
P. O. BOX 3394
CHARLESTON, WEST VIRGINIA 25333-3394

TELEPHONE: (304) 345-7250
FACSIMILE: (304) 345-9941
WEBSITE: www.agmtlaw.com

500 LEE STREET, EAST, SUITE 800
CHARLESTON, WEST VIRGINIA 25301

WRITER'S DIRECT DIAL
(304) 720-4233
e-mail: sdthacker@agmtlaw.com

October 3, 2011

Via Telefacsimile

The Honorable Donald Kopp, Clerk
Circuit Court of Harrison County
301 West Main Street
Clarksburg, WV 26301

Re: Perrine, et al. v. E. I. du Pont de Nemours and Company, et al.
Civil Action No. 04-C-296-2 (Cir. Ct. of Harrison County, W. Va.)

Dear Mr. Kopp:

Enclosed for filing in connection with the referenced civil action, please find "Reply Submission of E. I. du Pont de Nemours and Company in Connection with Preliminary CT Scan Guidelines and Preliminary Medical Monitoring Budget." Copies of the foregoing have this day been properly served.

Thank you for your attention to this matter.

Very truly yours,

STEPHANIE D. THACKER

SDT/klm

Enclosure

cc w/encl.: The Honorable Thomas A. Bedell (Via Telefacsimile)
Meredith McCarthy, Esq. (Via Electronic and U. S. Mail)
Perry B. Jones, Esq. (Via U. S. Mail)
Virginia Buchanan, Esq. (Via Electronic and U. S. Mail)
Edgar C. Gentle, III (Via Electronic and U. S. Mail)

MEMORANDUM

TO: **Edgar C. Gentle, III, Esq.**

FROM: **Terry D. Turner, Jr., Esq.**

DATE: **August 31, 2011**

RE: **Perrine-DuPont Settlement - DuPont Objections; Our File Nos. 4609-1 {R}, {NN} and {GG-1}**

The purpose of this memorandum is provide you with my critique of the Objections of E. I. DuPont De Nemours and Company to Proposed Second Budget and Proposed Order Regarding Same (the "DuPont Objections") filed by DuPont on August 19, 2011 and attached. The following paragraph numbers correspond to the paragraph numbers contained in the DuPont Objections.

2. DuPont states that the draft Budget is not based on actual numbers or negotiated testing rates. The Claims Administrator has experience in this area to provide an educated estimate on the projected budgetary expenses, and the Third Party Administrator is well qualified to provide a projection on testing rates.

9. DuPont cites the January 18, 2011 Order concerning the setting aside of reasonable reserves to cover the estimated cost of the medical monitoring program, although this can be viewed as a separate matter from actually funding the year Budget in advance.

11. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

15. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

19. The Budget does not assume that all active claimants will come in at once during the first year, it is based on a 75% show-up rate.

20. The attached Budget summary of projected expenses shows that we estimate a total of $4,535,873.12 in Medical Monitoring Program post-implementation date expenses. Of this amount, $480,963.66 represents administrative expenses (excluding FASB 5 Contingency Reserve amounts), which is 10.60% of the projected Medical Monitoring Program post-implementation date expenses. The FASB 5 Contingency Reserve is not only for possible additional administrative expenses, but is a general contingency for any other under-projected expenses.

In our latest draft of the proposed Budget, we have segregated CT scan costs and incremental administrative costs related thereto (excluding common expenses so it is not a fully-allocated cost

projection). We also allocated an additional $52,123.77 of the administrative expenses to CT scan related administrative expenses (taking into account reasonably foreseen future litigation expenses, design costs, and extraordinary administrative costs in administering this part of the Medical Monitoring Program), so that the Medical Monitoring Settlement Fund - Post September 1, 2011 Implementation Date Expenses (Excluding CT Scan Expenses) administrative expenses would equal approximately 10.36%.

Of the total medical monitoring program post-implementation date administrative expenses totaling $480,963.66 (excluding FASB 5 expenses), (i) $249,477.63, or 10.36%, of the $2,407,835.93 post-implementation date expenses (excluding CT scan expenses) represent administrative expenses; and (ii) $231,486.03, or 10.88%, of the $2,128,037.19 post-implementation date CT scan expenses represent administrative costs.

Finally, concerning Dr. Brookshire's administrative expense estimate, it may be that Dr. Brookshire estimated a 10% administrative fee rate for the Third Party Administrator, not Claims Administrator and Claims Office costs. In fact, the Third Party Administrative costs are now at 4.15%. Dr. Brookshire also assumed that implementation of the Medical Monitoring Plan would be non-controversial, absent complications respecting the CT Scan.

In a call with the Finance Committee on August 31, 2011, a question was asked about including Guardian Ad Litem fees in the CT Scan portion of the budget. Although the Guardian Ad Litem represents children, they will ultimately become adults who are CT Scan eligible, so we believe Guardian Ad Litem participation is appropriate. We split her budgeted fees as follows: 75% for Non-CT Scan Budget and 25% for CT Scan Budget.

Should you need anything further, please let me know.

TDTjr/
Attachment

PERRINE DUPONT SETTLEMENT CLAIMS OFFICE
ATTN: EDGAR C. GENTLE, CLAIMS ADMINISTRATOR
C/O SPELTER VOLUNTEER FIRE DEPARTMENT OFFICE
55 B Street
P. O. BOX 257
Spelter, West Virginia 26438
(304) 622-7443
(800) 345-0837
www.perrinedupont.com
perrinedupont@gtandslaw.com

MEMORANDUM

BY E-MAIL
CONFIDENTIAL

TO: **Virginia Buchanan, Esq.**
Stephanie D. Thacker, Esq.

FROM: **Edgar C. Gentle, III, Esq.**

DATE: **October 3, 2011**

RE: **Perrine v. DuPont Settlement - Weekly Medical Monitoring Form Status Report and Projection of Final Number of "Yes" Claimants and Final Number of Minor "No" Claimants; Our File No. 4609-1 {GG-2}**

Dear Virginia and Stephanie:

Attached, please find our weekly report, which now includes the above two projections.

Thank you for the opportunity to help administer this very interesting Settlement.

Yours very truly,

Ed Gentle,
Claims Administrator

ECGIII/kjm

cc: (via e-mail)(confidential)
Diandra S. Debrosse, Esq.
Katherine A. Harbison, Esq.
Katherine "A. Harbison, Esq.
Paige F. Osborn, Esq.
Michael A. Jacks, Esq.
William S. ("Buddy") Cox, Esq.

J. Keith Givens, Esq.
McDavid Flowers, Esq.
Farrest Taylor, Esq.
Ned McWilliams, Esq.
Perry B. Jones, Esq.
Angela Mason, Esq.
Meredith McCarthy, Esq.

PERRINE DUPONT SETTLEMENT WEEKLY MEDICAL MONITORING REGISTRATION FORMS STATUS REPORT AND PROJECTION OF "YES" CLAIMANTS AND MINOR "NO" CLAIMANTS OCTOBER 3, 2011

			"Yes" Claimants	Minor "No" Claimants	Projected "Yes" Claimants	Projected Minor "No" Claimants
A.	Total Forms Received	6,644	4,566	197	---	---
B.	Verified Registrants	(4,225)	3,079	92	(100%) 3,079	(100%) 92
C.	Verified But Personal Injury Exception	(0)				
D.	Submitted to Finance Committee as Ripe and Waiting Audit Results	(696)	441	13	(95%) 419	(95%) 12
E.	Incomplete					
	a. Claimant Sent Deficiency Letter	(552)	337	26	(50%) 169	(50%) 13
	b. Claims Office Trying to Complete	(284)	181	14	(50%) 90	(50%) 7
	c. Claimant Has Not Been Sent Deficiency Letter	(619)	401	33	(50%) 200	(50%) 16
	d. Claims Office Considered Complete Pending Claims Administrator Review	(7)	5	1	(95%) 5	(95%) 1
F.	Claim Not Reviewed	(0)				
G.	Claimant Ineligible and Has Been Notified	(223)	122	18	(10%) 12	(10%) 2
H.	Late Registrants	(38)				
I.	Reconciliation	0				
J.	Projected Final Number	N/A			3,974 (4,000)	143

MEMORANDUM

TO: **Edgar C. Gentle, III, Esq.**

FROM: **Stephen R. Creed**

DATE: **October 7, 2011**

RE: **Perrine-DuPont Settlement - Age Statistics of "Yes" Verified Ripe Claimants; Our File Nos. 4609-1 {GG-6}**

Ed,

Per your request, we reviewed the current Verified Ripe database to determine the number of Verified Ripe Yes Claimants 35 or Older. The results as of September 30, 2011, are as follows:

Total Number of Current Ripe Yes Claimants:	3,079
Percentage of Ripe Yes Claimants 35 or Older:	67% (or 2,050 Claimants)

Let me know if you need any additional information.

KAH/

Paige Osborn

From: EscrowAgen@aol.com
Sent: Friday, October 07, 2011 8:06 AM
To: Paige Osborn
Subject: Fwd: Revised budget estimates
Attachments: claim_BUDGET_W_ACTUAL_LABCORP_FEES.xls

From: escrowagen@aol.com
To: mcooper@gtandslaw.com
Sent: 9/30/2011 5:30:35 P.M. Central Daylight Time
Subj: Fwd: Revised budget estimates

Dload n print

-----Original Message-----
From: Donald Brandt <dbrandt@claimtechnologies.com>
To: EscrowAgen <EscrowAgen@aol.com>; tturner <tturner@gtandslaw.com>
Sent: 30-Sep-2011 16:15:05 +0000
Subject: Revised budget estimates

Ed/Terry Attached is the latest version of the claim budget.

Donald Brandt

President

Claim Technologies Inc.

100 Court Ave Suite 306

Des Moines, IA 50309

888-220-2445 x 233

515-244-8650 (fax)

This message (including any attachments) may contain confidential information and is covered by law. If you are not the intended recipient, any disclosure, copying, or distribution of this communication is prohibited. Please reply to sender that you have received this message in error and then delete it.

ADULT TESTING PROTOCOL (age 18 & above)

Initial Testing

1. The first visit to the Clinic will be for the purpose of collecting a urine sample and drawing blood. There will be collection of urine & blood samples. There will be a charge for a 5 minute office visit for established patients and a 10 minute office visit for new patients. Patients will also be given a stool hemocult card that will be sent directly to Lab Corp.

   1.a. Urinary System Tests will be given to age 18 and above.

   1.b. Plumbism Tests will be given to age 18 and above.

   1.c Urine & blood samples will be sent to LabCorp with

   1.d Stool sample cards will be sent to LabCorp with instructions to send test results via EDI to Physicians & to

2. LabCorp will perform 6 separate procedures for each participant and send the test results (via EDI) to the Physician & to CTI.

3. CTIA will contact participant to obtain release to maintain test results for subsequent analysis.

   3.a If release to maintain data is not obtained, CTIA will delete test results from it's data base. Test results will still be maintained for/by physician.

4. Subsequent Redos are also accounted for in this spreadsheet.

Number of Participants **4,000** ← Change as desired

Procedure Code	Description	Count Including Redos	Targeted Fee	Targeted First Year Cost
99201	10 Minute OFFICE VISIT OP NEW	1,878	$60.00	$112,664
99211	5 Minute OFFICE VISIT OP ESTABLISHED	1,878	$32.00	$60,087
99000	SPECIMEN HANDLING	3,873	$12.00	$46,477
36415	ROUTINE VENIPUNCTURE	3,745	$10.00	$37,453
81001	URINALYSIS, NONAUTO W/SCOPE	3,873	$3.50	$13,556
82274	OCCULT BLOOD, FECES	3,745	$20.00	$74,907
82232	ASSAY OF BETA-2 PROTEIN	3,745	$20.00	$74,907
82565	ASSAY OF CREATININE	3,745	$2.50	$9,363
84520	ASSAY OF UREA NITROGEN	3,991	$2.50	$9,977
83655	ASSAY OF LEAD	3,745	$10.00	$37,453
			Total	**$304,093**

First Consultation by Physician	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. The consultation will consist of a Physical Exam, review of laboratory findings, Physical Examination, explanation of the pros & cons of having a CT Scan, and scheduling of additional testing on an as needed basis.	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	1,814	$135.00	$244,890
1.a Some of the initial laboratory tests will have to be redone. Costs for these are included in the Initial Testing.	99243	40 Minute Office Visit Physical Exam, CT Scan	1,814	$170.00	$308,380
1.b. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be repeated.					
1.c. Adults testing positive to the Urinary system tests will require two follow-up consultations with a urologist. These tests will include Cystoscopy with biopsy, and CT Sans of the Abdomen and Pelvis. Some of these tests will have to be redone					
1.d. Adults testing positive to the Urinary system tests will require two follow-up consultations with a Urologist. These tests will					
1.e. Adults testing positive to the Urinary system tests or the BUN/Creatinine tests will require two follow-up consultations with a Nephrologist. These tests will include repeat Urine-Beta-2 and BUN/Creatinine.				**Total**	**$553,270**

Adult Skin Test with Dermatologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be redone.	99242	Consultation with Dermatologist	108	$140.00	$15,120
1.c Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	11100	BIOPSY, SKIN LESION	36	$110.00	$3,960
2. LabCorp will perform tests and send the test results (via EDI) to the Physician & to CTI.	88304	TISSUE EXAM BY PATHOLOGIST	36	$45.00	$1,620
				Total	**$20,700**

Follow-up with Urologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with an Urologist. Half of these patients will require additional testing.	99242	Consultation with Urologist	108	$140.00	$15,120
1.a. Two consultations will be required for each of the patients and two more for each of those requiring additional tests.	88112	CYTOPATH, CELL ENHANCE TECH	108	$32.00	$3,456
1.b Each patient will require a Cytopathology with Biopsy	52000	CYSTOSCOPY	108	$250.00	$27,000
1.c There will be an Outpatient Facility Charge for the Cytopathology	81001	URINALYSIS, NONAUTO W/SCOPE	108	$3.50	$378
1.d There will be a Charge for the Anesthesia	OP Facility	Out Patient Facility Charge	108	$850.00	$91,800
1.e CT Scan of Abdomen & CT Scan of Pelvis	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	108	$350.00	$37,800
1.f Reading of CT Scan of Abdomen & CT Scan of Pelvis	74176	CT Scan Abdomen & Pelvis	108	$350.00	$37,800
1.g CT Scan of of Pelvis	74176.26	Radiologist	108	$110.00	$11,880
1.h Reading of CT Scan of of Pelvis	72192	CT PELVIS W/O DYE	72	$300.00	$21,600
1.i Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	72192.26	Radiologist	72	$100.00	$7,200
1.j CT Scan will be sent to Radiologist with instructions to send test results via EDI to Urologist & to CTIA.					
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.					
3. Radiologist will read CT Scans and send the test results (via???) to the Urologist & to CTI.				Total	$254,034

Follow-up with Nephrologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with a Nephrologist to test for kidney failure.	99242	Consultation with Nephrologist	288	$140.00	$40,320
1.a. Two consultations will be required for each of the 108 patients.	99000	SPECIMEN HANDLING	144	$12.00	$1,728
1.b Each patient will require a Urinalysis	36415	ROUTINE VENIPUNCTURE	144	$10.00	$1,440
1.c Urine & blood samples will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	81001	URINALYSIS, NONAUTO W/SCOPE	144	$3.50	$504
1.c. Miscellaneous lab work to determine cause for kidney failure	84520	ASSAY OF UREA NITROGEN	144	$2.50	$360
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.	misc		144	$125.00	$18,000
				Total	**$62,352**

Follow-up with Gastroenterologist & Proctologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the stool sample tests will require follow-up with a Gastroenterologist followed by some patients with a Proctologist.	99242	Consultation with Gastroenterologist	181	$140.00	$25,387
1.a. A consultation with a Gastroenterologist will be required for each patient.	82274	OCCULT BLOOD, FECES	181	$20.00	$3,627
1.b Each patient will require another Stool Sample Test	99242	Consultation with Proctologist	27	$160.00	$4,267
1.c. A consultation with a Proctologist will be required for some patients.	82274	OCCULT BLOOD, FECES	27	$20.00	$533
1.d Each patient will require another Stool Sample Test & an Upper GI Endoscopy.	43239	UPPER GI ENDOSCOPY, BIOPSY	27	$350.00	$9,333
2. LabCorp will perform tests and send the test results (via EDI) to the Gastroenterologist, Proctologist, & to CTI.	OP Facility	Out Patient Facility Charge	1	$850.00	$826
	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	1	$350.00	$340
				Total	**$43,973**

Follow-up with Toxicologist & Psychologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the lead blood tests will require follow-up with a Medical Toxicologist followed by some patients with a Psychologist.	99242	Consultation with Toxicologist	283	$140.00	$39,573
1.a. Four consultations with a Medical Toxicologist will be required for each patients.	36415	ROUTINE VENIPUNCTURE	71	$10.00	$707
1.b. Each patient will require a complete blood count, lead, and zinc test.	85025	COMPLETE CBC W/AUTO DIFF WBC	71	$4.00	$283
1.c. Four one-hour tests with a Psychologist will be required for each of the 131 patients & 33 retests. (856 hours)	84202	ASSAY RBC PROTOPORPHYRIN	71	$10.00	$707
	83655	ASSAY OF LEAD	71	$10.00	$707
2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.	96118	NEUROPSYCH TST BY PSYCH/PHYS	1,141	$100.00	$114,133
				Total	**$156,109**

Adult CT Scans with Pulmonologist, Cardiologist, & Pulmonologist	Estimated Participation (change as desired)	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
	37.50%					
1. There are 86% adults in the population of participants. The percentage of CT Scans will be as indicated in the cell Estimated Participation. 1.a. 40% of the initial CT Scans will need to be repeated 1.b. Each patient will require a complete blood count, lead, and zinc test. 1.c. Four one-hour consultations with a Psychologist will be required for each patient. 2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.		71250	CT THORAX W/O DYE	1,290	$300.00	$387,000
		71250.26	CT THORAX W/O DYE	1,290	$100.00	$129,000
		71250	Repeat CT Scan of Chest	516	$300.00	$154,800
		71250.26	Repeat CT Scan of Chest	516	$100.00	$51,600
		99242	Consultation with Pulmonologist	129	$140.00	$18,060
		99242	Consultation with Cardiologist	65	$140.00	$9,030
		99242	Consultation with Cardiothoracic Surgeon	23	$140.00	$3,161
		32095	BIOPSY THROUGH CHEST WALL	23	$425.00	$9,594
		OP Facility	Out Patient Facility Charge	23	$850.00	$19,189
		00910	ANESTH, (3base @$70 + time)	23	$350.00	$7,901
		99242	Consultation with Pulmonologist	42	$140.00	$5,870
		32095	BIOPSY THROUGH CHEST WALL	42	$425.00	$17,818
		OP Facility	Out Patient Facility Charge	42	$850.00	$35,636
		00910	ANESTH, (3base @$70 + time)	42	$350.00	$14,674
					Total	**$863,333**

cap Using Targeted Fees	
Initial Testing	$304,093
First Consultation by Physician	$553,270
Adult Skin Test	$20,700
Follow-up with Urologist	$254,034
Follow-up with Nephrologist	$62,352
Follow-up with Gastroenterologist & Proctologist	$43,973
Follow-up with Toxicologist & Psychologist	$156,109
Adult CT Scans with Pulmonologist, Cardiologist, & Pulmonologist	$863,333
CT Scan participation estimated at 37.50%	**$2,257,863**

Procedure Code	Number of Procedures Every Other Year
81001	4,125
82270	0
82232	3,745
82565	3,745
84520	4,135
83655	3,816
88304	36
88112	108
85025	71
84202	71

Paige Osborn

From: EscrowAgen@aol.com
Sent: Friday, October 07, 2011 8:07 AM
To: Paige Osborn
Subject: Fwd: the missing attachment
Attachments: ProviderProtocol&fees.doc

From: EscrowAgen@aol.com
To: sdthacker@agmtlaw.com, wcox@lfwlaw.com, VBuchanan@levinlaw.com, mhmccarthy@citynet.net
CC: dbrandt@claimtechnologies.com, rbrandt@claimtechnologies.com, pgagne@claimtechnologies.com, mjacks@gtandslaw.com, kharbison@gtandslaw.com, ddebrosse@gtandslaw.com, posborn@gtandslaw.com
Sent: 10/3/2011 1:25:15 P.M. Central Daylight Time
Subj: Fwd: the missing attachment

Here's the attachment, Ed

From: dbrandt@claimtechnologies.com
To: EscrowAgen@aol.com
Sent: 10/3/2011 12:08:17 P.M. Central Daylight Time
Subj: the missing attachment

Donald Brandt

President

Claim Technologies Inc.

100 Court Ave Suite 306

Des Moines, IA 50309

888-220-2445 x 233

515-244-8650 (fax)

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The Perrine Medical Monitoring Plan
Product of the Perrine DuPont Settlement

October 5, 2011

Dr. John Doe
XYZ Clinic
E. STE 100
WV 35244

RE: Perrine Medical Monitoring Plan, *Product of the Perrine DuPont Settlement*

Dear Dr. Doe:

Thank you for taking the time to talk with me regarding the Perrine Medical Monitoring Plan (the Plan). We are pleased that you have tentatively agreed to participate as a provider of medical services for the Plan. As I explained to you, CTI Administrators, Inc. has been authorized to contract with a limited number of medical providers in and around Spelter, West Virginia to provide medical testing for participants in the Spelter Case Medical Monitoring Plan. The Plan will serve approximately 4,000 individuals residing in the vicinity of Spelter West Virginia. The Plan is expected to provide testing for the participants over the next 30 years.

Testing protocols for the medical monitoring Plan were recommended by Charles L. Werntz III, D.O., MPH in his report of March 30, 2007. Dr. Werntz's recommendations were subsequently approved by the court and need to be followed by the participating providers with one exception relating to the use of CT Scans. The recommended protocol for the use of CT Scans is still being reviewed and remains unresolved at this time.

Following is an outline of the complete set of protocols (including the use of CT scans) as recommended by Dr. Werntz. The outline also includes allowable fees. Again, please keep in mind that the recommended use of CT Scans is still unresolved at this time.

Two biannual testing protocols have been adopted for the Plan based upon the age of the participant:

- Adult Testing for participants ages 18 and above;
- Child testing for under age 18 participants.

Both protocols assume that there will be an initial set of tests followed by a consultation with the physician. The initial tests will be a urinalysis for all participants over age 15, blood tests for all participants, and stool samples for all participants age 18 and above. Tests will be taken on a biannual basis. The Plan has contracted with LabCorp to perform all necessary laboratory tests.

The consultation to review the test results and physical examination may also include an explanation to the patients of the pros and cons of CT Scans; an unresolved topic at this time.

Depending on the test results, retests may be required and/or referrals made to specialist including:

- **Urologist**, for consultations and Cytopathology for patients testing positive to Urinary system tests;
- **Dermatologist**, for skin tests for some patients testing positive to Urinary system tests;
- **Gastroenterologist and/or Proctologist**, for consultations, additional stool sample tests, and upper GI endoscopy; and/or
- a **Medical Toxicologist,** for consultations and complete blood count, lead and zinc tests.

Subsequent referrals may then be sent to a Psychologist, Radiologist, Pulmonologist, and/or Anesthesiologist. We will need to contract with these specialists so your recommendations regarding these specialists will be helpful. These specialists have been included in the table of Anticipated Procedures and Allowable Fees shown below:

All participants must use participating providers that have contracted with the Plan. The Plan will pay for benefits at the Allowable fees shown in the following table. Keep in mind that there are no deductibles, co-payments, or coinsurance to be paid by the participants. Since we will pay at 100% of Allowable Fees, providers will not need to balance bill the patients nor collect co-payments at the time of service.

Table of Anticipated Procedures and Allowable Fees

Initial Testing	Procedure Code	Description	Allowable Fee
	99201	10 Minute OFFICE VISIT OP NEW	$60.00
	99211	5 Minute OFFICE VISIT OP ESTABLISHED	$32.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	82274	OCCULT BLOOD, FECES	LabCorp
	82232	ASSAY OF BETA-2 PROTEIN	LabCorp
	82565	ASSAY OF CREATININE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Follow-up Consultation	**Procedure Code**	**Description**	**Allowable Fee**
	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$135.00
	99243	40 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$170.00

Skin Test with Dermatologist	Procedure Code	Description	Allowable Fee
	99242	Consultation with Dermatologist	$140.00
	11100	BIOPSY, SKIN LESION	$110.00
	88304	TISSUE EXAM BY PATHOLOGIST	LabCorp
Consultation with Urologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Urologist	$140.00
	88112	CYTOPATH, CELL ENHANCE TECH	LabCorp
	52000	CYSTOSCOPY	$250.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	$350.00
Anesthesiologist			
	74176	CT Scan Abdomen & Pelvis	$350.00
Radiologist	74176.26	Radiologist	$110.00
	72192	CT PELVIS W/O DYE	$300.00
	72192.26	Radiologist	$100.00
Consultation with Nephrologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Nephrologist	$140.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
Consultation with Gastroenterologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Gastroenterologist	$140.00
	82274	OCCULT BLOOD, FECES	LabCorp
Proctologist	99242	Consultation with Proctologist	$160.00
	82274	OCCULT BLOOD, FECES	LabCorp
	43239	UPPER GI ENDOSCOPY, BIOPSY	$350.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	$350.00
Anesthesiologist			
Consultation with Toxicologist & Psychologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Toxicologist	$140.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	85025	COMPLETE CBC W/AUTO DIFF WBC	LabCorp
	84202	ASSAY RBC PROTOPORPHYRIN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Psychologist	96118	NEUROPSYCH TST BY PSYCH/PHYS	$100.00
Other Specialties	**Procedure Code**	**Description**	**Allowable Fee**
	71250	CT THORAX W/O DYE	$300.00
	71250.26	CT THORAX W/O DYE	$100.00
	71250	Repeat CT Scan of Chest	$300.00
	71250.26	Repeat CT Scan of Chest	$100.00
Pulmonologist	99242	Consultation with Pulmonologist	$140.00
Cardiologist	99242	Consultation with Cardiologist	$140.00
Cardiothoracic Surgeon	99242	Consultation with Cardiothoracic Surgeon	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
Anesthesiologist	00910	ANESTH, (3base @$70 + time)	$350.00
	99242	Consultation with Pulmonologist	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, (3base @$70 + time)	$350.00

All laboratory services will be performed by LabCorp with facilities in Bridgeport, Morgantown, and Fairmont. Test results must be directed to rendering provider and to CTI Administrators, Inc. in EDI format specified by LabCorp. As required by the settlement, test results must be provided to CTI (via EDI) from LabCorp.

Providers must submit bills via EDI in HIPAA required formats. CTI prefers to use Emdeon as a claim clearinghouse but other arrangements can be made. Provider payments will be weekly with all patients on one remittance. Additionally, HIPAA Privacy rules will apply.

Your clinic will be required to agree to the aforementioned terms in return for being identified as one of the exclusive providers selected for this Plan.

Sincerely,

Donald R. Brandt
President

Copy: Edgar C. Gentle, III, Esq.
Special Master

Paige Osborn

From: EscrowAgen@aol.com
Sent: Friday, October 07, 2011 8:09 AM
To: Paige Osborn
Subject: Fwd: FW: Perrine Medical Monitoring Plan
Attachments: 2007report.pdf; ProviderProtocol&fees.doc

From: dbrandt@claimtechnologies.com
To: Waggyc@UHCWV.org, EscrowAgen@aol.com
Sent: 10/6/2011 12:28:51 P.M. Central Daylight Time
Subj: FW: Perrine Medical Monitoring Plan

Ms. Waggy,

It was a pleasure talking with you regarding the Perrine Medical Monitoring Plan (the Plan). Attached you will find a letter that explains, in more detail, how the program will work as well as the allowable fees. I have also attached a copy of Dr. Werntz's report which outlines the medical protocols that have been adopted by the Circuit Court of Harrison County, West Virginia for the Plan.

Thank you, I will call you next week to see if you have any questions. You may contact me sooner if you desire.

Donald Brandt

President

Claim Technologies Inc.

100 Court Ave Suite 306

Des Moines, IA 50309

888-220-2445 x 233

515-244-8650 (fax)

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West Virginia University
SCHOOL OF MEDICINE

Anticipated health effects of the contamination of Spelter, WV and surrounding communities with arsenic, cadmium, and lead, and recommendations for medical monitoring.

March 30, 2007

The residents in the area around Spelter have been exposed to arsenic, cadmium, and lead an extended time. There are clear associations between arsenic, cadmium, and lead with significantly increased risks of developing disease, primarily cancers. IARC lists arsenic and cadmium in Group 1 (Carcinogenic to Humans). Lead is listed in Group 2A (Probably Carcinogenic to Humans). Additionally, there have been several studies documenting increased cancer risk around smelter sites[1,2,3,4] where similar exposures have occurred.

I have reviewed the Dr. Kornberg's initial report of November 11, 2005 as well as his rebuttal report of March 3, 2006. I concur with most of Dr. Kornberg's conclusions and recommendations, however I have several updates to both focus the exams to those conditions associated with the arsenic, cadmium and lead exposures as well as to update the science to reflect new technology available for medical monitoring.

DEFINITION OF GEOGRAPHICAL TERMS

Dr Brown, in his incremental cancer risk map, shows the residual contamination across the class area. There are three distinct areas within the class area, separate in their degree of contamination, and thus the risk to the residents in those areas.

- Zone 1 ≡ The area delineated by Dr. Brown as within the 5×10^{-4} incremental risk contour for developing cancer.
- Zone 2 ≡ The area between the 5×10^{-4} incremental risk contour and the 1×10^{-4} incremental risk contour.
- Zone 3 ≡ The area within the class area but outside the 1×10^{-4} cumulative incremental risk contour.

The residents in all areas have a significantly increased risk of developing disease based upon their residence and exposures in the area. The toxic and carcinogenic effects of all

---

[1] Brown LM, Pottern LM, Blot WJ. Lung Cancer in Relation to Environmental Pollutants Emitted from Industrial Sources. *Environmental Research* Vol 34, 256–261.

[2] Pershagen G. *Lung Cancer Mortality among Men Living near an Arsenic-Emitting Smelter*. American Journal of Epidemiology. Volume 122, Number 4. *Pp. 684–694*

[3] ATSDR Public Health Assessment for National Zinc Company in Bartlesville, OK. Viewable at http://www.atsdr.cdc.gov/HAC/PHA/zinc/nzc_p2.html#PUBLIC

[4] Tokudome S, Kuratsune M. A cohort study on mortality from cancer and other causes among workers at a metal refinery. Int J Cancer. 1976 Mar 15;17(2):310-7.

Department of Community Medicine
Institute of Occupational and Environmental Health

3566 Robert C. Byrd Health Sciences Center
PO Box 9190
Morgantown, WV 26506-9190

Phone: 304-293-3693
Fax: 304-293-2529

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three of these agents are cumulative and additive[5]. As such, the longer one is exposed, and the more different toxins, the greater the likelihood of developing disease.

Arsenic is associated with cancers of the skin, lung, bladder, kidney, and liver. Cadmium accumulates in the kidney and can cause renal damage and ultimately renal failure. Cadmium is also a carcinogen, associated with cancer of the lung and kidney. There is also some evidence suggesting cancer of the prostate. Lead is associated with cancers of the lung, brain, stomach, and kidney. Additionally, elevated blood lead causes cognitive and behavioral difficulties and is a disease in its own right.

In response to these facts, I propose the following medical monitoring program for the residents of the affected area.

Residency Time Requirement

- For residents within Zone 1, an accumulation of one year of residence shall be required for entry into medical monitoring.
- For residents in the Zone 2, the accumulation of three years of residence in the class area shall be required for entry into medical monitoring.
- For residents in the Zone 3, the accumulation of five years of residence in the class area shall be required for entry into medical monitoring.
- Once a resident has qualified for entry into medical monitoring based upon their residence in the area, they shall remain in medical monitoring for 40 years past the remediation of their residence.

BASIS FOR THE RESIDENCY TIME RECOMMENDATIONS

My goal is to ensure that residents with a significantly increased risk are offered medical monitoring. However, reasonableness demands establishing a threshold for the minimum residency requirement. I also believe that it is appropriate to be moderate at each decision point.

In his report, Dr. Kornberg did calculations to estimate risk using the difference between the measured soil Arsenic levels to calculate the incremental risk, and concluded that 277 days of exposure would be required to reach an "action level". This was adequate to demonstrate the presence of increased risk, however more precise calculations of risk are now available on Dr. Brown's map titled "Incremental Total Cancer Risk for All Pathways" (copy attached as Appendix A), and these are the basis of the minimum residency time requirements for entry into the medical monitoring program delineated here.

General logic:

Based solely upon the risk of skin cancer from arsenic exposure via ingestion, and lung cancer from arsenic and cadmium inhalation, Dr. Brown has calculated the total cancer risk from the exposures in the class area. Clearly there are multiple additional cancer risks for the exposed population from the arsenic, cadmium, and lead that are not

[5] EPA Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A), sections 8.2.2 and 8.3; viewable at http://www.epa.gov/oswer/riskassessment/ragsa/pdf/ch8.pdf

included in these calculations, which would only increase the calculated risk. Starting with the 30 year total risk from Dr Brown's model, I calculated the time duration that would expose a person to a 1:100,000 risk of developing these two cancers for each of the zones.

Calculations:
Using a simple proportion, with the goal of calculating the total risk then the proportion was solved for time (X)

$$\frac{\text{Total Risk}}{30 \text{ Years}} = \frac{\text{Significant Risk}}{X}$$

$$X \times \text{Total Risk} = 30 \text{ Years} \times \text{Significant Risk}$$

$$X = \frac{30 \text{ Years} \times \text{Significant Risk}}{\text{Total Risk}}$$

Zone 1 (Inner)

$$X = \frac{30 \text{ Years} \times 10^{-5}}{1 \times 10^{-3}} = \frac{30 \times 10^{-5} \text{ Years}}{1 \times 10^{-3}} = 0.3 \text{ Years} = 109.5 \text{ Days}$$

Zone 1 (Outer)

$$X = \frac{30 \text{ Years} \times 10^{-5}}{5 \times 10^{-4}} = \frac{30 \times 10^{-5} \text{ Years}}{5 \times 10^{-4}} = 0.6 \text{ Years} = 217 \text{ Days}$$

Zone 2

$$X = \frac{30 \text{ Years} \times 10^{-5}}{1 \times 10^{-4}} = \frac{30 \times 10^{-5} \text{ Years}}{1 \times 10^{-4}} = 3 \text{ Years}$$

Zone 3

$$X = \frac{30 \text{ Years} \times 10^{-5}}{7 \times 10^{-5}} = \frac{30 \times 10^{-5} \text{ Years}}{7 \times 10^{-5}} = 4.28 \text{ Years}$$

Notes and codicils about residency time:

1. The contours on the map indicate that the area within the contour is at or above the listed risk. Thus, while a few residents just inside the contour line may have the risk level equal to the listed contour, most of the residents within the contour are exposed to a higher risk than that portrayed by the contour.

2. The exposure at individual residences will end only with the remediation of the contamination in the residences. Thus residence time calculations will end with the remediation of each individual residence.
3. The waste piles were capped in 2004, thus residence time in any home whose construction or installation was begun in 2005 or later would be excluded from the time calculations for medical monitoring, due to the much lower likelihood of the presence of large quantities of contaminated dust within the residence (although soil exposure risk remains).

I believe that it is appropriate to include moderating measures at each point in setting the minimum residency time.

Moderating measures used in calculating residency time included:

1. Using 1:100,000 as the threshold for "significant risk", rather than 1:1,000,000, which is a more common threshold.
2. The model discussed by Dr. Brown includes only skin cancer risk from arsenic and lung cancer risk from arsenic and cadmium. There are significant additional cancer risks that are not considered in this calculation. Thus, the actual cancer risk would be greater if these additional risks were considered.
3. The residence time was rounded up to the next reasonable interval (i.e. full year).
4. No cancer risk for lead was considered in the model

Moderating measures in medical surveillance program:

1. Only diseases clearly associated with arsenic, cadmium, and lead are monitored for.
2. Testing is limited to diseases and medical tests clearly supported by the literature or general medical practice.

GENERAL PRINCLPLES:

Once the entry criteria has been satisfied, the monitoring program shall be the same for all medical monitoring group members, except for differences by member age mentioned below.

Medical monitoring shall be conducted every 2 years for members of the medical monitoring group once entry criteria are met. While this spacing could miss some rapidly developing diseases, it will catch most diseases, and will not significantly increase the risk to the patients from the testing.

Medical monitoring shall continue until 40 years past the end of exposure. Generally this would be either 40 years beyond moving out of the class area or 40 years after their residence is remediated. This is based on the usual latencies of the diseases of interest.

Any resident whose residency within the class area ended more than 40 years ago, and has not resided within the class area within the past 40 years, shall be excluded from the medical monitoring eligibility.

Remediation

The residents in this community have been exposed to arsenic, cadmium, and Lead from the Spelter smelter site through breathing plant emissions during operations, soil contamination, exposure to fugitive emissions from the waste piles, living in houses contaminated with dust from the plant, soil contamination around their residence, incidental soil and dust ingestion, and consumption of contaminated vegetables, and perhaps drinking water contaminated by emissions from the plant site.

While clearly not of the magnitude as during smelter operations, exposure to arsenic, cadmium, and lead is ongoing for residents in the community. Several interventions have been undertaken to limit exposure, including extinguishing the fires in the piles, limiting access to the waste piles, and the capping of the piles to limit fugitive emissions, and establishment of municipal water for the affected area. I would encourage that additional interventions be undertaken to decrease or eliminate the exposure through the remaining routes. This would include remediating the homes to remove contaminated dust from the living spaces as well as the dust reservoir areas within the home (attic, basement, etc.), and remediating the soil around the residences.

Diseases considered to be related to the exposures from Spelter site. (Unfortunately, medical monitoring is not possible for all diseases associated with these exposures)

Arsenic[6,7]
Skin Cancer
Lung Cancer
Bladder Cancer
Kidney Cancer

Cadmium[8]
Lung Cancer
Kidney Cancer
Decreased Renal Function[9]
Renal Failure
Bone Fragility

Lead[10,11]
Plumbism (Lead Poisoning) – Having elevated whole blood lead is a disease in itself, causing mental retardation, poor school performance, and behavioral problems. In

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[6] Ferreccio C, Sancha AM. Arsenic exposure and its impact on health in Chile. J Health Popul Nutr. 2006 Jun;24(2):164-75
[7] IARC Monograph on Cadmium, viewed at http://monographs.iarc.fr/ENG/Monographs/vol23/volume23.pdf
[8] IARC Monograph on Cadmium, viewed at http://monographs.iarc.fr/ENG/Monographs/vol58/volume58.pdf
[9] NIOSH Worker Notification Program; Cadmium Recovery Workers (Cadmium); Viewed at http://www.cdc.gov/niosh/pgms/worknotify/cadmium.html#estimated
[10] IARC Monograph on Lead, viewed at http://monographs.iarc.fr/ENG/Monographs/vol23/volume23.pdf
[11] IARC Monograph on Lead, viewed at http://monographs.iarc.fr/ENG/Monographs/vol87/volume87.pdf

children, there is clear evidence of this effect at levels well below the CDC action level of 10 µg/dl.

Lung Cancer
Stomach Cancer[12]
Kidney Cancer
Decreased Renal Function[13]
Renal Failure[13]
Bone Fragility
Loss of teeth
Hypertension
Increased rates of criminal activity[14,15]

There are several additional cancers that have been proposed as due to lead exposure, but for which I do not yet find the literature compelling. At the present I would not recommend screening for these diseases, but I would recommend a review of the literature in several years to consider these conditions.

Brain Cancer
Stomach Cancer
Rectal Cancer
Prostate Cancer
Colon Cancer

General flow for each surveillance exam:

1. Laboratory (Blood and Urine) and Chest CT obtained
2. Await results from studies (likely < 2 weeks)
3. Brief history, physical examination, and review of the results by a Physician
    a. Referral to specialist for positive findings in diseases associated with the exposures (paid for by screening program)
    b. Referral to PCP for findings not associated with the exposures

The screening examination will be the same for all participants, except

- Start screening chest CT scans at age 35 (none below age 35)
- No CT scans of anyone who is pregnant or possibly pregnant. Urine pregnancy test for females age 35-55 prior to scan unless surgical sterilization.
- Below age 15, screen ONLY whole blood lead (capillary or veinous)

---

[12] Steenland K, Boffetta P. Lead and cancer in humans: where are we now? Am J Ind Med. 2000 Sep;38(3):295-9.
[13] Ekong EB, Jaar BG, Weaver VM. Lead-related nephrotoxicity: a review of the epidemiologic evidence. Kidney Int. 2006 Dec;70(12):2074-84. Epub 2006 Oct 25
[14] Needleman HL, McFarland C, Ness RB, Fienberg SE, Tobin MJ. Bone lead levels in adjudicated delinquents. A case control study. Neurotoxicol Teratol. 2002 Nov-Dec;24(6):711-7
[15] Stretesky PB, Lynch MJ. The relationship between lead exposure and homicide. Arch Pediatr Adolesc Med. 2001 May;155(5):579-82.

General Screening Examination:

- Single Breath Hold High Resolution Low Dose CT scan of the Chest[16] (>= age 35)
- Urine Collection for:
  a. Urinalysis (Dip)
  b. Urine Rapid Pregnancy (Females age 35 – 55, unless surgical sterilization)
  c. Urine Cytology
  d. Urine Beta-2-microglobulin
- Blood collection for:
  a. Creatinine
  b. BUN (Blood Urea Nitrogen)
  c. Calculated glomerular filtration rate (GFR)
  d. Whole Blood Lead
- Stool Blood (Hemoccult)
  a. Dispense Hemoccult cards at time of blood/urine collection
  b. Patient to return cards at physician exam
- Physician examination/interaction
  a. Record vital signs, including Blood Pressure
  b. Skin examination (head to toe, for skin cancer)
  c. HEENT exam, focus on dentition and mucosa
  d. Peripheral motor function (wrist & ankle extensors)
  e. Develop and review Hemoccult cards
  f. Review results of blood and urine screening
  g. Review CT scan results
  h. Order re-testing or make referrals based upon findings

Urinary System (Kidney & Bladder)

Screening exam:

- Urinalysis (dip stick)
- Urine Cytology
- Urine Beta-2 microglobulin
- BUN and Creatinine
- Calculated Glomerular Filtration Rate

Follow-up examination (Blood on UA or positive cytology)

- Consultation with Urologist (2 office visits)
- Repeat Urinalysis
- Cystoscopy with biopsy
- CT scan of Abdomen

Follow-up examination (Beta-2 microglobulin or BUN/Creatinine elevated)

- Consultation with a nephrologists (2 office visits)
- Repeat Urinalysis

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16 Bach PB, Jett JR, Pastorino U, Tockman MS, Swensen SJ, Begg CB. Computed tomography screening and lung cancer outcomes. JAMA. 2007 Mar 7;297(9):953-61.

- Repeat BUN/Creatinine
- Labwork to look for other causes of kidney failure
  - Blood Glucose
  - ESR

Lungs

Medical Surveillance Examination (For persons >= age 35); Perform every 2 years

- Single-breath-hold, high-resolution, low-exposure, CT scan of the chest

First Cycle Positives

- Repeat same CT scan several months later
- Consultation with ordering physician to review changes over time and refer as appropriate

Subsequent Cycle Positives

- Consultation with a pulmonologist (2-3 office visits)
- Repeat CT scan several Months later
- Lung Biopsy
  - By Cardiothoracic surgeon or
  - Pulmonologist, depending upon the location of the lesion within the lungs

Plumbism (Lead Poisoning)

Screening Examination

- Whole Blood Lead
  - Medical Action Level (above which additional investigation is needed):
    - Children (<18 Years Old): 10 µg/dl
    - Adults (>18 years old): 30 µg/dl
  - Neuropsychiatric Action Level (above which neuropsychiatric evaluation is needed):
    - Children (<18 Years Old): 5 µg/dl
    - Adults (>18 years old): 20 µg/dl

  Note: Repeat neuropsychiatric evaluation is not needed unless >25% increase in measured whole blood lead

Medical Follow-up examination

- Consultation with medical toxicologist/Environmental Medicine Specialist (4 office visits)
- Repeat whole blood lead (veinous) (Children 15%, Adults 15%)
  - If elevated, refer for evaluation and possible treatment
- Zinc Protoporphyrin
- Complete Blood Count
- Bone x-ray fluorescence testing to assess body burden

Neuropsychiatric follow-up

- Formal neuropsychiatric evaluation

Skin

Screening Examination

- Head-to-toe examination of the skin by the screening physician as part of the physical examination.

Follow-up examination

- Consultation with Dermatologist (1-2 visits)
- Biopsy by dermatologist if indicated

GI system (stomach, intestines, rectum)

Screening Examination

- Stool Hemoccult, cards distributed at blood/urine collection, developed at physician follow examination
- Follow-up examination
  - Refer to PCP for evaluation for colon disease
  - IF negative colon disease workup, then re-enter screening program to look for stomach cancer
    - Refer to Gastroenterologist for stomach evaluation
    - EGD (Endoscopic Gastroduodenoscopy)

Overall medical surveillance assumptions:

- Participation in the entire program is voluntary, and that a participant can choose to participate or discontinue participation at any time.
- That there will be one (or a small number) of physicians from the community supervising the medical monitoring program and performing the physical examinations. This is to ensure that the physician is familiar with the program, the diagnosis of the diseases of concern, and to ensure consistency.
- For the first cycle, the patients must have pre-testing access to a knowledgeable clinician (physician or nurse) be discuss the risks and benefits of the proposed testing
- That medical testing without physician interpretation of the results is inappropriate for the well being of the participant
- That the ideal is for a physician visit for results interpretation (and physical examination) following testing
- That without the physician examination, key portions of the evaluation will be missed, and that the physical examination is critical to identifying some of the diseases of concern.
- That any participant who fails to participate in the post-testing physician evaluation will receive a letter communicating their test results, and any recommendations for follow-up.
- In all cases, the evaluating physician shall have the freedom to repeat any test if there is evidence of a lab error or if no other clinical evidence is found to support the diagnosis suggested by the test result.
- If a patient has had any of the recommended tests within the past 6 months, and the written results these can be provided, those tests will not be repeated, and the patient-provided results used for the screening program.

- That following diagnosis with a disease of interest, the screening for that disease will cease, but other screenings will/could continue
- That some test results can be caused by multiple diseases. The interpreting physician will be charged with figuring these cases out.
- Despite targeted testing, it is possible conditions will be detected by the testing that are not related to the exposure. When that happens, the participant will be referred to their Primary Care Physician for follow-up and treatment.
- Workup of positive test results will continue until the determination of exposure-related or non-exposure-related can be made
- As soon as a non-exposure-related condition is identified, the patient will be referred to their PCP. The screening for the disease of interest will continue unmodified. This referral will occur each screening cycle. The patient can decline the referral if they deem it unnecessary.
- A patient with an abnormal finding related to the exposures will be referred to the appropriate specialist with each screening cycle. The patient can decline the referral if they deem it unnecessary.
- That a central repository of the screening, referrals, and outcomes data will be maintained, and depersonalized data made available for epidemiological evaluations. It is clear from my literature review in preparing this document that there is incomplete scientific evidence in the literature on screening programs, participation rates, referral rates, etc. This data could serve as the basis for answering many of these scientific questions.
- The screening program described here is based upon the best available medical knowledge in 2007. While I would not propose changing the diseases being monitored for, it is likely that in the future new technology or better understandings within medicine will require the updating of this protocol. This protocol should be reviewed periodically by the administering physician to ensure that the screenings and follow-up described here remain consistent with best medical practice.

Commentary on the differences between Dr. Komberg's proposal and this recommendation.

Overall, I concur with Dr. Komberg's assessment of the nature of the exposure as well as the diseases of concern associated with these exposures. My opinion differs from his only in the details.

1) The only disease caused by all three of the exposures is lung cancer. Dr Komberg recommended screening for lung cancer using chest x-rays. Unfortunately, by the time most lung cancers are large enough to be detected by chest x-ray they are incurable. Over the past several years there have been promising results from the use of low dose CT scans to screen for early lung cancers. This technology allows for the identification of much smaller tumors and the 3-D imaging makes it much easier to differentiate cancers from other lung lesions.

2) Some of the testing proposed by Dr Komberg was aimed at biomonitoring (monitoring levels in blood, urine, or hair) to assess for the presence of the Arsenic, Lead, and Cadmium. I fully support monitoring whole blood lead since an elevated blood Lead is a disease in its own right. However, for arsenic and cadmium I do not believe biomonitoring would be useful clinically. There are two reasons.

   a. First, at this point the exposures are lower level chronic exposures, and the available biomonitoring tests are designed to monitor acute exposures, such as monitoring pre- and post-shift urinary cadmium for cadmium workers to assess the efficacy of employer control measures.
   b. The second reason is that the presence of the exposures has been established, and there could be a false sense of security (or even confusion) generated by low values on the biomonitoring tests. The risks of disease persist, whatever biomonitoring levels are found.

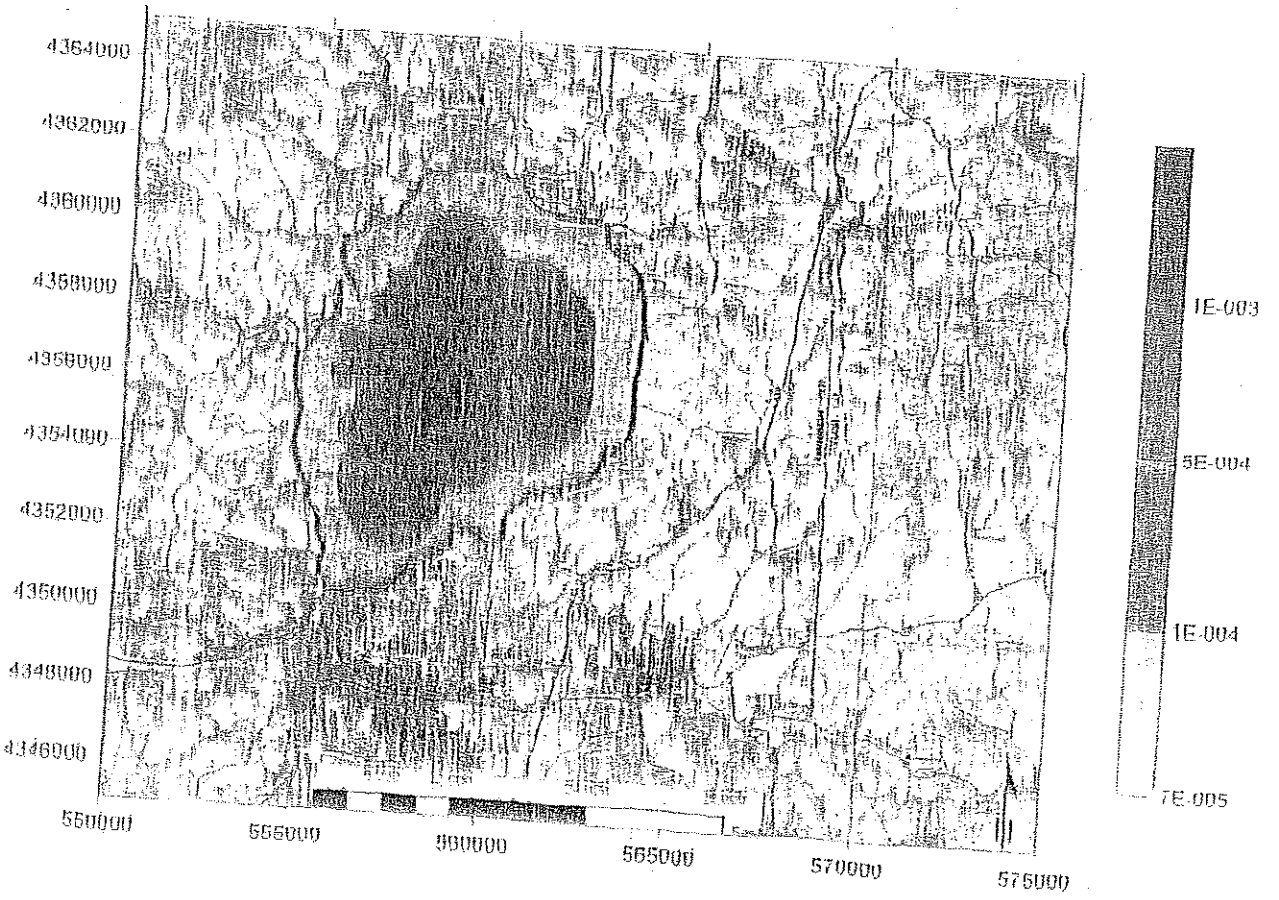
3) Dr Komberg seemed to be offering options for the evaluating physician to add or subtract tests from the screening examination. To actually make this work, it would be necessary to have two visits with the physician, which would clearly add to the complexity of implementing the program. Efficiently looking for the diseases of interest is the key, but making the screening program practical to implement is also quite important. Thus, for the "general screening examination" my goal is to establish criteria that are very easy to implement (such as age) as the only differentiating factor for what tests each patient needs. A standardized testing regimen will allow the ordering of the tests to be handled by an administrative person, and allow the physician to focus on the interpretation of the tests and examining the patients. I would concur with Dr Komberg's recommendation that current (< 6 months old) test results could be used in place of repeating the test.

4) There were several aspects of the screening examination proposed by Dr Komberg that are good general medical surveillance, but not directly related to long term exposure to arsenic, cadmium, or lead. I have tried to focus the examination and eliminate these tests. For example, he includes an electrocardiogram (ECG), however, I am not able to directly associate ECG changes with the arsenic, cadmium, or lead at the levels likely to be found in this population.

In Summary, it is my recommendation that on the basis of their exposures in Spelter and the remaining class area that there is a significantly increased risk of developing disease, and that medical monitoring is necessary to look for these diseases.

Charles L. Wernz III, D.O., MPH, FACOEM
Assistant Clinical Professor
Associate Residency Director
Institute for Occupational and Environmental Health
Department of Community Medicine
West Virginia University School of Medicine

Incremental Total Cancer Risk for All Pathways



West Virginia University
SCHOOL OF MEDICINE

Proposed Medical Monitoring due to the contamination of Spelter, WV and surrounding communities with arsenic, cadmium, and lead.

Including estimations of participation rates and testing outcomes for economic purposes

March 30, 2007

A medical monitoring program has been prescribed for Spelter and the surrounding community (the class area) due to the contamination of the area with arsenic, cadmium, and lead, and the significantly increased risk of developing disease due to these exposures.

For the purposes of costing of this program, estimates are needed for the participation rates and the likely outcomes of the testing. This document is prepared for that purpose. The details of the monitoring program are the same as those contained in my main report, only quantification has been added for the various decision points within the surveillance program.

All of the details contained in this document are estimates, they are not evidence based, nor are they based upon prior experience in this sort of a program. I am not able to locate literature on these topics in the medical literature. On the basis of my best professional judgment I am offering anticipated participation and outcome estimates. *These estimates will be in italics and underlined.*

To facilitate the costing of this program, Appendix A shows the cost for the listed tests and medical procedures at West Virginia University Hospitals and University Health Associates, prepared by Melissa Mitchell, a certified professional coder in my office.

The monitoring program shall be the same for all participants, except:

- Chest CT scans only for participants with age greater than or equal to 35 (none below age 35)
- No CT scans of anyone who is pregnant or possibly pregnant. Urine Pregnancy test for potentially pregnant females 35-55 years old unless surgical sterility prior to scan.
- Below age 15, screen ONLY whole blood lead (capillary or veinous), and the physician visit

Department of Community Medicine
Institute of Occupational and Environmental Health

3860 Robert C. Byrd Health Sciences Center
PO Box 9190
Morgantown, WV 26506-9190

Phone: 304-293-3693
Fax: 304-293-2629

Equal Opportunity/Affirmative Action Institution

General Estimates (evidence-based estimates welcome):

- *75% of eligible population will participate in initial screening. Of those:*
  - *85% will complete the testing and attend the physician visit*
  - *15% will not complete the testing and/or appear for the physician visit, and will require a letter reviewing their findings*
- *75% of those initially screened will appear for the second screening*
- *Thereafter (after the first two cycles of screening), there will be a 5% attrition rate each screening cycle*
- *5% of all blood and urine tests will need to be repeated due to suspicion of lab error or equivocal results*
- *2% of each test (except lead) in the initial screening battery will be unneeded due to the patient having had the same test within the past 6 months and being able to provide written results. 0% of the "follow-up" tests will not be needed for this reason.*

Medical Surveillance Program:

General flow for each surveillance exam:

1. Laboratory (Blood and Urine) and Chest CT obtained
2. Await results from studies (likely < 2 weeks)
3. Brief history, physical examination, and review of the results by a Physician
   a. Referral to specialist for positive findings in diseases associated with the exposures (paid for by screening program)
   b. Referral to PCP for findings not associated with the exposures

General Screening Examination:

- Single Breath Hold High Resolution Low Dose CT scan of the Chest (>= age 35)
- Urine Collection for:
  a. Urinalysis (Dip)
  b. Urine Rapid Pregnancy (Females age 35 – 55, unless surgical sterilization)
  c. Urine Cytology
  d. Urine Beta-2-microglobulin
- Blood collection for:
  a. Creatinine
  b. BUN (Blood Urea Nitrogen)
  c. Whole Blood Lead
- Stool Blood (Hemoccult)
  a. Dispense Hemoccult cards at time of blood/urine collection
  b. Patient to return cards at physician exam
- Physician examination/interaction (Level 5 for adults, Level 4 for children < 15)
  a. Record vital signs, including Blood Pressure
  b. Skin examination (head to toe, for skin cancer)*
  c. HEENT exam, focus on dentition and mucosa
  d. Peripheral motor function (wrist & ankle extensors)
  e. Develop and review Hemoccult cards*

f. Review results of blood and urine* screening
g. Review CT scan results*
h. Order re-testing or make referrals based upon findings
* = Omit for children < 15 years old

Urinary System (Kidney & Bladder)

Screening exam:

- Urinalysis (dip stick)
  - *10% Positives overall*
    - *Blood 2% (Target disease – Needs follow-up with urologist)*
    - *Glucose 5% (Not target disease)*
    - *Infection 3% (Not target disease)*
- Urine Cytology
  - *1% Positive (Target disease – Needs follow-up with urologist)*
- Urine Beta-2 microglobulin
  - *5% Positive*
    - *2% (Target disease – Needs follow-up with nephrologist)*
    - *3% other known causes of kidney disease (i.e. diabetes)*
- BUN and Creatinine
  - *5% Positive*
    - *2% (Target disease – Needs follow-up with nephrologist)*
    - *3% other known causes of kidney disease (i.e. diabetes)*

Follow-up examination (Blood or Cytology positive)

- Consultation with Urologist (2 office visits)
- Repeat Urinalysis
- Cystoscopy with biopsy (Hospital and Professional Charge)
- CT scan of Abdomen (Hospital and Professional Charge)

Follow-up examination (Beta-2 microglobulin or BUN/Creatinine positive)

- Consultation with a nephrologists (2 office visits)
- Repeat Urinalysis
- Repeat BUN/Creatinine
- Labwork to look for other causes of kidney failure
  - Blood Glucose
  - ESR

Final Outcome

- *40%* go on to treatment
- *60%* return for next screening (diseases of interest not found)

Lungs

Medical Surveillance Examination (For persons >= age 35); Perform every 2 years

- Single-breath-hold, high-resolution, low-exposure, CT scan of the chest (Hospital and Professional Charge)

First Cycle

- *30-50% will have a positive initial examination (per Harvard data), thus estimate 40% positives in our population*
  - Repeat same CT scan several months later (Hospital and Professional Charge)
  - Consultation with supervising physician to review changes over time and refer as appropriate

5% positives in all cycles

- Consultation with a pulmonologist (2-3 office visits)
- Repeat CT scan several Months later (Hospital and Professional Charge)
- *25% of repeat CT scans positive*
  - *Refer to Pulmonologist*
    - Watch and repeat CT Scan *(50%)*
    - Decision to get Lung Biopsy *(50%)*
      - If Biopsy – specialist depends upon location of lesion
        - *35%* - Cardiothoracic surgeon
          - Office Visit
          - Biopsy
            - Hospital Charge
            - Professional Charge
            - Anesthesia Charge
            - Pathologist Charge
        - Pulmonologist *(65%)*, depending upon the location of the lesion within the lungs
          - Biopsy
            - Hospital Charge
            - Professional Charge
            - Pathologist Charge

Final Outcome

- *25%* go on to treatment
- *75%* return for next screening (diseases of interest not found)

Plumbism (Lead Poisoning)

Screening Examination

- Whole Blood Lead

  Medical Action Level (above which additional investigation is needed):
  - Children (<18 Years Old): 10 µg/dl *(10% of tested)*
  - Adults (>18 years old): 30 µg/dl *(2% of tested)*

  Neuropsychiatric Action Level (above which neuropsychiatric evaluation is needed):
  - Children (<18 Years Old): 5 µg/dl *(20% of tested)*
  - Adults (>18 years old): 20 µg/dl *(5% of tested)*

  Note: Repeat neuropsychiatric evaluation is not needed unless >25% increase in measured whole blood lead *(Estimate this will mean that 75% of patients will NOT need re-evaluation with each cycle.)*

Medical Follow-up examination

- Consultation with medical toxicologist/Environmental Medicine Specialist (4 office visits)
- Repeat whole blood lead (veinous) *(Children 15% Adults 15%)*
  - If elevated, refer for evaluation and possible treatment
- Zinc Protoporphyrin (lab)
- Complete Blood Count (Lab)
- Bone x-ray fluorescence testing to assess body burden (Hospital and Professional Charge, Travel (Pittsburgh for Children, New York City for Adults))

Neuropsychiatric follow-up

- Formal neuropsychiatric evaluation

Final Outcome

- Treatment does NOT preclude re-exposure or need for re-treatment
- *100%* return for next screening (diseases of interest not found)

Skin

Screening Examination

- Head-to-toe skin examination *Estimate 5% Positives from physician examination*

Follow-up Examination

- Refer to Dermatologist for evaluation
  - Office Visit – Level 5 initial
  - *50% Biopsy by dermatologist*
    - Procedure code
    - Supplies
    - Pathology
    - Follow-up visit with dermatologist (level 3 return)

Final Outcome

- *5%* go on to treatment
- *95%* return for next screening (diseases of interest not found, or treated)

GI system (stomach, intestines, rectum)
Screening Examination

- Stool Hemoccult, cards distributed at blood/urine collection, developed at physician follow examination *Estimate 5% Positive hemoccult*
  Note: Most likely cause is colon disease, not a target disease
- Follow-up examination
  - Refer to PCP for evaluation for colon disease – *85% find colon disease (NOT target Disease)*
  - *15% will have negative colon disease workup* (and re-enter screening program to look for stomach cancer)
    - Refer to Gastroenterologist for stomach evaluation
    - EGD with biopsy
      - Procedure code
      - Supplies
      - Pathology

Final Outcome

- *25%* go on to treatment
- *75%* return for next screening (diseases of interest not found)

In Summary, the above is my prescription for the medical monitoring program for the community surrounding Spelter, along with estimates of participation and outcome rates based upon my professional judgment.

Charles L. Werntz III, D.O., MPH, FACOEM
Assistant Clinical Professor
Associate Residency Director
Institute for Occupational and Environmental Health
Department of Community Medicine
West Virginia University School of Medicine

MEDICAL MONITORING ECONOMICS – APPENDIX A

DESCRIPTION	CPT CODE	PROF CHARGE	HOSPITAL CHARGE	PATH CHARGE (pro)	PATH CHARGE (tech)	CYTO TECH	PHARMACY	ANESTHESIA
							*** For the anesthesia medicine, rate is $6.59/minute. This varies by procedure.	
CT Scan of Chest:								
w/o contrast	71250	$ 159.00	$ 1,030.50					
w/contrast	71260	$ 170.00	$ 1,158.00					
w/o contrast followed by w/contrast	71270	$ 189.00	$ 1,418.00					
CT scan of Abdomen:								
w/contrast	74160	$ 175.00	$ 1,011.50					
w/o contrast	74150	$ 163.00	$ 694.00					
w/o contrast followed by w/contrast	74170	$ 192.00	$ 1,156.50					
CT scan of Pelvis:								
w/contrast	72192	$ 150.00	$ 1,011.50					
w/o contrast	72193	$ 159.00	$ 694.00					
w/o contrast followed by w/contrast	72194	$ 167.00	$ 1,156.50					
Urinalysis:								
Dip	81002	$ 14.00						
Rapid Pregnancy	81025	$ 25.00						
Cytology	88108			$ 118.00	$ 93.00			
Beta -2 microglobulin	82043	$ 31.00						
Blood Collection:								
Venipuncture	36415	$ 15.00						
Creatinine	82565		$ 8.00					
BUN (Blood Urea Nitrogen)	84520							
Whole Blood Lead	83655		$ 13.00					
Blood Glucose	82947		$ 8.00					
ESR - erythrocyte sedimentation rate	85651							
Zinc Protoporphyrin	84202		$ 21.00					
CBC -complete blood count	85027		$ 10.00					
Stool Blood (Hemoccult)	82270	$ 15.00	$ 10.00					
Physicals - New Patients: (All specialities)								
<1 yr	99381	$ 151.00						
1-4 yrs	99382	$ 162.00						
5-11 yrs	99383	$ 169.00						

12-17 yrs	99384	$ 173.00						
18-39 yrs	99385	$ 173.00						
40-64 yrs	99386	$ 204.00						
>65 yrs	99387	$ 221.00						
Consult w/ Urologist	99245	$ 325.00						
Cystoscopy w/Biopsy	52354	$ 1,567.00	$ 8,500.00	$ 100.00	$ 151.00		Est 45 Minutes $261.55	00800 - $80/15 minutes
Consult w/Nephrologist	99245	$ 325.00						
Cardiothoracic Surgeon:							Estimate 1.5 hours	
Office Visit	99245	$ 325.00						
Lung Biopsy	32400	$ 999.00	$ 3,300.00	$ 183.00	$ 139.00	$ 139.50	$ 603.10	00522 - $80/15 minutes/Average $1,700.00
(Hospital charges for all if done as outpatient)	32402	$ 1,374.00	$ 3,300.00		$ 100.00	$ 151.00	$ 603.10	00522 - $80/15 minutes/Average $1,700.00
	32405	$ 271.00	$ 3,300.00				$ 603.10	00522 - $80/15 minutes/Average $1,700.00
	32602	$ 935.00	$ 3,300.00	$ 300.00	$ 266.50		$ 603.10	00522 - $80/15 minutes/Average $1,700.00
Pulmonologist:								
Office Visit	99245	$ 325.00						
Lung Biopsy	31625	$ 937.00	$ 725.00	$ 100.00	$ 151.00			
Neuropsychiatric Evaluation	96118	$223/hr	Est 3 Hours = $669 // $1,011 total					
	96119	$114/hr	Est 3 Hours = $342 //					
Consult w/Medical Toxicologist or Environmental Medicine Specialist	99245	$ 325.00						
Consult w/Dermatologist:	99245	$ 325.00						
Biopsy	11100	$ 209.00	$ 1,500.00 *	$ 100.00	$ 151.00			* 00400 - $80/15 minutes (Est 30 Min * $160)
EGD	43239	$ 734.00	$ 1,200.00	$ 100.00	$ 151.00		Est 15 Minutes $83.85	00740 - $80/15 minutes
Bone x-ray - Fluorescence Testing		Not performed at WVU - Will need price from Columbia University in New York						

NOTES:

1. All prices reported here are current charges as of 3/29/2007 at West Virginia University Hospitals, Inc and WVU Medical Corporation, Inc.
2. For procedures: the prices shown are the average, with overall estimates (per Dr Wentz in *underlined italics*) in parentheses
3. Normally skin biopsy is an outpatient procedure. A few ill patients may require a hospital biopsy *(estimate 3%) (Hosp Charge and Anes Charge)*

The Perrine Medical Monitoring Plan
Product of the Perrine DuPont Settlement

October 6, 2011

Ms. Cathy Waggy
Shinnston Healthcare
686 S Pike St
Shinnston WV 26431
WaggyC@uhcwv.org

RE: Perrine Medical Monitoring Plan, *Product of the Perrine DuPont Settlement*

Dear Ms. Waggy:

Thank you for taking the time to talk with me regarding the Perrine Medical Monitoring Plan (the Plan). We are pleased that you have agreed to participate as a provider of medical services for the Plan. As I explained to you, CTI Administrators, Inc. has been authorized to contract with a limited number of medical providers in and around Spelter, West Virginia to provide medical testing for participants in the Plan. The Plan will serve approximately 4,000 individuals residing in the vicinity of Spelter. As approved by the Circuit Court of Harrison County, the Plan is expected to provide testing for the participants over the next 30 years.

Testing protocols for the medical monitoring Plan were recommended by Charles L. Werntz III, D.O., MPH in his enclosed report of March 30, 2007. Dr. Werntz's recommendations were subsequently approved by the court and need to be followed by the participating providers with one exception relating to the use of CT Scans. The recommended protocol for the use of CT Scans is still being reviewed and remains unresolved at this time.

Following is an outline of the complete set of protocols (including the use of CT scans) as recommended by Dr. Werntz. The outline also includes allowable fees. Again, please keep in mind that the recommended use of CT Scans is still unresolved at this time.

Two biennial testing protocols have been adopted for the Plan based upon the age of the participant:

- Adult Testing for participants ages 18 and above;
- Child testing for under age 18 participants.

Both protocols assume that there will be an initial set of tests followed by a consultation with the physician. The initial tests will be a urinalysis for all participants over age 15, blood tests for all participants, and stool samples for all participants age 18 and above. Tests will be taken on a biennial basis. The Plan has contracted with LabCorp to perform all necessary laboratory tests.

The consultation to review the test results and physical examination may also include an explanation to the patients of the pros and cons of CT Scans.

Depending on the test results, retests may be required and/or referrals made to specialists including:

- **Urologist**, for consultations and Cytopathology for patients testing positive to Urinary system tests;
- **Dermatologist**, for skin tests for some patients testing positive to Urinary system tests;
- **Gastroenterologist and/or Proctologist**, for consultations, additional stool sample tests, and upper GI endoscopy; and/or
- a **Medical Toxicologist,** for consultations and complete blood count, lead and zinc tests.

Subsequent referrals may then be sent to a Psychologist, Radiologist, Pulmonologist, and/or Anesthesiologist. We will need to contract with these specialists and welcome your personal referral of physicians in these specialties. I have included a form for your recommendations of medical specialists with this letter. Please complete and return to CTI Administrators, Attention Donald Brandt, 100 Court Avenue Suite 306, Des Moines IA 50309 or via fax @ 515 244-8650.

All participants must use participating providers who have contracted with the Plan. The Plan will pay for benefits at the allowable fees shown in the enclosed table of Anticipated Procedures and Allowable Fees. Keep in mind that there are no deductibles, co-payments, or coinsurance to be paid by the participants. Since the Plan will pay at 100% of Allowable Fees, providers will not need to balance bill the patients nor collect co-payments at the time of service.

The Anticipated Procedures and Allowable Fees are shown in the following table:

Anticipated Procedures and Allowable Fees			
Initial Testing	**Procedure Code**	**Description**	**Allowable Fee**
Primary Care Physician	99201	10 Minute OFFICE VISIT OP NEW	$60.00
	99211	5 Minute OFFICE VISIT OP ESTABLISHED	$32.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	82274	OCCULT BLOOD, FECES	LabCorp
	82232	ASSAY OF BETA-2 PROTEIN	LabCorp
	82565	ASSAY OF CREATININE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Follow-up Consultation	**Procedure Code**	**Description**	**Allowable Fee**
Primary Care Physician	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$135.00
	99243	40 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$170.00
Skin Test with Dermatologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Dermatologist	$140.00
	11100	BIOPSY, SKIN LESION	$110.00
	88304	TISSUE EXAM BY PATHOLOGIST	LabCorp
Consultation with Urologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Urologist	$140.00
	88112	CYTOPATH, CELL ENHANCE TECH	LabCorp
	52000	CYSTOSCOPY	$250.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	OP Facility	Out Patient Facility Charge	$850.00
Anesthesiologist	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	$350.00
	74176	CT Scan Abdomen & Pelvis	$350.00
Radiologist	74176.26	Radiologist	$110.00
	72192	CT PELVIS W/O DYE	$300.00
	72192.26	Radiologist	$100.00

Consultation with Nephrologist	Procedure Code	Description	Allowable Fee
	99242	Consultation with Nephrologist	$140.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
Consultation with Gastroenterologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Gastroenterologist	$140.00
	82274	OCCULT BLOOD, FECES	LabCorp
Proctologist	99242	Consultation with Proctologist	$160.00
	82274	OCCULT BLOOD, FECES	LabCorp
	43239	UPPER GI ENDOSCOPY, BIOPSY	$350.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, BLADDER SURGERY (3base @$70 +	$350.00
Anesthesiologist		time)	
Consultation with Toxicologist & Psychologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Toxicologist	$140.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	85025	COMPLETE CBC W/AUTO DIFF WBC	LabCorp
	84202	ASSAY RBC PROTOPORPHYRIN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Psychologist	96118	NEUROPSYCH TST BY PSYCH/PHYS	$100.00
Other Specialties	**Procedure Code**	**Description**	**Allowable Fee**
	71250	CT THORAX W/O DYE	$300.00
	71250.26	CT THORAX W/O DYE	$100.00
	71250	Repeat CT Scan of Chest	$300.00
	71250.26	Repeat CT Scan of Chest	$100.00
Pulmonologist	99242	Consultation with Pulmonologist	$140.00
Cardiologist	99242	Consultation with Cardiologist	$140.00
General Surgeon	99242	Consultation with General Surgeon	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
Anesthesiologist	00910	ANESTH, (3base @$70 + time)	$350.00
	99242	Consultation with Pulmonologist	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, (3base @$70 + time)	$350.00

All laboratory services will be performed by LabCorp with facilities in Bridgeport, Morgantown, and Fairmont. Test results will be directed to rendering provider and to CTI Administrators, Inc. in EDI format specified by LabCorp. LabCorp is committed to industry standards for data transmission and is implementing the HL7 standard for interfaces with providers at this time. As required by the settlement, test results must be provided to CTI (via EDI) from LabCorp.

Providers must submit bills to CTI Administrators via EDI in HIPAA required formats. CTI prefers to use Emdeon as a claim clearinghouse but other arrangements can be made. Provider payments will be weekly with all patients on one remittance. Additionally, HIPAA Privacy rules will be followed by CTI Administrators.

CTI Administrators will work with your office to help schedule appointments for testing. We anticipate sending information to the participants regarding participating clinics and scheduling information in mid-November. We will develop computer driven letters to facilitate the scheduling process and will work with you to make sure that your policies and procedures are articulated correctly. We expect testing to begin in January 2012. Accordingly, we would like to execute Exclusive Provider Agreements by November 1st.

Your clinic will be required to agree to the aforementioned terms in return for being identified as one of the exclusive providers selected for the Plan. I will call you in several days to discuss the Plan's expectations and any concerns you may have. In the meantime, please complete the enclosed form for recommendations of specialty providers as well as facilities that can perform CT Scans in your local area. Thank you for your assistance and support for the Perrine Medical Monitoring Plan.

Sincerely,

Donald R. Brandt
President

Enclosures: Dr. Werntz's Report (as a separate attachment)
Recommendations of Specialist Form

Copy: Edgar C. Gentle, III, Esq.
Special Master, the Perrine Medical Monitoring Plan

The Perrine Medical Monitoring Plan
Product of the Perrine DuPont Settlement

Recommendations of Specialist needed by Perrine Medical Monitoring Plan

Specialty Needed	Name of Specialist	Specialist affiliated with your clinic?	Address of Specialist if not affiliated with your clinic	Phone Number of Specialist
Urologist		☐Yes ☐No		
Dermatologist		☐Yes ☐No		
Nephrologist		☐Yes ☐No		
Gastroenterologist		☐Yes ☐No		
Proctologist		☐Yes ☐No		
Medical Toxicologist		☐Yes ☐No		
Psychologist		☐Yes ☐No		
Anesthesiologist For Cystoscopy		☐Yes ☐No		
Facility to Perform CT Scans		☐Yes ☐No		
Radiologist to Evaluate CT Scans		☐Yes ☐No		
Cardiologist		☐Yes ☐No		
Pulmonologist		☐Yes ☐No		
General Surgeon for Lung Biopsy		☐Yes ☐No		

Paige Osborn

From: EscrowAgen@aol.com
Sent: Friday, October 07, 2011 8:08 AM
To: Paige Osborn
Subject: Fwd: Perrine v. DuPont Settlement - Draft Participating Provider Agreement; C...
Attachments: DraftParticipatingProviderAgreement10-4-11.pdf

From: ddebrosse@gtandslaw.com
To: escrowagen@aol.com, VBuchanan@levinlaw.com, sdthacker@agmtlaw.com
CC: tturner@gtandslaw.com, kharbison@gtandslaw.com, posborn@gtandslaw.com, mjacks@gtandslaw.com, wcox@lfwlaw.com, jkg@cochranfirm.com, mflowers@cochranfirm.com, farresttaylor@cochranfirm.com, NMcWilliams@levinlaw.com, pbjones@westandjones.com, angelamason@cochranfirm.com, mhmccarthy@citynet.net, leesgov@citynet.net, lhodge@balch.com
Sent: 10/4/2011 10:33:23 A.M. Central Daylight Time
Subj: RE: Perrine v. DuPont Settlement - Draft Participating Provider Agreement; Comments by Friday at Noon Please; Our File No. 4609-1{GG-}

Dear All:

We hope that all is well.

Please see the attached draft Participating Provider Agreement. Please provide any comments by Friday at noon.

Sincerely,

Diandra S. "Fu" Debrosse

Shareholder

GENTLE TURNER & SEXTON

501 Riverchase Parkway East

Suite 100
Hoover, AL 35244
(205) 716-3000 (telephone)

(205) 716-3010 (facsimile)

ddebrosse@gtandslaw.com

www.gtandslaw.com

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From: escrowagen@aol.com [mailto:escrowagen@aol.com]
Sent: Tuesday, October 04, 2011 10:19 AM
To: VBuchanan@levinlaw.com; sdthacker@agmtlaw.com
Cc: Terry D. Turner Jr.; Diandra Debrosse; Kip Harbison; Paige Osborn; Mike Jacks; wcox@lfwlaw.com; jkg@cochranfirm.com; mflowers@cochranfirm.com; farresttaylor@cochranfirm.com; NMcWilliams@levinlaw.com; pbjones@westandjones.com; angelamason@cochranfirm.com; mhmccarthy@citynet.net; leesgov@citynet.net; lhodge@balch.com
Subject: Perrine v. DuPont Settlement - Suggested Finance Committee Topics for the Friday, October 7, 2011 9:00 a.m. Central Conf. Call

Please see attached in pdf format including call access

PARTICIPATING PROVIDER AGREEMENT

THIS PARTICIPATING PROVIDER AGREEMENT ("Agreement") is made and entered into as of November 1, 2011 by and between The Perrine Medical Monitoring Plan (the Plan) and XYZ Clinic a West Virginia corporation ("Provider").

RECITALS

WHEREAS, Provider is either (i) an individual health care provider or (ii) a professional corporation, medical corporation, or other entity duly organized and existing under and pursuant to the laws of the state in which it is formed, in either case that is duly licensed and authorized to deliver health care services in the state of West Virginia.

WHEREAS, the Plan desires (i) to obtain a network of health care providers for the Plan and (ii) to engage Provider to furnish such services; and

WHEREAS, Provider desires to be engaged by the Plan to furnish such services and shall furnish such services in accordance with the terms of this agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

ARTICLE I - DEFINITIONS

1.1 **Benefits.** "Benefits" means Medical testing, consultations, and surgeries as defined by the Plan.

1.2 **Claim Clearing House.** "Claim Clearing House" means an organization that receives claims in an electronic format and forwards claims to Insurance Carriers, Third Party Administrators, and/or PPO Networks.

1.3 **Confidential Information.** "Confidential Information" means information of the Plan and Providers that shall be subject to patent, copyright, trademark, trade name or service mark protection, or not otherwise in the public domain and related to the business and operations of the Plan or Providers, including, without limitation, this Agreement and the Exhibits hereto, eligibility data, manuals, software, information relating to financial status of the Plans, and medical records of Participants in control and possession of Provider.

1.4 **Covered Services.** "Covered Services" means the procedures identified in the Fee Schedule subject to the Benefit limitations specified by the Plans.

1.5 **Fee Schedule.** "Fee Schedule" means the allowable fees paid for services provided for specific Clinical Procedure Codes as set forth in EXHIBIT A.

1.6 **HIPAA.** "HIPAA" means the Health Insurance Portability and Accountability Act of 1996.

1.7 **Medically Necessary.** "Medically Necessary" or "Medical Necessity" means services or supplies which, under the provision of this agreement are determined to

be (i) appropriate and necessary for the symptoms, diagnosis or treatment of the injury or disease; (ii) provided for the diagnosis or direct care and treatment of the injury or disease; (iii) preventative services as provided in the Plans; (iv) within good medical practice within the organized medical community; (v) not primarily for the convenience of the Participant or of any Provider providing Benefits to the Participant; (vi) an appropriate supply or level of service needed to provide safe and adequate care: and (vii) provided in a setting consistent with the required level of care.

1.8 **Participant.** "Participant" means any person who has satisfied the eligibility requirements of the Plan.

1.9 **PHI.** "PHI" means Protected Health Information. It is the Individually Identifiable Health Information as defined by HIPAA.

1.10 **Payment.** "Payment" means the actual value made to or on behalf of the Participants for benefits described in the Plans.

1.11 **Plans.** "Plans" means the Medical and Dental Plans as described by WAMC.

1.12 **Third Party Administrator** "TPA" means CTI Administrators, Inc. 100 Court Avenue, Des Moines, IA 50309. CTI Administrators, Inc. has contracted with the Plan to perform administrative services including; but not limited to, maintenance of participant eligibility, interface with Providers, determination of allowable fees, claim payments, communication with Participants and Providers and maintenance of test results.

ARTICLE II - OBLIGATIONS OF THE PLAN

2.1 **Information.** The Plan shall make available current information regarding Participants and Plan Benefits to Provider via the internet or other electronic media. The Plan shall make available to Participants information regarding Plan Benefits.

2.2 **Liability for Claims Decisions.**

2.2.1 The Plan shall not be responsible for payment of claims submitted for services that are not covered by the Plan of benefits nor to persons that are not eligible Participants.

ARTICLE III – SERVICES AND OBLIGATIONS OF PROVIDER

3.1 **Provider Shall:**

3.1.1 provide Covered Services to eligible Participants for which Provider is qualified and which Provider customarily furnishes to the general public from the office location indicated on the signature page;

3.1.2 follow the biannual medical monitoring protocols as set forth by the Plan and modified from time to time;

3.1.3 obtain a biannual patient consent/reject authorization for CT Scans after explaining benefits and risks as part of the biannual testing protocols and physical examination with copies to the TPA;

3.1.4 perform Covered Services pursuant to the standards of good medical practice within the organized medical community;

3.1.5 (i) obtain from eligible Participant necessary authorization and confidentiality release forms, including without limitation, written assignment of benefits and an appropriate release to bill the Plan directly for Covered Services furnished by Provider; (ii) bill the Plan directly via electronic transmission of necessary claim data within 60 days of rendering services; (iii) accept as payment in full for Covered Services rendered the reimbursement amount specified in the Fee Schedule shown in EXHIBIT A; and (iv) cooperate and comply with the billing and other procedures established by the Plan.

3.1.6 within ten (10) days of occurrence, notify the Plan and provide the Plan with all information with respect to any disciplinary or malpractice actions or judgments against or settlements by Provider;

3.1.7 treat Participants in all respects no less favorably than Provider treats all other patients. Provider shall not discriminate against Participant based upon race, religion, national origin, color, sex, marital status, age, health status, disability, or source of payment. Nothing in this Agreement is intended to create, nor shall it be construed to create, any right of the Plan, or their respective designees, to intervene in any manner with, nor shall it render them responsible for, the provision of Provider services or care to Participants;

3.1.8 submit all tests specified by the Plan to LabCorp for analysis and direct test results, in electronic format, to the servicing provider and to CTI Administrators;

3.1.9 coordinate with the Plan in payment of Participant benefits by Government and other insurance plans, including but not limited to, Medicare, Medicaid, and private health insurance plans (collectively "Third Party Sources") so as to provide reasonable assurance that Third Party Sources are not billed in addition to the Plan.

3.2 **Provider Insurance.** Provider shall maintain during the term of this agreement, at Providers expense, in amounts reasonably satisfactory to the Plan policies of general and professional liability insurance with companies reasonably acceptable to the Plan. Upon request, Provider shall provide the Plan with evidence of such insurance. Provider shall provide the Plan with prior notification of any cancellation, non-renewal or other material change in such insurance.

ARTICLE IV – CONFIDENTIAL INFORMATION

4.1 **Legal Restrictions.** Neither party hereto shall be in default for failure to supply information which such party, in good faith, believes cannot be supplied due to prevailing law, or for supplying information which such party, in good faith, believes is required to be supplied due to prevailing law.

4.2 **Non-Disclosure of Confidential Information.** Provider and the respective officers, directors, employees, agents, members, and assigns shall hold any and all Confidential Information in the strictest confidence as a fiduciary, and shall not, voluntarily or involuntarily, use, sell, transfer, publish, disclose, display or otherwise make available to others any portion of the Confidential Information without the express written permission of the Plan.

ARTICLE V – NEW OR ADDITIONAL SERVICES

5.1 **Services.** The Plan and Provider may from time to time mutually agree to add new or additional services to those then set forth in Exhibit A, and to amend the allowed fees specified in Exhibit A. The Plan and Provider shall evidence their agreement as to any new or additional services or as to any new Types of Services and Fees by means of a new Exhibit A or by an addendum to Exhibit A, of this agreement, in either event which shall be executed by both the Plan and Provider.

ARTICLE VI – METHOD OF PAYMENT

6.1 **Frequency of Payment.** The Plan agrees that the payment for Covered Services provided to Participants will be sent to the Provider within five days after the last day of each business week for services incurred and submitted to the Plan for reimbursement during said week.

6.2 **Amount of Payment.** The Plan will reimburse Provider for Covered Services to Participants according to the Fee Schedule shown in Exhibit A. Medical procedures not included in the Fee Schedule shown in Exhibit A will not be reimbursed.

ARTICLE VII – TERM

7.1 **Initial Term.** Initial Term Effective Date This Agreement shall become effective November 1, 2011, and shall continue in full force through the period ending December 31, 2013.

7.2 **Renewal Term.** The term of this Agreement shall automatically continue for an additional term of one year ("Renewal Term") following the expiration of the Initial Term or any Renewal Term, upon the same terms and conditions, unless the Agreement is terminated or amended.

7.3 **Termination.**

7.3.1 **Notification.** This Agreement will terminate at the end of the Initial Term or at the end of any Renewal Term by providing written notice of termination to the other party at least sixty (60) days prior to the date ending the Term.

7.3.2 **Cure Provision.** If either party materially breaches this Agreement, the other party may terminate the Agreement provided that it notifies, in writing, the breaching party of the specific breach and allows the breaching party the opportunity to cure the breach within sixty (60) days of the date of the notice. If the breach has not been corrected in sixty (60) days, the Agreement may be terminated without further notice

ARTICLE VIII – MODIFICATIONS

8.1 **Modifications and Improvements.** Modifications and improvements in existing procedures and systems may be made by the Plan, in its sole discretion. Any such modifications and improvements, which would affect Provider's procedures, will be communicated to Provider by the Plan. The Plan may also make, in its sole discretion, modifications in existing procedures and systems at the sole request of Provider; provided, however, that Provider shall in all events reimburse the Plan for all costs and expenses incurred by the Plan to make and effectuate modifications and improvements requested by Provider.

ARTICLE IX – LIABILITY

9.1 **Right to Reprocess.** In the event of any error or omission on the part of the Plan that is reasonably correctable by the reprocessing of Information, the Plan will reprocess such Information with the cooperation of Provider and such reprocessing shall be in full satisfaction of all of Provider's claims with respect to the error or omission in question. The conclusion of such error or omission designation shall be a mutual conclusion on behalf of the Plan and Provider.

9.2 **Indemnification.**

9.2.1 **Indemnification of Provider** the Plan agrees to indemnify and hold harmless Provider with respect to any and all claims, liabilities, losses, damages or expenses including reasonable attorney's fees caused by the Plan's sole negligence or willful misconduct in its administering and maintaining the Plans. However, this indemnification provision shall not apply to any claims, liabilities, losses, damages or expenses caused by any action or undertaking of Provider, its agents, servants or employees when acting outside the scope of their authority or in any negligent or criminal matter.

9.2.2 **Indemnification of the Plan** Provider agrees to indemnify and hold harmless the Plan or any of its officers, or employees from any and all losses, liability, damages, expenses or other cost or obligation, resulting from or arising out of claims, demands, lawsuits or judgments brought against Provider in the performance of its responsibilities pursuant to the provisions of this Agreement or the provisions of the Plans, except any such claims, losses, liabilities, damages, or expense which arise out of or in connection with the Plan's sole negligence, willful misconduct, or criminal misconduct.

ARTICLE X – PROVIDER-PATIENT RELATIONSHIP

10.1 Nothing contained in this Agreement shall interfere with or in any way alter any Provider-patient relationship.

ARTICLE XI – FORCE MAJEURE

11.1 Notwithstanding anything herein or otherwise which may appear to be to the contrary, the Plan shall not be responsible for delays or failures in performance under this Agreement resulting from any force majeure or acts beyond the reasonable control of the Plan or due to or in any way related to or connected with any act or omission of Provider or any employee, agent, personnel or other representative of Provider. Such acts shall include, without limitation, acts of God, strikes, blackouts, riots, acts of war, epidemics, governmental regulations, fire, communication line failure, power failures, mechanical failures, storms or other disasters.

ARTICLE XII – NOTICES

12.1 Any notice or demand desired or required to be given hereunder shall be in writing and deemed given when personally delivered or three (3) days after deposit in the United States Mail, postage prepaid, sent certified or registered, addressed as follows:

A. If to the Plan, to:
?????
Attention: ?????

B. If to Provider, to:
Quality of Life Services, Inc.
?????
?????
Attention: ???.

or to such other address or person as hereafter shall be designated in writing by the applicable party.

ARTICLE XIII – ENTIRE AGREEMENT

13.1 This Agreement and all exhibits and schedules hereto constitute the entire agreement between the parties hereto pertaining to the subject matters hereof and supersede all negotiations, preliminary agreements and all prior or

contemporaneous discussions and understandings of the parties hereto in connection with the subject matters hereof. All exhibits and schedules are incorporated into this Agreement as if set forth in their entirety and constitute a part thereof.

ARTICLE XIV – NO WAIVER; MODIFICATIONS IN WRITING

14.1 No failure or delay on the part of any party in exercising any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or remedy, preclude any other or further exercise thereof or the exercise of any other right, power or remedy. The remedies provided for herein to the Plan are cumulative and are not exclusive of any remedies that may be available to the Plan at law or in equity or otherwise. No amendment, modification, supplement, termination or waiver of or to any provision of this Agreement, nor consent to any departure therefrom, shall be effective unless the same shall be in writing and designed by or on behalf of the party to be charged with the enforcement thereof. Any amendment, modification or supplement of or to any provision of the Agreement, any waiver of any provision of this Agreement, and any consent to any departure from the terms of any provisions of this Agreement, shall be effective only in the specific instance and for the specific purpose for which made or given.

ARTICLE XV – SEVERABILITY

15.1 In the event any provision of this Agreement is held invalid, illegal or unenforceable, in whole or in part, the remaining provisions of this Agreement shall not be affected thereby and shall continue to be valid and enforceable. In the event any provision of this Agreement is held to be unenforceable as written, but enforceable if modified, then such provision shall be deemed to be amended to such extent as shall be necessary for such provision to be enforceable and shall be enforced to that extent.

ARTICLE XVI – GOVERNING LAW

16.1 This Agreement shall be governed by and construed in accordance with the laws of the State of West Virginia. Additional governance regarding resolution of disputes is described in Article XXI.

ARTICLE XVII – RELATIONSHIP

17.1 Nothing contained in this Agreement and no action taken by the parties pursuant hereto shall be deemed to constitute the parties a partnership, an association, a joint venture or other entity.

ARTICLE XVIII – HEADINGS AND CAPTIONS

18.1 The titles or captions of sections and paragraphs in this Agreement are provided for convenience of reference only, and shall not be considered a part hereof for purposes of interpreting or applying this Agreement, and such titles or captions doe not define, limit, extend, explain or describe the scope or extent of this Agreement or any of its terms or conditions.

ARTICLE XIX – BINDING EFFECT ON SUCCESSORS AND ASSIGNS

19.1 This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, legal representatives, successors and assigns. In the event of assignment, all of the terms, covenants and conditions of this Agreement shall remain in full force and effect and the party making the assignment shall remain liable and responsible for the due performance of all of the terms, covenants and conditions of this Agreement that it is obligated to observe and perform. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto (and their respective heirs, successors, legal representatives and permitted assigns) any rights, remedies, liabilities or obligations under or by reason of this Agreement. However, neither the Provider nor the Plan may assign the rights and obligations provided hereunder without the prior written express permission of the other party. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, and in making proof hereof, it shall not be necessary to produce or account for more than one such counterpart.

ARTICLE XX – MISCELLANEOUS

20.1 Changes in Laws. If changes in the laws materially affect a party's rights and obligations under this Agreement or render any portion illegal or unenforceable, then the parties agree to negotiate modifications to the terms of this Agreement in good faith. If the parties cannot agree to modify terms that comply with the changes in laws, then either party may terminate this Agreement upon thirty (30) days prior written notice.

ARTICLE XXI – RESOLUTION OF DISPUTES

21.1 The Court in ???? retains continuous and exclusive jurisdiction, and supervision over the Plan and over this Agreement. Any judicial proceeding arising out of or relating to this Agreement may be brought only before the Court, and any judgment against a Party may be enforced only by a proceeding before the Court. The Parties irrevocably submit to the jurisdiction of the Court over any such proceeding. The Parties irrevocably waive any objection that they might now or hereafter have to the laying of venue for such proceeding in the Court and any claim that any such proceeding in the Court has been brought in an inconvenient forum.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

The undersigned certifies that he or she has legal authority to bind the Plan.	The undersigned certifies that he or she has legal authority to bind Provider.
The Perrine Medical Monitoring Plan	**XYZ Clinic**
By: _____	By: _____
Title: ?????	Title: ?????
Date: _____	Date: _____

EXHIBIT "A" FEE SCHEDULE

Anticipated Procedures and Allowable Fees			
Initial Testing	**Procedure Code**	**Description**	**Allowable Fee**
	99201	10 Minute OFFICE VISIT OP NEW	$60.00
	99211	5 Minute OFFICE VISIT OP ESTABLISHED	$32.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	82274	OCCULT BLOOD, FECES	LabCorp
	82232	ASSAY OF BETA-2 PROTEIN	LabCorp
	82565	ASSAY OF CREATININE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Follow-up Consultation	**Procedure Code**	**Description**	**Allowable Fee**
	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$135.00
	99243	40 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of tests	$170.00
Skin Test with Dermatologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Dermatologist	$140.00
	11100	BIOPSY, SKIN LESION	$110.00
	88304	TISSUE EXAM BY PATHOLOGIST	LabCorp
Consultation with Urologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Urologist	$140.00
	88112	CYTOPATH, CELL ENHANCE TECH	LabCorp
	52000	CYSTOSCOPY	$250.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	OP Facility	Out Patient Facility Charge	$850.00
Anesthesiologist	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	$350.00
	74176	CT Scan Abdomen & Pelvis	$350.00
Radiologist	74176.26	Radiologist	$110.00
	72192	CT PELVIS W/O DYE	$300.00
	72192.26	Radiologist	$100.00

Consultation with Nephrologist	Procedure Code	Description	Allowable Fee
	99242	Consultation with Nephrologist	$140.00
	99000	SPECIMEN HANDLING	$12.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	81001	URINALYSIS, NONAUTO W/SCOPE	LabCorp
	84520	ASSAY OF UREA NITROGEN	LabCorp
Consultation with Gastroenterologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Gastroenterologist	$140.00
	82274	OCCULT BLOOD, FECES	LabCorp
Proctologist	99242	Consultation with Proctologist	$160.00
	82274	OCCULT BLOOD, FECES	LabCorp
	43239	UPPER GI ENDOSCOPY, BIOPSY	$350.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	$350.00
Anesthesiologist			
Consultation with Toxicologist & Psychologist	**Procedure Code**	**Description**	**Allowable Fee**
	99242	Consultation with Toxicologist	$140.00
	36415	ROUTINE VENIPUNCTURE	$10.00
	85025	COMPLETE CBC W/AUTO DIFF WBC	LabCorp
	84202	ASSAY RBC PROTOPORPHYRIN	LabCorp
	83655	ASSAY OF LEAD	LabCorp
Psychologist	96118	NEUROPSYCH TST BY PSYCH/PHYS	$100.00
Other Specialties	**Procedure Code**	**Description**	**Allowable Fee**
	71250	CT THORAX W/O DYE	$300.00
	71250.26	CT THORAX W/O DYE	$100.00
	71250	Repeat CT Scan of Chest	$300.00
	71250.26	Repeat CT Scan of Chest	$100.00
Pulmonologist	99242	Consultation with Pulmonologist	$140.00
Cardiologist	99242	Consultation with Cardiologist	$140.00
Cardiothoracic Surgeon	99242	Consultation with Cardiothoracic Surgeon	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
Anesthesiologist	00910	ANESTH, (3base @$70 + time)	$350.00
	99242	Consultation with Pulmonologist	$140.00
	32095	BIOPSY THROUGH CHEST WALL	$425.00
	OP Facility	Out Patient Facility Charge	$850.00
	00910	ANESTH, (3base @$70 + time)	$350.00

GENTLE, TURNER & SEXTON
ATTORNEYS AND COUNSELLORS AT LAW
SUITE 100 - 501 RIVERCHASE PARKWAY EAST
HOOVER, ALABAMA 35244

4609-1/Kdgs

EDGAR C. GENTLE, III
TERRY D. TURNER, JR.*
K. EDWARD SEXTON, II
DIANDRA S. DEBROSSE
KATHERINE A. HARBISON
M. BRANDON WALKER
J. CHRISTOPHER SMITH
PAIGE F. OSBORN
ROBERT E. HAWTHORNE, III

TELEPHONE (205) 716-3000
TELECOPIER (205) 716-3010

*ALSO ADMITTED IN FLORIDA

January 28, 2011

VIA FEDERAL EXPRESS and
TELECOPIER

The Honorable Thomas A. Bedell
Circuit Judge of Harrison County
301 West Main Street, Room 321
Clarksburg, West Virginia 26301

Re: **Perrine, et al. v. DuPont, et al.;**
Civil Action No. 04-C-296-2 (Circuit Court of Harrison County, West Virginia) - Initial Medical Monitoring and Property Remediation Time Lines and Punch Lists;
Our File No. 4609-1 {Z}

Dear Judge Bedell:

In accordance with the January 18, 2011 Order respecting medical monitoring, please find the initial time line and punch list for medical monitoring and the initial time line and punch list for property remediation. We are submitting these to you simultaneously, because the two time lines are interrelated. In accordance with the Order, and as reflected in the time lines, we are using our best efforts to share resources and expenditures of the Settlement in carrying out both medical monitoring and property remediation in tandem.

Thank you for the Court's consideration.

Yours very truly,

Edgar C. Gentle, III

ECGIII/kjm
Enclosures

cc: (with enclosures)(by e-mail)

Stephanie D. Thacker, Esq.,
DuPont Representative on the Settlement Finance Committee

Virginia Buchanan, Esq.
Plaintiff Class Representative on the Finance Committee

Meredith McCarthy, Esq.,
Guardian Ad Litem for Children

cc: (with enclosures)(by fax)
Clerk of Court of Harrison County,
West Virginia, for filing (via telecopier: (304) 624-8710)

A. PREAMBLE TO SUGGESTED INITIAL MEDICAL MONITORING AND PROPERTY PROGRAM TIME LINES AND PUNCH LISTS

In accordance with the Court's January 18, 2011 Final Order Setting Forth the Scope and Operation of the Medical Monitoring Plan, at decretal paragraphs 2 and 9, below are the Initial Proposed Time Lines and Punch Lists for the Medical Monitoring and Property Programs developed by the Claims Administrator in collaboration with the Finance Committee. In carrying out the Settlement, the Claims Administrator and the Finance Committee have agreed to work by consensus to the fullest extent practicable. To this end, and to the extent practicable, the Claims Administrator, to the extent practicable, will provide the Finance Committee with draft submissions to the Court five business days before they are filed, in order to obtain comments and possible resolution. The Finance Committee has agreed not to make filings with the Court concerning the administration of the Settlement without likewise sharing them with the Claims Administrator and all members of the Finance Committee, to the extent practicable, five business days in advance for comment and possible resolution. In a similar vein, the schedule of proposed payment vouchering procedures to be filed with the Court shortly to provide the Finance Committee a reasonable time (at least two business days to the extent practicable) to review proposed Claims Administrator disbursements from either of the two qualified settlement funds before they are made.

THE BELOW COMPLETION DATES ARE PROJECTED. THEY COULD BE CHANGED DUE TO UNFORSEEN EVENTS.

B. SUGGESTED MEDICAL MONITORING PROGRAM INITIAL TIME LINE AND PUNCH LIST

Milestone	Suggested Completion Date
Court establishment of Settlement Finance Committee ("SFC")	January 18, 2011
Class Counsel and DuPont provide the Court and the Claims Administrator their nominees for SFC Representative	January 24, 2011
Claims Administrator submits to the SFC draft initial medical monitoring budget (through 6 month sign up period), and Medical Monitoring Fund payment vouchering procedures, written accounting internal controls, and written investment policy	January 24, 2011
Class Counsel provides Claims Administrator in soft medium the Class Area mail-out address list that was used in Settlement Notice, and to be used in noticing the below town meetings and a description of how it was generated, and Parties provide lists of ineligible Graselli properties	January 24, 2011

Claims Administrator and SFC select Claims Administrator office site and finalize lease for possible Court approval, and Claims Administrator submits the lease to the Court	January 26, 2011
Claims Administrator provides SFC with proposed town meeting Notice mailing list and a description of how it was generated, and lists received from the two sides of the case re property program ineligible Graselli properties	January 26, 2011
Claims Administrator provides SFC draft Class member Notice (for publication and mailing) and registration* forms and draft eligibility criteria for Class medical monitoring program	January 28, 2011
Claims Administrator creates and provides to SFC for review draft list of candidates for medical monitoring third party claims administrator and Claims Administrator provides to SFC for review draft medical monitoring third party claims administrator request for proposals	January 28, 2011
Claims Administrator files medical monitoring and property remediation initial time lines and punch lists with the Court	January 28, 2011
Claims Administrator's Office opens	February 1, 2011
Class Counsel and Claims Administrator nominate to the Court Claimants Advisory Committee for in-Class Area (5 members) after Claims Administrator meets with Class Representatives on February 1.	February 4, 2011
Claimants Advisory Committee nominees convene	February 4, 2011
Claims Administrator and SFC finalize initial medical monitoring budget (through 6 month sign-up period), and Medical Monitoring Fund written accounting internal controls, payment vouchering procedures, and written investment policy, and submit to the Court for review	February 4, 2011
The finalized Class Member Notice and registration* forms and eligibility criteria for the Class Medical Monitoring Program are finalized and submitted to the Court for review	February 7, 2011

*Registration means proving medical monitoring Class membership. It does not require participation in the medical monitoring testing program

The Court considers entering an Order approving: (a) the initial medical monitoring time line and punch list; (b) SFC Party Representatives; (c) Claimants Advisory Committee in-Class Area members; (d) the initial budget for the medical monitoring program (through 6 month sign up period); (e) the Medical Monitoring Fund written accounting internal controls, payment vouchering procedures and written investment policy; (f) the Class Member Notice and medical monitoring registration* forms and eligibility criteria; and (g) payment of $100 to medical monitoring Class Members after they register, with the balance to be paid at end of registration*	February 10, 2011
Medical Monitoring registration* Notice is published** and town meeting notice invitation letters and registration* forms are mailed to Class Area addresses	February 15, 2011
The medical monitoring third party claims administrator candidate list and request for proposals are finalized and submitted by the Claims Administrator to the Court for review	February 21, 2011
Class medical monitoring registration* begins on February 28, 2011 and ends August 31, 2011, inclusive (medical monitoring registration* will be available at the February 28 to March 12, 2011 town meetings)	February 28, 2011
The Court considers approving medical monitoring third party claims administrator candidate list and request for proposals	February 28, 2011
Medical monitoring registration* and property program design town meetings at Spelter Fire Station	Weekdays of February 28 to March 11, 2011 (morning 9 a.m. and afternoon 2 p.m. sessions)
RFP issued by Claims Administrator to third party claims administrator candidates	March 1, 2011
Claims Administrator submits to Court recommendations for out-of-Class Area Claimants Advisory Committee Members (4 persons)	March 17, 2011
The Court considers approving out-of-Class Area Claimants Advisory Committee Members	March 24, 2011

** In same newspapers as Class Settlement hearing notice.

Initial medical monitoring Class member cash payments begin as Class membership is proven (maybe $100/each)	March 31, 2011
Third party claims administrator bids received by Claims Administrator and shared with the SFC and the Court for review	April 1, 2011
Third party claims administrator candidates interviewed by Claims Administrator, Claimants Advisory Committee, and SFC. Claims Administrator, after consulting with the SFC, submits report to the Court recommending third party claims administrator selection	April 29, 2011
The Court considers approving medical monitoring third party claims administrator	May 16, 2011
Third party claims administrator interviews University of West Virginia and other area medical testing providers, surveys Class Area and out-of-Class Area medical monitoring physicians and laboratory prospects, for medical testing provisioning, and prepares for Claims Administrator and SFC for review: (A) medical monitoring implementation recommendations, based on a "retail model" of paying for medical monitoring building blocks; (B) list of in-Class Area and out-of-Class Area potential medical monitoring physicians and laboratories; and (C) draft medical monitoring roll out time line draft (collectively, the "Medical Monitoring Implementation Plan")	July 15, 2011
Claims Administrator prepares for review by SFC and third party claims administrator draft budget for year one (begins with Implementation Date)	July 15, 2011
Medical Monitoring Implementation Plan is finalized by the Claims Administrator, the SFC and the third party administrator and submitted to the Court for review	August 1, 2011
Third party claims administrator and Claims Administrator, after consulting with the SFC and Claimants Advisory Committee, submit medical monitoring implementation budget for year one (beginning with Implementation Date) to the Court for review	August 1, 2011
The Court considers approving the Medical Monitoring Implementation Plan and the year one (beginning with Implementation Date) medical monitoring budget	August 15, 2011
Class medical monitoring registration* ends	August 31, 2011
Medical monitoring testing begins (Implementation Date)	September 8, 2011

Final list of medical monitoring Class members is approved by the Court, and balance of medical monitoring class member cash is paid to registered* medical monitoring Class members	November 15, 2011

C. SUGGESTED PROPERTY PROGRAM INITIAL TIME LINE AND PUNCH LIST

Milestone	Suggested Completion Date after Effective Date
Court establishment of Settlement Finance Committee ("SFC")	January 18, 2011
Class Counsel and DuPont provide the Court and the Claims Administrator their nominees for SFC Representative	January 24, 2011
Claims Administrator submits to the SFC draft initial property program budget (pre-remediation start date) , and Property Fund payment vouchering procedures, written accounting internal controls, and investment policy	January 24, 2011
Class Counsel provides Claims Administrator in soft medium the Class Area mail-out address list that was used in Settlement Notice, and to be used in noticing the below town meetings and a description of how it was generated, and Parties provide lists of ineligible properties	January 24, 2011
Claims Administrator and SFC select Claims Administrator Office site and finalize lease for possible Court approval, and Claims Administrator submits the lease to the Court	January 26, 2011
Claims Administrator provides SFC with proposed Notice mailing list and a description of how it was generated, and lists received from the two sides of the case re property program exempt Graselli properties	January 26, 2011
Claims Administrator provides SFC list of potential property remediation technical advisor candidates	January 28, 2011
Claims Administrator submits to the SFC proposed town meeting notice form for medical monitoring sign-up and claimant discussion of property program design	January 28, 2011
Claims Administrator files medical monitoring and property remediation initial time lines and punch lists with the Court	January 28, 2011

Claims Administrator's Office opens	February 1, 2011
Property remediation technical advisor candidates selected for review provide cost proposals	February 3, 2011
Class Counsel and Claims Administrator nominate to the Court Claimants Advisory Committee for in-Class Area (5 members) after Claims Administrator meets with Class Representatives on February 1	February 4, 2011
Claimants Advisory Committee nominees convene	February 4, 2011
Claims Administrator and SFC (a) finalize and submit to the Court for review proposed initial property program (pre-remediation start date) budget, and Property Fund payment vouchering procedures, accounting internal controls, and investment policy, and submit to the Court for review, and (b) nominate for the Court's consideration property remediation technical advisor	February 4, 2011
Property remediation technical advisor candidates selected for a telephone interview are interviewed by the Claims Administrator and SFC, and the Claims Administrator, after consultation with the SFC, provides report and remediation technical adviser nominee(s) to the Court	February 7, 2011
The Court considers issuing an Order approving (a) the initial property program time line and punch list; (b) the SFC Party Representatives; (c) Claimants Advisory Committee in-Class Area Members; and (d) the initial budget for the property program (pre-remediation start date), and Property Fund written accounting internal controls, payment vouchering procedures and written investment policy, (e) the town meeting notice and (f) the property remediation monitoring technical advisor	February 10, 2011
Notice of town meetings (11 meetings for about 250 households each based on alpha sort of tax record property owner last names) is published ** sent to property Class addresses to discuss property program and medical monitoring program	February 15, 2011

** In same newspapers as Class Settlement hearing notice.

Medical monitoring registration* and property program design town meetings at Spelter Fire Station	Weekdays of February 28 to March 11, 2011 (morning 9 a.m. and afternoon 2 p.m. sessions)
Claims Administrator, in consultation with technical advisor and SFC, designs follow-up property program Class member questionnaire re property program design, and submits to the Court for review	March 29, 2011
The Court considers approving questionnaire	April 7, 2011
Questionnaires are mailed to property Class addresses	April 14, 2011
Questionnaire results are received and compiled by the Claims Administrator and submitted to the SFC and the Court for review	May 16, 2011
Property Program Fairness Hearing by the Court, with the Court and the Claims Administrator to obtain final Class member input on property program design	June 1-2, 2011
The Court considers determining in an Order the structure of the property program	June 15, 2011
Claims Administrator, after consulting with the technical advisor and SFC, provides the Court for approval draft property Class member registration forms and eligibility criteria for property program	July 1, 2011
Claims Administrator, technical advisor and SFC submit to the Court RFP for property remediation general contractor and proposed list of candidates for property remediation general contractor for review by the Court (to the extent applicable)	July 1, 2011
The Court considers issuing an Order approving (a) the proposed property program registration forms and (b) the RFP for property remediation general contractor and proposed candidates for property remediation general contractor (to the extent applicable)	July 8, 2011
Property Class Program notice by mail and publication is given, and registration begins, with registration being provided in-person at the Claims Administrator's office, and by mail	July 11, 2011
General contractor RFP issued (to the extent applicable)	July 18, 2011
Property Class cash payments (to the extent applicable) begin to be made on a rolling (as Class members register) basis	August 10, 2011

General contractor bids received, general contractor candidates interviewed by Claims Administrator and Technical Advisor and SFC. Claims Administrator and Technical Advisor, in collaboration with the SFC, submit report to Court recommending selection of property remediation general contractor (to the extent applicable)	August 18, 2011
Court considers approving hiring of property remediation general contractor(s) (to the extent applicable)	August 25, 2011
Property remediation year one implementation budget, time line and punch list (beginning with Implementation Date) (to the extent applicable) are prepared by Claims Administrator, property remediation technical advisor (if applicable), property remediation general contractor (to the extent applicable) and the SFC, and are submitted to the Court for review	September 7, 2011
Court considers approving of year one property remediation implementation budget, time line and punch list (to the extent applicable)	September 14, 2011
Remediation relief (to the extent applicable) for Class members in zones 1, 2 and 3 (to the extent applicable) begins	September 21, 2011
Following verification of Class Member eligibility and the achievement of sufficient remediation registrants to make remediation economical to begin, remediation begins (to the extent applicable) (Implementation Date)	November 1, 2011

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E.I. DU PONT DE NEMOURS AND COMPANY, et al.,

Defendants.

FINAL ORDER SETTING FORTH THE SCOPE AND OPERATION OF THE MEDICAL MONITORING PLAN

Presently pending before the Court is the "Special Master's Report No. 1 (Medical Monitoring), Recommendations, Requests for Comments, and Prayer for Relief from the Court," which was prepared at the Order of the Court and filed on or about June 23, 2008. Additionally, the Special Master filed a Supplement to Report No. 1 on or about October 25, 2010. Both the Report and the Supplement outline proposed actions for the Court to take while directing the administration of the medical monitoring program. The Report contemplated the original plan as outlined in the verdict. The Supplement slightly modified the Report to accommodate the judgment granted by this Court to the minors and incompetents in the medical monitoring class. Additionally, the Court previously entered the "Final Order Regarding the Scope, Duration, and Cost of the Medical Monitoring Plan," on February 25, 2008, although certain aspects of that Order have changed in conjunction with the Settlement, as noted in this Order and the Final Order Approving Settlement entered on January 4, 2011.

Jan. 18. 2011 3:34PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 3

In relation to the medical monitoring program and the settlement of this case, the Parties have filed several motions. Namely, the Plaintiffs filed the "Motion for Appointment of Claims Administrator for Property Remediation," and the "Motion to Appoint a Claims Administrator & Establish Medical Monitoring Settlement Executive Committee," on December 22, 2010. On December 27, 2010, the Defendants filed a "Motion to Establish Medical Monitoring Settlement Executive Committee." On December 28, 2010, the Defendants filed a Response to the Plaintiffs' Motion to state that the Parties are not in agreement about the function of the proposed settlement executive committees.

Finally, the Parties and the Settlement Administrator, Edgar Gentle, executed the "Stipulation of Parties and Settlement Administrator," on or about January 10, 2011, for the purpose of "acknowledg[ing] the clear meaning of the aforesaid Memorandum of Understanding." The Stipulation includes two (2) provisions, the first, generally stated, is that DuPont has fully funded the administrative start up costs for the medical monitoring program through the seventy ($70,000,000.00) million dollar settlement and will only have to provide additional administrative costs once testing commences. The second provision is that "there shall be no requirement that a medical monitoring class member register for or avail themselves of the medical monitoring program or service in order to receive a cash payment from the medical monitoring fund, provided that class membership is proven."

The Court will now address the Parties' Motions as to the Claims Administrator and proposed settlement executive committees.

Jan. 18. 2011 3:34PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 4

Two primary observations greatly simplify the Court's decision on these Motions: first, there is no need to appoint a claims administrator for either the property class or the medical monitoring class because Edgar Gentle, of the law firm Gentle, Turner and Sexton, is the Claims Administrator for both classes as of the February 25, 2008, Order of this Court. Second, the Parties are not in dispute about the property remediation class, so its administration will proceed under the direction of Mr. Gentle, as previously Ordered by this Court.

The February 25, 2008, "Order Appointing Claims Administrator," specifically held that:

> The Court hereby engages Edgar C. Gentle, III, as the Claims Administrator and Special Master to aid the Court in carrying out the medical monitoring, property remediation, and punitive damages distribution aspects of this case. Mr. Gentle will serve as Claims Administrator and Special Master at the discretion of the Court. The Court may modify this Order at any time... Mr. Gentle's appointment is under the authority of West Virginia law[1] allowing the Court to exercise general powers and responsibilities over class actions. His actions as Claims Administrator and Special Master (and those of his agents and employees), in accordance with this Order and all future Orders of this Court, will constitute judicial actions of this Court and be protected, to the maximum extent allowable by law, by the doctrine of judicial immunity. Lastly, pursuant to W. Va. R. Civ. Rule 54(b), the Court directs the entry of this Order as to the claims above upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

The only aspect of the above cited Order which is no longer relevant is the distribution of money for punitive damages, as the award for punitive damages has been eliminated through the settlement, and the Court sees no reason to change the above quoted Order in any other respect.

[1] Aluise v. Nationwide Mutual Fire Insurance, 218 W. Va. 498, 625 S.E.2d 260 (2005); State ex rel Mantz v. Zakaib, 216 W. Va. 656, 609 S.E.2d 870 (2004).

Jan. 18. 2011 3:35PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 5

Therefore, although the Court has the power to revisit its previous Orders as necessary, both of the Plaintiffs' Motions are **DENIED** as **MOOT**, because Mr. Gentle is the Claims Administrator for both classes pursuant to Order of the Court dated February 25, 2008.[2]

Next, the Court has considered the Defendants' arguments in the "Motion to Establish Medical Monitoring Settlement Executive Committee" and compared the function of said committee against the recommended plan in the Report and Supplement to the Report. Further, the Court has reviewed the November 19, 2010, Memorandum of Understanding, which outlines several agreed provisions of the medical monitoring plan, and the Stipulation of January 10, 2011. The Defendants now request, in contradiction to the Memorandum of Understanding and prior February 25, 2008, "Order Appointing Claims Administrator," that the ultimate administrative authority for running the medical monitoring plan should rest with a three person panel serving two year terms, with the authority to hire or fire the actual administrator of the plan and the authority to act as an intermediate appeal board for issues regarding exclusion or inclusion of potential class members. The Defendants assert that the power to administer the plan should not be vested in one individual due to the thirty (30) year length of the plan and that control of the plan needs to be "institutional."

The Court understands and appreciates the Defendant's concern with the course of the plan over the next thirty years, but the proposed settlement executive committee is unnecessary. First, the Court notes that Mr. Gentle and his firm have the prior

[2] However, the Parties should note, as further outlined in this Order, the Finance Committee as established by the Court will have many of the responsibilities that the Parties have requested for the proposed settlement executive committees.

Jan. 18. 2011 3:35PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 6

experience and expertise[3] needed to administer this plan, while the members of the proposed committee are unknown and likely would not have the same experience. Second, Mr. Gentle has been involved with this case for more than two (2) years and is ready to begin to administer the plan, while it would take time to form a committee, whose members would need even more time to understand the massive undertaking presented by this case. Third, a committee is unnecessarily expensive because Mr. Gentle can administer the plan with the oversight of the Court as a safeguard. Fourth, the creation of unnecessary committees is better suited to the legislative and executive branches of government. Fifth, the Court alone is the institutional oversight that the Defendants seek; namely, should Mr. Gentle retire, pass away, or commit some malfeasance, the Court will replace him. The Circuit Court has been serving the Citizens of Harrison County since 1863 and, from all indications, will continue to do so for the next thirty (30) years while the medical monitoring plan is implemented.

Mr. Gentle has not been appointed for life, but instead serves under the supervision and direction of the Court. Mr. Gentle, as Special Master and Claims Administrator, answers to the Court, and the Court serves the Citizens of this County and the State of West Virginia. Should the administration of the plan fail to satisfy any

[3] The Court notes that Mr. Gentle has administered large class action settlements for approximately twenty years. Specifically, Mr. Gentle has served as a Special Master for the MDL 926 Court in the Baxter, Bristol, and 3M Breast Implant Settlement since 1992 which has involved more than 1.1 billion dollars, worldwide claimants, and over two hundred thousand (200,000) checks issued to claimants. Additionally, Mr. Gentle has been in charge of more than 1 billion dollars in investments for the Dow Corning breast implant settlement. Next, Mr. Gentle has administered the settlement of a class action over PCB contamination involving more than 18,000 claimants, a fund of approximately 300 million dollars, and the defendants Solutia, Inc., Monsanto Co., and Pharmacia Corporation. Said administration has resulted in more than seventy thousand checks being issued to claimants. *See* Gentle, Edgar C., III, "Administration of the 2003 Tolbert PCB Settlement in Anniston, Alabama: An Attempted Collaborative and Holistic Remedy," 60 Ala. L. Rev. 1249 (2009). Finally, Mr. Gentle is a Rhodes Scholar, and along with his law partner Terry Turner, drafted a complete and revised Constitution for the State of Alabama from 2000 to 2001.

Jan. 18. 2011 3:35PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 7

of the Parties, they may petition the Court to change the administrator of the plan, and as outlined in the settlement, this Court retains jurisdiction over this case, and the Court's decisions are always subject to review by the Supreme Court.

The Court finds that it is critical that the Administrator be answerable to the Court and not subject to influential pressure from one side or the other or subject to deal making by the Parties. To create an executive committee with such vast authority as proposed by the Defendants would be an impermissible delegation of the Court's authority and responsibilities to the Parties. To do so would be tantamount to the inmates running the asylum.

For the foregoing reasons, the Court hereby **DENIES** the Defendants' "Motion to Establish Medical Monitoring Settlement Executive Committee."

Next, the Court **ORDERS** the following as to the establishment of the medical monitoring plan:

a. There shall be an initial enrollment period of six (6) months, beginning no later than **April 15, 2011**, whereby the Claims Administrator, Edgar Gentle, will set up a system for any Plaintiff who is a member of the medical monitoring class to enroll in the medical monitoring program to avail themselves of the future monitoring benefits of the program. During this six (6) month enrollment period, any qualified Member of the Plaintiff Medical Monitoring Class may enroll in the medical monitoring program. No class member shall be entitled to participate in said program unless he or she has enrolled during the initial six (6) month enrollment period. However, if a purported class member submits an application to enroll

Jan. 18. 2011 3:36PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 8

during the six (6) month period and such enrollment is disputed or unclear and a final determination as to the eligibility of the class member is made outside of the six (6) month period, said enrollment shall be retroactive to the application date, assuming that the individual is eligible, and the individual shall have timely enrolled in the Class. As long as the Class Member has continuously lived in the Class Area prior to reaching the minimum residence threshold, a Class Member's number of years of residence in each respective Class Area will be accumulated to determine if the threshold has been met. For example, if a Class Member lived ½ year in Zone 1 and 1 ½ years in Zone 2, he or she would qualify for medical monitoring, having fulfilled 50% of the residency required in each zone.

b. A Finance Committee, comprised of three individuals, including one representative from class counsel, one from Dupont, and the Claims Administrator, Edgar Gentle, shall be created for purposes of advising the Court on the structure and execution of the medical monitoring program. Class Counsel and DuPont shall inform the Court of their respective choices for representatives on the Finance Committee within five (5) days of the entry of this Order.

c. The Finance Committee shall exist for the purpose of providing guidance and advice for the operation of the medical monitoring program. In the event any decision is made by the Claims Administrator with respect to the payment for services or costs in the medical monitoring program to which

Jan. 18. 2011 3:36PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 9

either Party takes exception, then either Party shall have the right to bring such objection or exception to the Court and, if necessary, may appeal the determination of the Court within the West Virginia judicial system.

d. The Finance Committee will provide guidance and, hopefully, will operate in a collaborative fashion to provide an effective and efficient medical monitoring program. In the event that the Finance Committee cannot reach an agreement on how to proceed on any issue before it, final decision making authority shall rest with the Claims Administrator, Edgar Gentle, with such decision(s) reviewable by the Court.

e. The Parties reserve the right to reasonably challenge the enrollment of any class member in the medical monitoring program. With respect to any challenge relevant to the issue of eligibility for enrollment, the challenger shall pay reasonable costs and attorney fees if the challenge is unsuccessful. The Court will hear any disputes as to the inclusion or exclusion of a potential class member.

f. On an annual basis the Court, upon recommendation of the Finance Committee, shall direct DuPont to pay a sum certain that will be set aside for each such calendar year to reasonably secure such expenditures as are reasonably necessary to execute the Medical Monitoring Program, in advance, for such following calendar year. In each subsequent year after the first, DuPont shall be credited with any amounts remaining from the prior year in determining the amount of payment for the subsequent year. Additionally, should there be a monetary shortfall during a calendar year

Jan. 18. 2011 3:36PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 10

due to reasonable expenditures exceeding the budget; the Class Administrator shall petition DuPont for such reasonable and necessary monies as to remedy the shortfall. DuPont shall provide such monies within twenty (20) business days of receipt of the Petition.

g. The program shall be implemented consistent the Court's Order of February 25, 2008, and as modified by the Final Order Approving Settlement and this Order. The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008, with the exception that the duration of the program shall be thirty (30) years in length, and that no routine CT scans shall be performed. CT scans will only be performed as part of the medical monitoring program when a competent physician determines that a CT scan is diagnostically medically necessary as relevant to the possible exposure to heavy metal contamination. Any disputes and/or objections to the necessity of providing a CT scan in a given situation shall be decided by the Claims Administrator with such decision reviewable by this Court.

h. Additionally, after the initial six (6) month sign-up period has concluded and the number of participating Plaintiffs, be they adults or minors, is known, Defendant DuPont, in the ordinary course of its business, shall set aside reasonable reserves as required by applicable law which shall cover the estimated cost of the entire thirty (30) year medical monitoring program.

Jan. 18. 2011 3:36PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 11

i. In regards to the four (4) million dollar ($4,000,000.00) fund specifically ear-marked for cash payments to the medical monitoring class by the Memorandum of Understanding, the Court makes the following Orders:

i. The four (4) million dollar ($4,000,000.00) fund is specifically for the sole benefit of the medical monitoring class and shall provide cash payments to the same, in a form and fashion to be determined by the Finance Committee and Claims Administrator and approved by the Court.

ii. There shall be two separate lists of medical monitoring claimants: the first shall be for only cash payments, and the second shall be for medical monitoring. Class members may sign up for either or both lists.

iii. There shall be no requirement that a medical monitoring class member register for or avail themselves of the medical monitoring program or service in order to receive a cash payment from the medical monitoring fund, provided that class membership is proven.

j. The money to fund the administrative start-up expenses of the medical monitoring program, including providing notice to potential class members, shall come from the four million dollar ($4,000,000.00) Qualified Settlement Fund. The Court finds that the most equitable solution to funding the start up costs of the medical monitoring program is to have only those individuals who are members of the medical

Jan. 18. 2011 3:37PM THOMAS A. BEDELL Chief Judge No. 5033 P. 12

monitoring class shoulder the burden. Distribution of start up expenses from the sixty-six million dollar fund would negatively impact those property class members who do not participate, or are not eligible to participate, in the medical monitoring program.

k. DuPont, by paying the sum of seventy million dollars ($70,000,000.00) as part of the settlement of this matter, has paid in full for any and all start up costs and expenses necessary for the medical monitoring program, and DuPont will not be billed for or responsible for any associated costs or expenses until the testing commences. At that time, consistent with the yearly budget procedure outlined above, DuPont shall fund the medical monitoring program, including administrative costs, on an annual basis. Finally, the Claims Administrator shall attempt to combine administrative expenses between the property and medical monitoring classes to be as cost effective as possible. For such costs that are equally attributable to either class, the Claims Administrator shall establish an equitable ratio to split the costs between the property and medical monitoring classes.

l. Any and all decisions of the Claims Administrator shall be reviewable by this Court, and each Settling Party shall have the right to pursue any and all appeals of this Court's final orders and decisions to the extent such is permissible under West Virginia law.

To accomplish the above stated guidelines, the Claims Administrator, Edgar Gentle, is hereby ORDERED to accomplish the following:

Jan. 18. 2011 3:37PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 13

1. Within ten (10) days after the entry of this Order, the Claims Administrator should submit to the Parties and the Court the proposed Class Member Medical Monitoring registration forms and the recommended criteria for proof of Class Member Medical Monitoring eligibility. To the extent practicable, objective and easily obtained proof of residency in the Class Area for the period necessary to be eligible for Medical Monitoring will be utilized, with source documents such as Class Area voter registration rolls, Class Area ad valorem property tax records, Class Area Medical Clinic patient rolls, and Class Area utility billing records. For children, source documents will include Class Area school registration rolls and Class Area Medical Clinic patient rolls. To the extent possible, such source documents will be kept confidential.

2. Additionally, within ten (10) days after the entry of this Order, the Claims Administrator shall submit a timeline of reasonable goals and dates to accomplish the directives of the Court and any other administrative details that may be necessary to the Parties and the Court, including starting class sign ups on or before April 15, 2011.

3. The putative Class Members shall be given appropriate notice of and information concerning the Medical Monitoring Program's terms. Notice measures shall include a notice mail-out to those putative Class Members which have been identified, and publication of notice in local or prominent West Virginia newspapers. To facilitate notice to putative Class Members living outside the Class Area, the registering Class Members will be asked to complete a questionnaire providing the names and address of relatives and acquaintances known to live or to have previously lived in the Class Area, followed by a notice mail-out to these additional putative Class Members. No additional

Jan. 18. 2011 3:37PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 14

funding beyond the seventy million dollar settlement funds shall be required from DuPont to accomplish these preliminary notices.

4. In order to organize and coordinate the medical monitoring program inside and outside of the Class Area, which will involve the completion of detailed health questionnaires, direct physical examinations, and collection of lab samples for analysis, the Claims Administrator shall create a computer-based data gathering system, with data for all Class Members to be entered into the same database wherever the participating medical provider and Class Member are located. Subject to the terms of a Protective Order, which shall be considered by the Finance Committee and the Claims Administrator and recommended to the Court, and after signing a Confidentiality Agreement, which shall likewise be considered by the Finance Committee and the Claims Administrator and recommended to the Court, the Claims Administrator shall have real time access to the database, and DuPont and Class Counsel shall have access to the database with claimant-specific information redacted and unique identifiers, such as a numbering system, used instead of names.

5. Next, the Claims Administrator shall initiate a bidding process through a Third Party Administrator of health plans who shall be engaged to facilitate identification of a national laboratory or other such vendor to provide out-of-Class Area medical monitoring and in-Class Area medical providers, located in or near the Class Area, to provide medical monitoring in the Class Area, while assuring testing and access to care per the Medical Monitoring Order of February 25, 2008, at page 10. The Third Party Administrator of health plans using the CPT Codes contained in Appendix A to Dr. Werntz's March 30, 2007 Proposed Medical Monitoring, shall negotiate prices charged

Jan. 18. 2011 3:37PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 15

by in-Class Area and out-of-Class Area medical providers, subject to review by the Parties through the Finance Committee and approval by the Claims Administrator and, ultimately, the Court. In the medical monitoring registration process, Class Members living both inside and outside the Class Area will be asked which medical providers they prefer to conduct the testing, which will be a material factor in selecting the providers utilized for medical monitoring along with the lowest cost per unit of testing.

6. The Court has determined that there shall be a Medical Advisory Panel to facilitate the Claims Administrator's quality control audits of the medical monitoring program, and to advise the Claims Administrator and the Court, with input from the Parties, on periodically updating medical monitoring protocols based on scientific and medical developments following the first five years of medical monitoring, as contemplated on page 15, decretal paragraph 1 of the Medical Monitoring Order of February 25, 2008. The Parties, via the Finance Committee, shall have input concerning the appropriate make up of the Medical Advisory Panel, its membership and its specific duties for the Court's review.

7. Next, the Court Orders that the Claims Administrator, Edgar Gentle, establish a Claimants' Advisory Committee, to consist of class members willing and able to provide input as to the administration of the medical monitoring plan. Said Committee shall only have an advisory capacity. The Committee will exist in order to ensure that Class Members are heard in the design and implementation of the Medical Monitoring Program, and other aspects of the Claim Administrator's duties. The Claimants' Advisory Committee shall be established as soon after the Effective Date as practicable, with 5 members to be residents of the Class Area and 4 to be non-residents of the

Jan. 18. 2011 3:38PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 16

Class Area. It is requested that Claimants Advisory Committee nominations be provided by Class Counsel within 15 days after the Effective Date. In nominating potential Committee members, Class Counsel should provide adequate facts to facilitate the Court's determination of each candidate. To the extent practicable, Committee members will be incumbent Class Representatives, and the Parties, via their role on the Finance Committee, will be invited to provide input on the proposed Committee members prior to their selection. The Committee will have an initial organizational meeting with the Court, the Claims Administrator, and the Finance Committee in person, conduct periodic telephonic meetings, and have one annual meeting with the Court, the Claims Administrator and the Parties in person thereafter.

8. In order for the Claims Administrator, in collaboration with the Finance Committee, to prepare the initial budget and administrative actions for the Medical Monitoring Program for review and approval by the Court, the logistics for this aspect of the case should be finalized as soon as practicable. The Claims Administrator shall attempt to find usable office space for lease in the Class Area in or near Spelter and utilize the same office space for both the property and medical monitoring classes.

9. To facilitate efficient utilization of the class funds and to minimize administrative expenses, the Claims Administrator shall look into obtaining living quarters in the Class Area for the first two (2) years of medical monitoring, during which time the Claims Administrator's staff will have an ongoing presence. Such a residence will be more cost effective than a hotel, and create less of a burden on the classes. Additionally, the Claims Administrator shall look into the cost effectiveness of obtaining a vehicle to reduce rental car bills. Said living quarters and/ or administrative vehicle

Jan. 18. 2011 3:38PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 17

shall be discussed by the Finance Committee and recommended by the Claims Administrator to the Court for final approval.

The Court, as noted in the Final Order Approving Settlement, shall retain continuing jurisdiction and the ultimate authority over the administration of this settlement.

Next, because the administration of the property remediation settlement has not yet been brought before the Court, the Claims Administrator is directed to prepare a proposed time line and punch list for the same and submit it to the Parties and the Court within twenty (20) business days of the entry of this Order.

The Court intends to retain the services of the Guardian *ad litem*, Meredith McCarthy, for the purposes of providing legal representation to the minors and incompetents in the classes, assuming that she is still ready and willing to serve. The details and necessary duties of the Guardian *ad litem* can be determined as a need for such services becomes apparent. The Court directs the Finance Committee and the Claims Administrator to orchestrate such necessary services for the classes and provide direction to Mrs. McCarthy. The Guardian *ad litem* shall serve at the previously established rate, or such additional just rate of compensation to be determined by the Finance Committee and the Claims Administrator and paid along with the administrative and start up costs for each of the classes.

Jan. 18. 2011 3:38PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 18

Lastly, pursuant to Rule 54(b) of the West Virginia Rules of Civil Procedure, the Court directs entry of this Order as a Final Order as to the claims and issues above upon an express determination that there is no just reason for delay and upon an express direction for the entry for judgment.

IT IS SO ORDERED.

Finally, it is ORDERED that the Clerk of this Court shall provide certified copies of this Order to the following:

David B. Thomas
James S. Arnold
Stephanie Thacker
Allen Guthrie & Thomas, PLLC
500 Lee St., East, Suite 800
P.O. Box 3394
Charleston, WV 25333-3394

Meredith McCarthy
901 W. Main St.
Bridgeport, WV 26330
Guardian ad litem

Edgar Gentle, III
Gentle, Turner, & Sexton
501 Riverchase Parkway East,
Suite 100
Hoover, AL 35244
Special Master

J. Farrest Taylor
Cochran, Cherry, Givens, Smith,
Lane & Taylor, P.C.
163 West Main St.
Dothan, AL 36301.

ENTER: January 18, 2011

Thomas A. Bedell, Circuit Judge

Jan. 18. 2011 3:39PM THOMAS A. BEDELL, Chief Judge No. 5033 P. 19

VII.

B. Alternative I (CT Rule and CT Scan Verification Form Utilized)

PERRINE DUPONT SETTLEMENT ADMINISTRATION BUDGET NO. 2
SEPTEMBER 1, 2011 THROUGH AUGUST 31, 2012

October 7, 2011 (CT=50%) DRAFT

	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING*	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES)**		D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES##	TOTAL
September 2011	$644,965.13	$159,959.63	$12,592.91	+		$817,517.67
October 2011	$644,965.13	$104,834.63	$13,931.66	+		$763,731.42
November 2011	$644,965.13	$44,542.31	$114,594.30		$48,213.38	$852,315.12
December 2011	$651,051.19	$24,018.75	$229,710.82		$99,779.41	$1,004,560.17
January 2012	$650,919.94	$11,025.00	$230,635.41		$100,193.57	$992,773.92
February 2012	$663,126.19	$0.00	$230,104.57		$99,779.41	$993,010.17
March 2012	$661,944.94	$0.00	$227,837.18		$98,940.12	$988,722.24
April 2012	$1,207,514.44	$0.00	$228,761.76		$99,354.28	$1,535,630.48
May 2012	$1,207,514.44	$0.00	$227,837.18		$98,940.12	$1,534,291.74
June 2012	$1,207,514.44	$0.00	$227,837.18		$98,940.12	$1,534,291.74
July 2012	$1,249,514.44	$35,000.01	$120,644.51		$47,787.93	$1,452,946.89
August 2012	$1,207,514.44	$0.00	$112,719.93		$47,373.76	$1,367,608.13
TOTALS	$10,641,509.85	$379,380.33	$1,977,207.41	#	$839,302.10	$13,837,399.69

+ $26,524.57 in Bridge Funding with ultimate payment obligation (DuPont or original Medical Monitoring Fund deposit) to be determined by the Court.

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont (with caveat in footnote + above).

The total amount includes $41,420 in projected CTI Administrators expenses for a Central Repository for Scientific Research Concerning Test Results, with these projected expenses only being used for the purpose of collecting and maintaining the test results, and NOT to do research, which may be performed by an independent researcher. This issue was resolved by the Court on August 24, 2011, with test results to be stored for consenting claimants.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court. This draft of the Budget estimates that of the 75% of Medical Monitoring claimants that may be eligible to have a CT scan, only 50% of those CT scans may be considered diagnostically medically necessary.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES #	Total
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 5,000.00	$ -		$ 5,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 86,000.00**	**$ -**	**$ -**	**$ 200,550.00**
B. Property Program Only Expenses ***					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00					$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00					$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -			$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**	**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -	$ 50,000.00	$ 11,993.25	+		$ 61,993.25
Medical Provider Medical Monitoring Expenses	$ -		$ -			$ -
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -			$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 55,000.00**	**$ 11,993.25**	+	**$ -**	**$ 66,993.25**
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00				$ 10,000.00
Printing Costs	$ 500.00	$ 500.00				$ 1,000.00
Web Hosting	$ 12.50	$ 12.50				$ 25.00
Claims Office Rent	$ 350.00	$ 350.00				$ 700.00 [1]
Office Cleaning	$ 12.50	$ 12.50				$ 25.00
Copy Machine Rental	$ 200.00	$ 200.00				$ 400.00
Office Insurance	$ 100.00	$ 100.00				$ 200.00
Photocopies	$ 1,250.00	$ 1,250.00				$ 2,500.00
Telecopies	$ 125.00	$ 125.00				$ 250.00
Postage	$ 250.00	$ 250.00				$ 500.00
Federal Express	$ 125.00	$ 125.00				$ 250.00
Office Supplies	$ 250.00	$ 250.00				$ 500.00
Office Equipment	$ 125.00	$ 125.00				$ 250.00
Telephone Service	$ 625.00	$ 625.00				$ 1,250.00
Westlaw Legal Research	$ 75.00	$ 75.00				$ 150.00
Vehicle Insurance and Repairs	$ 100.00	$ 100.00				$ 200.00
Claims Administrator Residence Rent	$ 300.00	$ 300.00				$ 600.00
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50				$ 125.00
Airfare (6 round trips from Alabama)	$ 1,550.00	$ 1,550.00				$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00				$ 360.00
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00				$ 300.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Total Common Expenses	$ 11,342.50	$ 11,342.50	$ -		$ -	$ 22,685.00
E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 7,617.13	$ 599.66	+	$ -	$ 38,929.41
TOTAL of A, B, C, D and E	$ 644,965.13	$ 159,959.63	$ 12,592.91	+	$ -	$ 817,517.66

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

+ After adjusting the estimated number of Medical Monitoring claimants to 3,500, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to 27,300.00 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $775.43, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMTATION DATE CT SCAN INCREMENTAL EXPENSES #	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 2,500.00	$ -		$ 2,500.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 83,500.00**	**$ -**	**$ -**	**$ 198,050.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 ***

Property Program Soil and House Testing Payments	$ 199,860.00		$ -				$ 199,860.00	
Property Clean-up Technical Advisor	$ 25,000.00		$ -				$ 25,000.00	
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**		**$ 488,360.00**	
C. Medical Monitoring Program Only Expenses ****								
Third Party Administrator Fees and Expenses	$ -	$ -	$ 13,268.25	+			$ 13,268.25	2
Medical Provider Medical Monitoring Expenses	$ -		$ -				$ -	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -				$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 5,000.00**	**$ 13,268.25**	**+**	**$ -**		**$ 18,268.25**	
D. Common Expenses Shared by Both Settlement Programs								
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00					$ 10,000.00	
Printing costs	$ 500.00	$ 500.00					$ 1,000.00	
Web Hosting	$ 12.50	$ 12.50					$ 25.00	
Claims Office Rent	$ 350.00	$ 350.00					$ 700.00	1
Office Cleaning	$ 12.50	$ 12.50					$ 25.00	
Copy Machine Rental	$ 200.00	$ 200.00					$ 400.00	
Office Insurance	$ 100.00	$ 100.00					$ 200.00	
Photocopies	$ 1,250.00	$ 1,250.00					$ 2,500.00	
Telecopies	$ 125.00	$ 125.00					$ 250.00	
Postage	$ 250.00	$ 250.00					$ 500.00	
Federal Express	$ 125.00	$ 125.00					$ 250.00	
Office Supplies	$ 250.00	$ 250.00					$ 500.00	
Office Equipment	$ 125.00	$ 125.00					$ 250.00	
Telephone Service	$ 625.00	$ 625.00					$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 75.00					$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 100.00					$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 300.00					$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50					$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 1,550.00					$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00					$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00					$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 11,342.50**	**$ -**		**$ -**		**$ 22,685.00**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 4,992.13	$ 663.41	+	$ -	$ 36,368.16
TOTAL of A, B, C, D and E	$ 644,965.13	$ 104,834.63	$ 13,931.66	+	$ -	$ 763,731.41

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

2. An additional $1,275 in expenses were included for October 2011, January 2012, April 2010, and July 2012 for quarterly meeting attendance expenses.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

+ After adjusting the estimated number of Medical Monitoring claimants to 4,000, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to $28,139.75 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $1,615.18, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 35,500.00	$ 7,251.65	$ 3,248.35	$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 1,250.00	$ -		$ 1,250.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 36,750.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 171,800.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -		$ 10,482.69	$ 4,695.69	$ 15,178.38	
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 33,629.80	$ 108,705.30	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 89,308.19**	**$ 39,575.49**	**$ 128,883.68**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 2,500.00	$ 2,500.00		$ 10,000.00	
Printing Costs	$ 500.00	$ 250.00	$ 250.00		$ 1,000.00	
Web Hosting	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Claims Office Rent	$ 350.00	$ 175.00	$ 175.00		$ 700.00	1
Office Cleaning	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Copy Machine Rental	$ 200.00	$ 100.00	$ 100.00		$ 400.00	
Office Insurance	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Photocopies	$ 1,250.00	$ 625.00	$ 625.00		$ 2,500.00	
Telecopies	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Postage	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Federal Express	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Office Supplies	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Office Equipment	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Telephone Service	$ 625.00	$ 312.50	$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 37.50	$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 150.00	$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 31.25	$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 775.00	$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 90.00	$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 75.00	$ 75.00		$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 5,671.25**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 2,121.06	$ 5,456.87	$ 2,295.88	$ 40,586.43	
TOTAL of A, B, C, D and E	$ 644,965.13	$ 44,542.31	$ 114,594.30	$ 48,213.38	$ 852,315.11	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:25:25 basis between A, Property Remediation ($11,342.50), B, Medical Monitoring (Pre-Implemenation Date) ($5,671.25) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,125.00	$ 22,875.00	$ 7,251.65	$ 3,248.35	$ 79,500.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,675.00**	**$ 22,875.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 158,050.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -		$ 12,866.76	$ 5,763.62	$ 18,630.38	
Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,942.98**	**$ 88,685.99**	**$ 287,628.97**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	$ 31,002.44	$ 1,143.75	$ 10,938.61	$ 4,751.40	$ 47,836.20	
TOTAL of A, B, C, D and E	$ 651,051.19	$ 24,018.75	$ 229,710.82	$ 99,779.41	$ 1,004,560.17	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 10,500.00	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 10,500.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 13,747.32	$ 6,158.06	$ 19,905.38

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 199,823.54**	**$ 89,080.43**	**$ 288,903.97**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 30,996.19**	**$ 525.00**	**$ 10,982.64**	**$ 4,771.12**	**$ 47,274.95**	
TOTAL of A, B, C, D and E	**$ 650,919.94**	**$ 11,025.00**	**$ 230,635.41**	**$ 100,193.57**	**$ 992,773.92**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 12,866.76	$ 5,763.62	$ 18,630.38
Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,942.98**	**$ 88,685.99**	**$ 287,628.97**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Claims Administrator Office Vehicle 1 Year Warranty	$ 1,125.00		$ 375.00		$ 1,500.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 18,138.75**	**$ -**	**$ 6,046.25**	**$ -**	**$ 24,185.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,577.44**	**$ -**	**$ 10,957.36**	**$ 4,751.40**	**$ 47,286.20**	
TOTAL of A, B, C, D and E	**$ 663,126.19**	**$ -**	**$ 230,104.57**	**$ 99,779.41**	**$ 993,010.17**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($18,138.75), B, Medical Monitoring (Pre-Implementation Date) ($1.00) and C, Medical Monitoring (Post Implementation) ($6,046.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00	$ -	$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00	$ -	$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00	$ -	$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 ***

Third Party Administrator Fees and Expenses	$ -	$ -	$ 11,082.34	$ 4,964.29	$ 16,046.63	
Medical Provider Medical Monitoring Expenses	$ -	$ -	$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ -	$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.55**	**$ 87,886.67**	**$ 285,045.22**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,521.19**	**$ -**	**$ 10,849.39**	**$ 4,711.43**	**$ 47,082.01**	
TOTAL of A, B, C, D and E	**$ 661,944.94**	**$ -**	**$ 227,837.18**	**$ 98,940.12**	**$ 988,722.23**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implemenation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00		$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,962.89	$ 5,358.74	$ 17,321.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,039.11**	**$ 88,281.11**	**$ 286,320.22**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,893.42**	**$ 4,731.16**	**$ 73,125.26**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 228,761.76**	**$ 99,354.28**	**$ 1,535,630.48**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**	**$ -**	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,082.34	$ 4,964.29	$ 16,046.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.55**	**$ 87,886.67**	**$ 285,045.22**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,849.39**	**$ 4,711.43**	**$ 73,061.51**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 227,837.18**	**$ 98,940.12**	**$ 1,534,291.73**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
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*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
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PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
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Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
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Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,082.34	$ 4,964.29	$ 16,046.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 81,672.37	$ 263,998.59	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.55**	**$ 87,886.67**	**$ 285,045.22**	
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Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,849.39**	**$ 4,711.43**	**$ 73,061.51**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 227,837.18**	**$ 98,940.12**	**$ 1,534,291.73**	

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
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PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses * **					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ** **					
Third Party Administrator Fees and Expenses	$ -		$ 9,578.14	$ 4,290.49	$ 13,868.63
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 33,629.80	$ 108,705.30

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 88,403.64**	**$ 39,170.29**	**$ 127,573.93**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Audit and Income Tax Return	$ 40,000.00	$ 33,333.34	$ 6,666.66		$ 80,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 57,013.75**	**$ 33,333.34**	**$ 12,337.91**	**$ -**	**$ 102,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 59,500.69**	**$ 1,666.67**	**$ 5,744.98**	**$ 2,275.62**	**$ 69,187.95**	
TOTAL of A, B, C, D and E	**$ 1,249,514.44**	**$ 35,000.01**	**$ 120,644.51**	**$ 47,787.93**	**$ 1,452,946.88**	

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 ***

** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhbit E.
***** For this month, common overhead expenses (excluding Audit and income Tax Return) are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25). Audit and Income Tax Return expenses were split as follows: (1) 50% (or $40,000) charged to the Property Remediation Fund and 50% (or $40,000) charged to the Medical Monitoring Fund; and (2) for the Medical Monitoring Fund, its portion of Audit and Income Tax Return expenses were further split, assessing Medical Monitoring (Pre-Implementation Date) with 8/12 (January 2011 through August 2011) of these expenses and dividing the remaining 4/12 (September 2011 through December 2011) equally between Medical Monitoring (Pre-Implementation Date) and Medical Monitoring (Post-Implementation).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	$ -	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	$ -	$ -	$ -	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 8,697.58	$ 3,896.05	$ 12,593.63
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 33,629.80	$ 108,705.30

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 87,523.08**	**$ 38,775.85**	**$ 126,298.93**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
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Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
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Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
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Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 5,367.62**	**$ 2,255.89**	**$ 65,124.20**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 112,719.93**	**$ 47,373.76**	**$ 1,367,608.13**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

SCHEDULE OF APPENDIX AND EXHIBITS

Appendix A:	Suggested Fees Appendix
Exhibit A:	Detailed Property Program Budget Developed by Claims Administrator and Property Technical Advisor
Exhibit B:	Non-Binding Medical Monitoring Program Third Party Administration Budget Dated October 6, 2011*
Exhibit C:	Medical Monitoring Program Medical Providers Budget Developed by Third Party Administrator*
Exhibit D:	Claims Office Rent Adjustment Substantiation
Exhibit E:	Third Party Administrator and Medical Provider Medical Monitoring Fees and Expenses

* Assumes 4,000 Medical Monitoring claimants.

APPENDIX A

SUGGESTED FEES APPENDIX

A. Claims Office and General Case Administration Services
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)), and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A (Property Remediation Settlement Fund) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation))]

Legal Assistant/Receptionist at Office $50/h x 145	= $ 7,250
Associate Attorney $150/h x 110	= $16,500
Partners $200/h x 15	= $ 3,000
Claims Administrator $250/h x 25	= $ 6,250
	$33,000

B. Database Loading and Programming

1.	$ 80 (blended) /h x 625	= $50,000	[Sep '11 thru Nov '11] 50% to A (Property Remediation Settlement Fund) and 50% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
2.	$ 80 (blended) /h x 468.75	= $37,500	[December 2011] 67% to A (Property Remediation Settlement Fund) and 33% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
3.	$ 80 (blended) /h x 150	= $25,000	[Jan '12 to August '12] 100% to A (Property Remediation Settlement Fund)

C. Tax and Accounting Support
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A and 25% to C]

$150 (blended) /h x 60 = $ 9,000

D. Property Program Soil and House Testing Class Member Checks
4,965 checks for 7 months (September 2011 to March 2012)
@ $5.00/check[1] = $24,825

E. Medical Monitoring Registered Class Member Checks
1,000 checks for September, 500 checks
For October and 250 checks for
November @ $5.00/check[1] = $8,750.00

F. Medical Monitoring Monthly Provisioning

Legal Assistant
$50/h x 7 = $ 350

Accountant
$80/h x 5 = $ 400

Associate Attorney
$150/h x 15 = $ 2,250

Partner
$200/h x 20 = $ 4,000

Claims Administrator
$250/h x 12 = $ 3,000
$10,000

[1] This amount represents the Claims Administrator's estimated costs related to the issuance of a Class Member Property Program Soil and/or House testing check and a Class Member Medical Monitoring check, which includes, but is not limited to, check stock, envelopes, preparation time, postage, and printing. Not included in this amount is the cost of issuing a Federal Form 1099-MISC if the check amount exceeds $600. The Claims Administrator will bill the actual costs; if the actual costs are less than $5 per check, the Claims Administrator will bill the lesser amount.

G. Property Program Oversight (September 2011 Through March 2012)[2]

Legal Assistant	
$50/h x 250	= $ 12,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 200	= $ 30,000
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 65,000

H. Previously Approved Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Cash (October 2011)

Issuance of 5,000 Checks @$5/check	= $25,000
Accountant/Attorney	
$125 (blended) x 100	= $ 12,500
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 50,000

I. Property Program Oversight (April 2012 Through August 2012[2])

Legal Assistant	
$50/h x 370	= $ 18,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 250	= $ 37,500
Partner	
$200/h x 100	= $ 20,000
Claims Administrator	
$250/h x 40	= $ 10,000
	$ 96,000

[2] Under the Property Program, Claimant registration is projected to be from July 2011 through October 10, 2011. Soil and house testing is projected to be from August 2011 through March 2012. Soil remediation is projected to be from April 2012 through March 2013. House remediation is projected to be from April 2013 to March 2015.

EXHIBIT A

Terry D. Turner Jr.

Subject: Perrine Zone v1A; 4609-1-dd

This budget estimate for the Zone 1A Spelter Remediation work is very preliminary. So far we have: Testing, Interior Residential Cleaning, Soil Replacement, and Remediation Project Administration.

1. Testing - 227 homes expending $5,500.00 each for testing and inconvenience has an estimated cost totaling $1,249,000.00

2. Interior Residential Cleaning – 227 homes expending 13,959.58 for Cleaning, additional sampling, and temporary relocation for an estimated cost totaling $3,169,000.00

3. Soil Replacement – Time, materials, for collection, replacement, and disposal has an estimated total cost of $7,482,000.00

4. Project Administration for Zone 1A – Including Project Management. Supervision, Record Keeping, Information Databases, Administration, Bonding and Insurances, and a contingency at an estimated total of $3,410,000.00

The total estimated cost for Zone 1A is $15,308,000.00.

Some detail breakdowns are available, but they have not yet been put into a presentable form.

How detailed do you want to tie these figures down. The Cleaning and soils work is provided by Mr. Marc Glass. The overhead figures are based on percentages, not detailed information. They include 5% Project Management, 4% Supervision, 1% Record Keeping, 1% Informational Databases, 2% Administration, 10% Bonding and Insurance, and a 3% contingency.

Bill Sublett
2853 Avenida De Soto
Navarre, Florida 32566
Phone (850) 485-2643
E-Mail: Sublett01@AOL.com

Preliminary Cost Estimation Zone 1A
Interior Residential Cleaning and Soil Replacement
Perrine Class Area

I. Zone 1A Interior Residential

Zone 1 Interior Clean/Home	12,559.58
Zone 1A Homes	227
	$2,851,024.66
Pre/Post (90-day) Sampling	1,200.00
	$272,400.00
2-day Relocation for Res/Pets	$200.00
	$45,400.00
Total Avg. per Home	$13,959.58
Sub-Total	$3,168,824.66

II. Residential Remediation

Data:

Pre-Qualification Sampling, Excavation 6-inch soil from Residential Lots, Replace, Site Restoration, Post Sample

Number Zone 1A Residential Lots	227
Avg. sq. ft. Residential Lot	9120
Avg. cu. Ft. Residential Lot (6-inch)	4560
Avg. cu. Yd. Residential Lot (6-inch deep)	168.8888889 cubic yard/residential lot
1.35 tons per cubic yard	228 tons soil to remove/replace/residential lot
Total Zone 1A Cubic yard	38,337.7778
Total Zone 1A Tons	51,756.0000 tons soil to remove/replace

Per Res. Lot Time and Material Calculation

Soil transport/disposal	$13,741.56
Soil Backfill Placement	$13,148.76
Labor/Site Restore	$4,912.80
Pre/Post (90-day) Sampling	$1,155.00
Avg. Res. Lot	$32,958.12
Sub-Total	$7,481,493.24

*Estimated Zone 1A On-Site Remediation $10,650,317.90

*On-site estimates based on average per property remediation time and material estimates and are not inclusive of overall project management/supervision, recordkeeping, informational databases, or administration.

EXHIBIT B

October 6, 2011 DRAFT

Projection of CTI Administrators Administrative Fees for the Perrine DuPont Medical Monitoring Program

Description of Fee Component	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Initial Set-Up Fee [1]	$ 6,500	$ 0	$ 0	$ 0	$ 0	$ 6,500
Provider Negotiations of Fees Schedules [2]	$ 0	$ 10,000	$ 0	$ 10,000	$ 0	$ 20,000
Communication Materials [3]	$ 10,805	$ 10,805	$ 10,805	$ 10,805	$ 10,805	$ 54,025
Production/Distribution of Plastic ID Cards [4]	$ 9,160	$ 916	$ 916	$ 916	$ 916	$ 12,824
Administrative Fee per Active Claimant [5]	$ 92,640	$ 91,656	$ 90,539	$ 102,900	$ 101,259	$ 478,994

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[1] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Based on Fee Pricing Schedule provided by CTI Administrators.

[2] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Estimated utilizing blended hourly rates for approximately 48 hours of services with an estimated three service providers from the Fee Pricing Schedule. This is based upon CTI Administrators renegotiating fees every two years.

[3] Based on 26.67% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 4,000 claimants in the Medical Monitoring Program. Dr. Michael Brookshire's May 23, 2007 study of costs for the Medical Monitoring Program utilized a 5% attrition rate each year for claimants, but this was offset by a projected 5% increase each year in materials cost.

[4] Based on 4,000 claimants receiving their ID cards in year one, with the Fee Pricing Schedule showing a cost of $1.85 per claimant and adding $0.44 for postage, and assuming 10% need to be replaced each year.

[5] Based on Fee Pricing Schedule per active claimant and incorporating Dr. Brookshire's 5% attrition rate each year for claimants.

Projection of CTI Administrators Administrative Fees for the Perrine DuPont Medical Monitoring Program

Scheduling/Appointment Reminder Letters [6]	$ 11,040	$ 10,773	$ 10,505	$ 10,239	$ 9,969	$ 52,526
Central Repository for Possible Scientific Research Concerning Test Results [7]	$ 48,323	$ 38,086	$ 37,307	$ 36,509	$ 39,424	$ 199,649
Quarterly Meetings [8]	$ 5,100	$ 5,355	$ 5,623	$ 5,904	$ 6,199	$ 28,181
Consulting Services [9]	$ 14,000	$ 14,700	$ 15,435	$ 16,207	$ 17,017	$ 77,359
Totals	**$ 197,568**	**$ 182,291**	**$ 171,130**	**$ 193,480**	**$ 185,589**	**$ 930,058**

[6] Based on Fee Pricing Schedule, which includes up to three letters to a claimant every other year, with one and a half letters being used for projection purposes each year. This expense also incorporates Dr. Brookshire's 5% attrition rate each year for claimants.

[7] These expenses would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. Based on Fee Pricing Schedule per test per claimant. The expense also utilizes Dr. Brookshire's May 23, 2007 study to determine the approximate amount of claimants that would participate in each of five different tests each year, which include urinary, lungs, plumbism, skin and gastro intestinal.

[8] Based on a combination of the Fee Pricing Schedule and yearly average of travel costs experienced in the Tolbert Healthcare Project, with travel costs being increased by 5% each year. The Court, CTIA, and the Claims Administrator, after consulting with the Finance Committee, may review the need to have quarterly in-person meetings from time to time.

[9] These are described in Agreement Section II, I, on page 15. Based on 50% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 4,000 claimants in the Medical Monitoring Program. It is estimated that consulting services would still be an essential part of the Medical Monitoring Program, thus this cost was not reduced strictly in accordance with the ratio of claimants. Since this expense contains travel expenses, it was also increased by 5% each year.

EXHIBIT C

Assumptions used in budget estimate.

The seven tests, clinical procedures, and number of tests recommended were extracted from the report, Estimate of the present value of medical monitoring costs per 1,000 persons, 2008-2046 by Michael L. Brookshire, Ph.D. dated May 23, 2007. We have outlined the tests to reflect the manner that we believe to be the most effective and least costly.

The cost estimates were made assuming an initial population of **4,000** participants. The population can be adjusted by changing the Number of Participants field (cell L1) in the worksheet "Adult's Testing Protocol". This will also change the "Child Testing Protocol" worksheet calculations.

Estimates for CT Scans also can be adjusted by changing the Estimated Participation cell (cell FGH75) to the percentage thought to be most accurate. I have started with 37.5%. Just replace 37.5% with the % you think to be the most appropriate.

Clinical Procedure Codes (CPT) were derived from the Physicians' Fee Reference PFR 2011, 28th Edition. Dr. Brookshire's report did not include CPT codes so we used our best judgment as to the procedure codes we thought to be most appropriate.

Targeted Fees are the fees we hope to negotiate with the clinics, facilities, and laboratory (Lab Corp). We have a good idea about the various discounts are available in the Spelter area and have an ongoing discount arrangement with LabCorp.

Costs were adjusted for Geographic area. The Geographic Multiplier for the Spelter/Morgantown area is .91.

Details of each test are shown in two separate worksheets; one for the adults & one for the children.

Estimated Costs are for payments to providers of service and do not include administration fees.

Revised First year claim budget projections using above assumptions are:

Children	$106,979	
Adults	$2,067,127	Estimated adult CT Scans @ 37.5%

Claim expenses do not include administration fees.

ADULT TESTING PROTOCOL (age 18 & above)	Number of Participants	4,000	← Change as desired		
Initial Testing	**Procedure Code**	**Description**	**Count Including Redos**	**Targeted Fee**	**Targeted First Year Cost**
1. The first visit to the Clinic will be for the purpose of collecting a urine sample and drawing blood. There will be collection of urine & blood samples. There will be a charge for a 5 minute office visit for established patients and a 10 minute office visit for new patients. Patients will also be given a stool hemocult card that will be sent directly to Lab Corp.					
1.a. Urinary System Tests will be given to age 18 and above.	99201	10 Minute OFFICE VISIT OP NEW	1,878	$60.00	$112,664
	99211	5 Minute OFFICE VISIT OP ESTABLISHED	1,878	$32.00	$60,087
1.b. Plumbism Tests will be given to age 18 and above.					
1.c Urine & blood samples will be sent to LabCorp with	99000	SPECIMEN HANDLING	3,873	$12.00	$46,477
1.d Stool sample cards will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	36415	ROUTINE VENIPUNCTURE	3,745	$10.00	$37,453
2. LabCorp will perform 6 separate procedures for each participant and send the test results (via EDI) to the Physician & to CTI.	81001	URINALYSIS, NONAUTO W/SCOPE	3,873	$3.50	$13,556
3. CTIA will contact participant to obtain release to maintain test results for subsequent analysis.	82274	OCCULT BLOOD, FECES	3,745	$20.00	$74,907
3.a If release to maintain data is not obtained, CTIA will delete test results from it's data base. Test results will still be maintained for/by physician.	82232	ASSAY OF BETA-2 PROTEIN	3,745	$20.00	$74,907
4. Subsequent Redos are also accounted for in this spreadsheet.	82565	ASSAY OF CREATININE	3,745	$2.50	$9,363
	84520	ASSAY OF UREA NITROGEN	3,991	$2.50	$9,977
	83655	ASSAY OF LEAD	3,745	$10.00	$37,453
				Total	**$304,093**

First Consultation by Primary Care Physician	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. The consultation will consist of a Physical Exam, review of laboratory findings, Physical Examination, explanation of the pros & cons of having a CT Scan, and scheduling of additional testing on an as needed basis. 1.a Some of the initial laboratory tests will have to be redone. Costs for these are included in the Initial Testing. 1.b. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be repeated. 1.c. Adults testing positive to the Urinary system tests will require two follow-up consultations with a urologist. These tests will include Cystoscopy with biopsy, and CT Sans of the Abdomen and Pelvis. Some of these tests will have to be redone 1.d. Adults testing positive to the Urinary system tests will require two follow-up consultations with a Urologist. These tests will 1.e. Adults testing positive to the Urinary system tests or the BUN/Creatinine tests will require two follow-up consultations with a Nephrologist. These tests will include repeat Urine-Beta-2 and BUN/Creatinine.	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	1,814	$135.00	$244,890
	99243	40 Minute Office Visit Physical Exam, CT Scan	1,814	$170.00	$308,380
				Total	**$553,270**

Adult Skin Test with Dermatologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be redone.	99242	Consultation with Dermatologist	108	$140.00	$15,120
1.c Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	11100	BIOPSY, SKIN LESION	36	$110.00	$3,960
2. LabCorp will perform tests and send the test results (via EDI) to the Physician & to CTI.	88304	TISSUE EXAM BY PATHOLOGIST	36	$45.00	$1,620
				Total	**$20,700**

Follow-up with Urologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with an Urologist. Half of these patients will require additional testing.	99242	Consultation with Urologist	108	$140.00	$15,120
1.a. Two consultations will be required for each of the patients and two more for each of those requiring additional tests.	88112	CYTOPATH, CELL ENHANCE TECH	108	$32.00	$3,456
1.b Each patient will require a Cytopathology with Biopsy	52000	CYSTOSCOPY	108	$250.00	$27,000
1.c There will be an Outpatient Facility Charge for the Cytopathology	81001	URINALYSIS, NONAUTO W/SCOPE	108	$3.50	$378
1.d There will be a Charge for the Anesthesia	OP Facility	Out Patient Facility Charge	108	$850.00	$91,800
1.e CT Scan of Abdomen & CT Scan of Pelvis	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	108	$350.00	$37,800
1.f Reading of CT Scan of Abdomen & CT Scan of Pelvis	74176	CT Scan Abdomen & Pelvis	108	$350.00	$37,800
1.g CT Scan of of Pelvis	74176.26	Radiologist	108	$110.00	$11,880
1.h Reading of CT Scan of of Pelvis	72192	CT PELVIS W/O DYE	72	$300.00	$21,600
1.i Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	72192.26	Radiologist	72	$100.00	$7,200
1.j CT Scan will be sent to Radiologist with instructions to send test results via EDI to Urologist & to CTIA.					
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.					
3. Radiologist will read CT Scans and send the test results (via???) to the Urologist & to CTI.				**Total**	**$254,034**

Follow-up with Nephrologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with a Nephrologist to test for kidney failure.	99242	Consultation with Nephrologist	288	$140.00	$40,320
1.a. Two consultations will be required for each of the 108 patients.	99000	SPECIMEN HANDLING	144	$12.00	$1,728
1.b Each patient will require a Urinalysis	36415	ROUTINE VENIPUNCTURE	144	$10.00	$1,440
1.c Urine & blood samples will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	81001	URINALYSIS, NONAUTO W/SCOPE	144	$3.50	$504
	84520	ASSAY OF UREA NITROGEN	144	$2.50	$360
1.c. Miscellaneous lab work to determine cause for kidney failure	misc	misc lab work to determine cause of kidney failure	144	$125.00	$18,000
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.				**Total**	**$62,352**

Follow-up with Gastroenterologist & Proctologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the stool sample tests will require follow-up with a Gastroenterologist followed by some patients with a Proctologist. 1.a. A consultation with a Gastroenterologist will be required for each patient. 1.b Each patient will require another Stool Sample Test 1.c. A consultation with a Proctologist will be required for some patients. 1.d Each patient will require another Stool Sample Test & an Upper GI Endoscopy. 2. LabCorp will perform tests and send the test results (via EDI) to the Gastroenterologist, Proctologist, & to CTI.	99242	Consultation with Gastroenterologist	181	$140.00	$25,387
	82274	OCCULT BLOOD, FECES	181	$20.00	$3,627
	99242	Consultation with Proctologist	27	$160.00	$4,267
	82274	OCCULT BLOOD, FECES	27	$20.00	$533
	43239	UPPER GI ENDOSCOPY, BIOPSY	27	$350.00	$9,333
	OP Facility	Out Patient Facility Charge	1	$850.00	$826
	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	1	$350.00	$340
				Total	**$43,973**

Follow-up with Toxicologist & Psychologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the lead blood tests will require follow-up with a Medical Toxicologist followed by some patients with a Psychologist. 1.a. Four consultations with a Medical Toxicologist will be required for each patients. 1.b. Each patient will require a complete blood count, lead, and zinc test. 1.c. Four one-hour tests with a Psychologist will be required for each of the 131 patients & 33 retests. (856 hours) 2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.	99242	Consultation with Toxicologist	283	$140.00	$39,573
	36415	ROUTINE VENIPUNCTURE	71	$10.00	$707
	85025	COMPLETE CBC W/AUTO DIFF WBC	71	$4.00	$283
	84202	ASSAY RBC PROTOPORPHYRIN	71	$10.00	$707
	83655	ASSAY OF LEAD	71	$10.00	$707
	96118	NEUROPSYCH TST BY PSYCH/PHYS	1,141	$100.00	$114,133
				Total	**$156,109**

Adult CT Scans with Cardiologist, & Pulmonologist	Estimated Participation (change as desired)		Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
	37.50%	←	Change as desired				
1. There are 67% adults in the population of participants over age 35. The percentage of CT Scans will be as indicated in the cell Estimated Participation. 1.a. 40% of the initial CT Scans will need to be repeated 1.b. Each patient will require a complete blood count, lead, and zinc test. 1.c. Four one-hour consultations with a Pulmonologist will be required for each patient. 2. LabCorp will perform tests and send the test results (via EDI) to the Cardiologist & Pulmonologist, & to CTI.			71250	CT THORAX W/O DYE	1,005	$300.00	$301,500
			71250.26	CT THORAX W/O DYE	1,005	$100.00	$100,500
			71250	Repeat CT Scan of Chest	402	$300.00	$120,600
			71250.26	Repeat CT Scan of Chest	402	$100.00	$40,200
			99242	Consultation with Pulmonologist	101	$140.00	$14,070
			99242	Consultation with Cardiologist	50	$140.00	$7,035
			99242	Consultation with General Surgeon	18	$140.00	$2,462
			32095	BIOPSY THROUGH CHEST WALL	18	$425.00	$7,475
			OP Facility	Out Patient Facility Charge	18	$850.00	$14,949
			00910	ANESTH, (3base @$70 + time)	18	$350.00	$6,156
			99242	Consultation with Pulmonologist	33	$140.00	$4,573
			32095	BIOPSY THROUGH CHEST WALL	33	$425.00	$13,882
			OP Facility	Out Patient Facility Charge	33	$850.00	$27,763
			00910	ANESTH, (3base @$70 + time)	33	$350.00	$11,432
						Total	$672,596

cap Using Targeted Fees	
Initial Testing	$304,093
First Consultation by Primary Care Physician	$553,270
Adult Skin Test	$20,700
Follow-up with Urologist	$254,034
Follow-up with Nephrologist	$62,352
Follow-up with Gastroenterologist & Proctologist	$43,973
Follow-up with Toxicologist & Psychologist	$156,109
Adult CT Scans with Pulmonologist, Cardiologist, & Pulmonologist	$672,596
CT Scan participation estimated at 37.50%	**$2,067,127**

Procedure Code	Number of Procedures Every Other Year
81001	4,125
82270	0
82232	3,745
82565	3,745
84520	4,135
83655	3,816
88304	36
88112	108
85025	71
84202	71

CHILD TESTING PROTOCOL

Initial Testing

1. The first visit to the Clinic will be for the purpose of collecting urine & blood samples. There will be a charge for a 5 minute office visit for established patients and a 10 minute office visit for new patients.

    1.a. Plumbism Tests will be given to age 18 and below.

    1.b. Urine Tests will be given to age 15 -18.

    1.b Blood samples will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.

2. LabCorp will perform 3 separate procedures for each participant and send the test results (via EDI) to the Physician & to CTI.
3. CTIA will contact participant to obtain release to maintain test results for subsequent analysis.

    3.a If release to maintain data is not obtained, CTIA will delete test results from it's data base. Test results will still be maintained for/by physician.

4. Subsequent Redos are also accounted for in this spreadsheet.

			4,000		
	Procedure Code	**Description**	**Count Including Redos**	**Targeted Fee**	**Targeted First Year Cost**
	99201	10 Minute OFFICE VISIT OP NEW	294	$60.00	$17,640
	99211	5 Minute OFFICE VISIT OP ESTABLISHED	294	$32.00	$9,408
	36415	ROUTINE VENIPUNCTURE	588	$10.00	$5,880
	81001	URINALYSIS, NONAUTO W/SCOPE	118	$3.50	$412
	83655	ASSAY OF LEAD	588	$10.00	$5,880
	82232	ASSAY OF BETA-2 PROTEIN	588	$20.00	$11,760
	82565	ASSAY OF CREATININE	588	$2.50	$1,470
				Total	**$19,522**

First Consultation by Primary Care Physician	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. The consultation will consist of a Physical Exam, review of laboratory findings, & and scheduling of additional testing on an as needed basis. There will be no consultation regarding CT Scans.	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	294	$135.00	$39,690
1.a Some of the initial laboratory tests will have to be redone. Costs for these are included in the Initial Testing.	99243	40 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	294	$170.00	$49,980
				Total	**$49,980**

Follow-up with Toxicologist & Psychologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1.Children testing positive to the lead blood tests (53) will require follow-up with a Medical Toxicologist followed by another 131 patients with a Psychologist.	99242	Consultation with Toxicologist	224	$135.00	$30,240
1.a. Four consultations with a Medical Toxicologist will be required for each of the 42 patients. (212 total)	36415	ROUTINE VENIPUNCTURE	56	$10.00	$560
1.b. Each patient will require a complete blood count, lead, and zinc test.	85025	COMPLETE CBC W/AUTO DIFF WBC	56	$4.00	$224
1.c. Four one-hour tests with a Psychologist will be required for each of the 8 patients & 2 retests. (10 hours)	84202	ASSAY RBC PROTOPORPHYRIN	56	$10.00	$560
	83655	ASSAY OF LEAD	56	$10.00	$560
2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.	96118	NEUROPSYCH TST BY PSYCH/PHYS	53	$100.00	$5,333
				Total	**$37,477**

Child Testing Recap Using Targeted Fees	
Initial Testing	$19,522
First Consultation by Primary Care Physician	$49,980
Follow-up with Toxicologist & Psychologist	$37,477
Total	**$106,979**

Procedure Code	Number of Procedures Every Other Year
81001	118
82272	0
82232	588
82565	588
84520	0
83655	644
88304	0
88112	0
85025	56
84202	56

EXHIBIT D

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $240.29

Due Date MAY 13, 2010

Rate Code/Schedule 003/E Check Digit 0801 Page 1 of 1

port an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related ions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present APR 22, 2010 - Actual Reading	30105
Previous MAR 18, 2010 - Estimated Reading	27531
Total KWH Used for 35 Days	2574

Allegheny Power

Balance Last Bill	347.87
Payment - MAR 25, 2010	347.87 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 2574 KWH	230.71
Environmental Control Charge	9.58
Current Charges	$240.29

TOTAL AMOUNT DUE $240.29

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2009	03/18/2010	04/22/2010
	35	29	35
	4700	3767	2574
ng Type	Actual	Estimated	Actual
aily Usg	134	130	74
amp	45	33	50
aily Cost	$11.48	$12.00	$6.87
thly Usg	5276	4880	4697
nth Usg	63048	58256	58130

neter reading will be estimated, see back of provide a customer reading between 16, 2010 and MAY 17, 2010.

Paid 4-26-10 CK# 3123

MEMORANDUM

TO: Edgar C. Gentle, III, Esq.

FROM: Terry D. Turner, Jr., Esq.

DATE: August 31, 2011

RE: **Perrine-DuPont Settlement - DuPont Objections; Our File Nos. 4609-1 {R}, {NN} and {GG-1}**

The purpose of this memorandum is provide you with my critique of the Objections of E. I. DuPont De Nemours and Company to Proposed Second Budget and Proposed Order Regarding Same (the "DuPont Objections") filed by DuPont on August 19, 2011 and attached. The following paragraph numbers correspond to the paragraph numbers contained in the DuPont Objections.

2. DuPont states that the draft Budget is not based on actual numbers or negotiated testing rates. The Claims Administrator has experience in this area to provide an educated estimate on the projected budgetary expenses, and the Third Party Administrator is well qualified to provide a projection on testing rates.

9. DuPont cites the January 18, 2011 Order concerning the setting aside of reasonable reserves to cover the estimated cost of the medical monitoring program, although this can be viewed as a separate matter from actually funding the year Budget in advance.

11. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

15. This appears to address the Bridge Funding issue, to be briefed then decided by the Court.

19. The Budget does not assume that all active claimants will come in at once during the first year, it is based on a 75% show-up rate.

20. The attached Budget summary of projected expenses shows that we estimate a total of $4,535,873.12 in Medical Monitoring Program post-implementation date expenses. Of this amount, $480,963.66 represents administrative expenses (excluding FASB 5 Contingency Reserve amounts), which is 10.60% of the projected Medical Monitoring Program post-implementation date expenses. The FASB 5 Contingency Reserve is not only for possible additional administrative expenses, but is a general contingency for any other under-projected expenses.

In our latest draft of the proposed Budget, we have segregated CT scan costs and incremental administrative costs related thereto (excluding common expenses so it is not a fully-allocated cost

projection). We also allocated an additional $52,123.77 of the administrative expenses to CT scan related administrative expenses (taking into account reasonably foreseen future litigation expenses, design costs, and extraordinary administrative costs in administering this part of the Medical Monitoring Program), so that the Medical Monitoring Settlement Fund - Post September 1, 2011 Implementation Date Expenses (Excluding CT Scan Expenses) administrative expenses would equal approximately 10.36%.

Of the total medical monitoring program post-implementation date administrative expenses totaling $480,963.66 (excluding FASB 5 expenses), (i) $249,477.63, or 10.36%, of the $2,407,835.93 post-implementation date expenses (excluding CT scan expenses) represent administrative expenses; and (ii) $231,486.03, or 10.88%, of the $2,128,037.19 post-implementation date CT scan expenses represent administrative costs.

Finally, concerning Dr. Brookshire's administrative expense estimate, it may be that Dr. Brookshire estimated a 10% administrative fee rate for the Third Party Administrator, not Claims Administrator and Claims Office costs. In fact, the Third Party Administrative costs are now at 4.15%. Dr. Brookshire also assumed that implementation of the Medical Monitoring Plan would be non-controversial, absent complications respecting the CT Scan.

In a call with the Finance Committee on August 31, 2011, a question was asked about including Guardian Ad Litem fees in the CT Scan portion of the budget. Although the Guardian Ad Litem represents children, they will ultimately become adults who are CT Scan eligible, so we believe Guardian Ad Litem participation is appropriate. We split her budgeted fees as follows: 75% for Non-CT Scan Budget and 25% for CT Scan Budget.

Should you need anything further, please let me know.

TDTjr/
Attachment

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number	3 10 10 454 08150 2
Amount Due	$347.33
Due Date	JUN 08, 2010
Rate Code/Schedule 003/S	Check Digit 0825

ort an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related ons, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

average cost per day is higher than your ious bill. This may be due to temperature ge, estimated reading or customer controlled e change.

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863167

Present MAY 18, 2010 - Estimated Reading	33866
Previous APR 22, 2010 - Actual Reading	30105
Total KWH Used for 26 Days	3761

Allegheny Power

Balance Last Bill	240.29
Payment - APR 27, 2010	240.29 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3761 KWH	333.34
Environmental Control Charge	13.99
Current Charges	$347.33

TOTAL AMOUNT DUE **$347.33**

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	05/18/2009	04/22/2010	05/18/2010
	26	35	26
	4069	2574	3761
ng Type	Estimated	Actual	Estimated
ily Usg	157	74	145
amp	58	50	57
ily Cost	$13.42	$6.67	$13.36
thly Usg	5215	4697	4666
nth Usg	62422	58130	55822

meter reading is scheduled for JUN 17, 2010.

Paid 5-21-10 CK# 3140

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $703.68

Due Date JUL 15, 2010

Rate Code/Schedule 003/8 Check Digit 0816 Page 1 of 1

port an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related tions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

ir average cost per day is higher than your vious bill. This may be due to temperature nge, estimated reading or customer controlled ge change.

i now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2010 - Actual Reading	41578
Previous MAY 18, 2010 - Estimated Reading	33866
Total KWH Used for 35 Days	7712

Allegheny Power

Balance Last Bill	347.33
Payment - MAY 22, 2010	347.33 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 7712 KWH	674.99
Environmental Control Charge	28.69
Current Charges	$703.68

TOTAL AMOUNT DUE $703.68

Corrected Bill

Paid 6-27-10
CK# 3161

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	06/22/2009	05/18/2010	06/22/2010
	35	26	35
	6620	3761	7712
ling Type	Actual	Estimated	Actual
Daily Usg	189	145	220
Temp	66	57	68
Daily Cost	$16.08	$13.36	$20.11
Mthly Usg	5307	4666	4758
onth Usg	63685	55822	58914

: meter reading will be estimated, see back of o provide a customer reading between 17, 2010 and JUL 18, 2010.

MonPower
A FirstEnergy Company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $360.42

Due Date MAY 16, 2011

Rate Code/Schedule 003/B Check Digit 0810

port an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call
ave from 7:00 a.m. until 6:00 p.m.

Important Information

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present APR 18, 2011 - Estimated Reading	83798
Previous MAR 18, 2011 - Estimated Reading	79990
Total KWH Used for 31 Days	3808

Mon Power

Balance Last Bill	285.90
Payment - MAR 25, 2011	285.90 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3808 KWH	347.36
Environmental Control Charge	13.06
Current Charges	$360.42

TOTAL AMOUNT DUE $360.42

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2010	03/18/2011	04/18/2011
	35	24	31
	2574	3020	3808
ng Type	Actual	Estimated	Estimated
ally Usg	74	126	123
emp	50	41	47
ally Cost	$6.67	$11.91	$11.63
thly Usg	4697	4382	4544
nth Usg	56130	52459	54288

neter reading will be estimated, see back of
provide a customer reading between
6, 2011 and MAY 17, 2011.

Paid 4-27-11 CK # 3347

MonPower
A FirstEnergy Company

Name	SPELTER VOL FIRE DEPT	Account Number	3 10 16 454 08150 2
Service Address	55 B ST SPELTER WV 26438	Amount Due	$865.21
	Non-Residential	Due Date	JUL 13, 2011
		Rate Code/Schedule 003/B	Check Digit 0962

To report an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

Your average cost per day is higher than your previous bill. This may be due to temperature change, estimated reading or customer controlled usage change.

You now have the option of enrolling in PowerPay, our direct payment plan, by signing the back of the bill stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2011 - Actual Reading	98723
Previous MAY 18, 2011 - Estimated Reading	89440
Total KWH Used for 35 Days	9283

Mon Power

Balance Last Bill	529.51
Payment - MAY 24, 2011	529.51 C
Balance Remaining	$0.00
Current Charges:	
Base Charge for 9283 KWH	833.37
Environmental Control Charge	31.84
Current Charges	$865.21

TOTAL AMOUNT DUE $865.21

Paid 6-17-11 CK# 3388

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
Date	06/22/2010	05/18/2011	06/22/2011
Days	35	30	35
KWH	7712	5642	9283
Reading Type	Actual	Estimated	Actual
Avg Daily Usg	220	188	265
Avg Temp	88	56	67
Avg Daily Cost	$20.11	$17.65	$24.72
Avg Mthly Usg	4758	4636	4788
12 Month Usg	56914	55574	57145

Next meter reading will be estimated, see back of bill to provide a customer reading between JUL 17, 2011 and JUL 18, 2011.

EXHIBIT E

THIRD PARTY ADMINISTRATOR AND MEDICAL PROVIDER MEDICAL MONITORING FEES AND EXPENSES

The Third Party Administrator (the "TPA") and the Medical Provider Medical Monitoring fees and expenses are based on the assumption that there will be 4,000 Medical Monitoring claimants, based on the non-binding projection attached as Exhibit B. The Medical Provider Medical Monitoring fees and expenses for the Budget period are projected by the Third Party Administrator at $2,174,106 for 4,000 Medical Monitoring claimants, and we have adjusted the Medical Monitoring Medical Provider fees and expenses projection downward from $3,813,654 (based on our September 1, 2011 draft Budget projection) to $2,174,106, with these amounts being projected utilizing the following assumptions: (1) Dr. Michael L. Brookshire's Expert Report estimated that only 75% of the Medical Monitoring claimants would show up for their tests; (2) we are estimating that of the 75% of Medical Monitoring claimants that may be eligible to have a CT scan, only 50% of those CT scans may be considered diagnostically medically necessary; and (3) 67% of the adult population is 35 or older (acquired by reviewing the Medical Monitoring Registration Forms received to date) and may be eligible for CT scans. Our estimate for the projected number of CT scans is predicated on Section 3(c) of the Memorandum of Understanding (the "MOU") that no routine CT scans shall be performed as part of the medical monitoring program, although the Defendant shall provide CT scans that are diagnostically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in the litigation. In accordance with Section 3 of the MOU between the Parties, the Defendant shall provide a medical monitoring program for all enrolled Plaintiffs on a pay-as-you-go basis, paying a sum certain each calendar year that reasonably secures such medical monitoring expenses for each such calendar year and, if the sum certain is not sufficient for payment of anticipated medical monitoring expenses, the Defendant shall make an additional payment to reasonably secure such medical monitoring expenses for the calendar year. It is estimated that the additional Third Party Administrator and Medical Provider fees and expense for each additional Medical Monitoring claimant over 4,000 total claimants per year would equal $592.96 per claimant[1].

Medical Provider Medical Monitoring Expenses: Because the TPA projects dividing the Medical Monitoring claimants into 4 groups for testing during the months of November 2011 through February 2012, we have allocated the projected Budget period Medical Provider Medical Monitoring Expenses of $2,174,106 as follows: (i) 5% of the total (or $108,705.30) allocated to November 2011 (the beginning of testing); (ii) 5% of the total (or $108,705.30) each to July 2012 and August 2012; and (iii) the remaining 85% (or $1,847,990.10) was allocated evenly among the months of December 2011 through June 2011.

The Medical Provider Medical Monitoring Expenses include estimated CT scan and consultation expenses totalling $672,596. The budgeted amount for CT scan expenses is in dispute among the Parties, thus, we have separated these CT scan expenses and the related administrative expenses into a separate Budget column, column D.

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[1] Of this amount, $168.15 represents the additional testing cost per Medical Monitoring claimant per year related to CT scans.

Third Party Administrator Fees and Expenses: Included within Third Party Administrator Fees and Expenses are $48,324 in expenses during the Budget period for a Central Repository for Scientific Research Concerning Test Results and would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. For the Budget period, these Central Repository expenses were allocated based upon the same method as Medical Provider Medical Monitoring Expenses, discussed above.

As for the remaining Third Party Administrator Fees and Expenses: (i) those expenses that are claimant sensitive (Communication Materials, Production/Distribution of ID Cards, and Scheduling/Appointment Reminder Letters) were allocated during the Budget year with 75% of the Budget year expense split evenly among the first 6 months, and 25% of the Budget year expenses shared evenly among the remaining six months; (ii) the Administrative Fee Per Active Claimant and Consulting Services expenses were allocated evenly each month throughout the Budget year; and (iii) the Quarterly Meetings expenses were allocated quarterly during the months of October 2011, January 2012, April 2012, and July 2012.

VII.

C. Alternative II (Baseline CT Scans)

PERRINE DUPONT SETTLEMENT ADMINISTRATION BUDGET NO. 2
SEPTEMBER 1, 2011 THROUGH AUGUST 31, 2012

October 7, 2011 (CT=75%) DRAFT

	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING*	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES)**		D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES##	TOTAL
September 2011	$644,965.13	$159,959.63	$12,592.91	+		$817,517.67
October 2011	$644,965.13	$104,834.63	$13,931.66	+		$763,731.42
November 2011	$644,965.13	$44,542.31	$114,594.30		$65,869.02	$869,970.76
December 2011	$651,051.19	$24,018.75	$229,710.82		$142,657.40	$1,047,438.16
January 2012	$650,919.94	$11,025.00	$230,635.41		$143,071.56	$1,035,651.91
February 2012	$663,126.19	$0.00	$230,104.57		$142,657.40	$1,035,888.16
March 2012	$661,944.94	$0.00	$227,837.18		$141,818.10	$1,031,600.22
April 2012	$1,207,514.44	$0.00	$228,761.76		$142,232.27	$1,578,508.47
May 2012	$1,207,514.44	$0.00	$227,837.18		$141,818.10	$1,577,169.72
June 2012	$1,207,514.44	$0.00	$227,837.18		$141,818.10	$1,577,169.72
July 2012	$1,249,514.44	$35,000.01	$120,644.51		$65,443.57	$1,470,602.53
August 2012	$1,207,514.44	$0.00	$112,719.93		$65,029.41	$1,385,263.78
TOTALS	$10,641,509.85	$379,380.33	$1,977,207.41	#	$1,192,414.93	$14,190,512.52

+ $26,524.57 in Bridge Funding with ultimate payment obligation (DuPont or original Medical Monitoring Fund deposit) to be determined by the Court.

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont (with caveat in footnote + above).

The total amount includes $41,420 in projected CTI Administrators expenses for a Central Repository for Scientific Research Concerning Test Results, with these projected expenses only being used for the purpose of collecting and maintaining the test results, and NOT to do research, which may be performed by an independent researcher. This issue was resolved by the Court on August 24, 2011, with test results to be stored for consenting claimants.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court. This draft of the Budget estimates that of the 75% of Medical Monitoring claimants that may be eligible to have a CT scan, only 75% of those CT scans may be considered diagnostically medically necessary.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES #	Total
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 5,000.00	$ -		$ 5,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 86,000.00**	**$ -**	**$ -**	**$ 200,550.00**
B. Property Program Only Expenses ***					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 ***

Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00					$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00					$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -			$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**	**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -	$ 50,000.00	$ 11,993.25	+		$ 61,993.25
Medical Provider Medical Monitoring Expenses	$ -		$ -			$ -
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -			$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 55,000.00**	**$ 11,993.25**	+	**$ -**	**$ 66,993.25**
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00				$ 10,000.00
Printing Costs	$ 500.00	$ 500.00				$ 1,000.00
Web Hosting	$ 12.50	$ 12.50				$ 25.00
Claims Office Rent	$ 350.00	$ 350.00				$ 700.00 [1]
Office Cleaning	$ 12.50	$ 12.50				$ 25.00
Copy Machine Rental	$ 200.00	$ 200.00				$ 400.00
Office Insurance	$ 100.00	$ 100.00				$ 200.00
Photocopies	$ 1,250.00	$ 1,250.00				$ 2,500.00
Telecopies	$ 125.00	$ 125.00				$ 250.00
Postage	$ 250.00	$ 250.00				$ 500.00
Federal Express	$ 125.00	$ 125.00				$ 250.00
Office Supplies	$ 250.00	$ 250.00				$ 500.00
Office Equipment	$ 125.00	$ 125.00				$ 250.00
Telephone Service	$ 625.00	$ 625.00				$ 1,250.00
Westlaw Legal Research	$ 75.00	$ 75.00				$ 150.00
Vehicle Insurance and Repairs	$ 100.00	$ 100.00				$ 200.00
Claims Administrator Residence Rent	$ 300.00	$ 300.00				$ 600.00
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50				$ 125.00
Airfare (6 round trips from Alabama)	$ 1,550.00	$ 1,550.00				$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00				$ 360.00
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00				$ 300.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

SEPTEMBER 2011 *****

Total Common Expenses	$ 11,342.50	$ 11,342.50	$ -		$ -	$ 22,685.00
E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 7,617.13	$ 599.66	+	$ -	$ 38,929.41
TOTAL of A, B, C, D and E	$ 644,965.13	$ 159,959.63	$ 12,592.91	+	$ -	$ 817,517.66

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

+ After adjusting the estimated number of Medical Monitoring claimants to 3,500, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to 27,300.00 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $775.43, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMTATION DATE CT SCAN INCREMENTAL EXPENSES #	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 46,000.00	$ -		$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 2,500.00	$ -		$ 2,500.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ 10,000.00	$ -		$ 10,000.00
Previously Approved Claims Administrator Legal Fees for Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Class Member Cash	$ -	$ 25,000.00	$ -		$ 25,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 83,500.00**	**$ -**	**$ -**	**$ 198,050.00**
B. Property Program Only Expenses * **					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 ***

Property Program Soil and House Testing Payments	$ 199,860.00		$ -			$ 199,860.00	
Property Clean-up Technical Advisor	$ 25,000.00		$ -			$ 25,000.00	
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ -**	**$ 488,360.00**	
C. Medical Monitoring Program Only Expenses ****							
Third Party Administrator Fees and Expenses	$ -	$ -	$ 13,268.25	+		$ 13,268.25	[2]
Medical Provider Medical Monitoring Expenses	$ -		$ -			$ -	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ 5,000.00	$ -			$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ 5,000.00**	**$ 13,268.25**	+	**$ -**	**$ 18,268.25**	
D. Common Expenses Shared by Both Settlement Programs							
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 5,000.00				$ 10,000.00	
Printing costs	$ 500.00	$ 500.00				$ 1,000.00	
Web Hosting	$ 12.50	$ 12.50				$ 25.00	
Claims Office Rent	$ 350.00	$ 350.00				$ 700.00	[1]
Office Cleaning	$ 12.50	$ 12.50				$ 25.00	
Copy Machine Rental	$ 200.00	$ 200.00				$ 400.00	
Office Insurance	$ 100.00	$ 100.00				$ 200.00	
Photocopies	$ 1,250.00	$ 1,250.00				$ 2,500.00	
Telecopies	$ 125.00	$ 125.00				$ 250.00	
Postage	$ 250.00	$ 250.00				$ 500.00	
Federal Express	$ 125.00	$ 125.00				$ 250.00	
Office Supplies	$ 250.00	$ 250.00				$ 500.00	
Office Equipment	$ 125.00	$ 125.00				$ 250.00	
Telephone Service	$ 625.00	$ 625.00				$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 75.00				$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 100.00				$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 300.00				$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 62.50				$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 1,550.00				$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 180.00				$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 150.00				$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 11,342.50**	**$ -**		**$ -**	**$ 22,685.00**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

OCTOBER 2011 *****

E. FASB 5 Contingency Reserve (5% of above accounts)	$ 30,712.63	$ 4,992.13	$ 663.41	+	$ -	$ 36,368.16
TOTAL of A, B, C, D and E	$ 644,965.13	$ 104,834.63	$ 13,931.66	+	$ -	$ 763,731.41

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of

remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:50 basis between A, Property Remediation ($11,342.50) and B, Medical Monitoring (Pre-Implementation Date) ($11,342.50).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

2. An additional $1,275 in expenses were included for October 2011, January 2012, April 2010, and July 2012 for quarterly meeting attendance expenses.

The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

+ After adjusting the estimated number of Medical Monitoring claimants to 4,000, the projected TPA pre-Implementation Date Medical Monitoring claimant preparation services during September and October 2011 increased from $26,524.57 to $28,139.75 (including the 5% FASB 5 Reserve). We anticipate that the FASB 5 Reserve for September and October 2011 should be sufficient to fund this additional amount of $1,615.18, so we have excluded this additional amount from the Budget and it will not affect the requested Bridge Funding amount.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 35,500.00	$ 7,251.65	$ 3,248.35	$ 92,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00				$ 3,550.00
Claims Administrator Medical Monitoring Registered Class Member Check Issuance Fees	$ -	$ 1,250.00	$ -		$ 1,250.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00		$ -		$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 36,750.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 171,800.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -		$ 10,482.69	$ 4,695.69	$ 15,178.38	
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 50,444.70	$ 125,520.20	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 89,308.19**	**$ 56,390.39**	**$ 145,698.58**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 5,000.00	$ 2,500.00	$ 2,500.00		$ 10,000.00	
Printing Costs	$ 500.00	$ 250.00	$ 250.00		$ 1,000.00	
Web Hosting	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Claims Office Rent	$ 350.00	$ 175.00	$ 175.00		$ 700.00	[1]
Office Cleaning	$ 12.50	$ 6.25	$ 6.25		$ 25.00	
Copy Machine Rental	$ 200.00	$ 100.00	$ 100.00		$ 400.00	
Office Insurance	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Photocopies	$ 1,250.00	$ 625.00	$ 625.00		$ 2,500.00	
Telecopies	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Postage	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Federal Express	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Office Supplies	$ 250.00	$ 125.00	$ 125.00		$ 500.00	
Office Equipment	$ 125.00	$ 62.50	$ 62.50		$ 250.00	
Telephone Service	$ 625.00	$ 312.50	$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 75.00	$ 37.50	$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 100.00	$ 50.00	$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 300.00	$ 150.00	$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 62.50	$ 31.25	$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 1,550.00	$ 775.00	$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 180.00	$ 90.00	$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 150.00	$ 75.00	$ 75.00		$ 300.00	
Total Common Expenses	**$ 11,342.50**	**$ 5,671.25**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 30,712.63**	**$ 2,121.06**	**$ 5,456.87**	**$ 3,136.62**	**$ 41,427.18**	
TOTAL of A, B, C, D and E	**$ 644,965.13**	**$ 44,542.31**	**$ 114,594.30**	**$ 65,869.03**	**$ 869,970.76**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

NOVEMBER 2011 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

** To be funded by an additional contribution by DuPont.

*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.

**** See Exhibit E.

***** For this month, common overhead expenses are split on a 50:25:25 basis between A, Property Remediation ($11,342.50), B, Medical Monitoring (Pre-Implemenation Date) ($5,671.25) and C, Medical Monitoring (Post Implementation) ($5,671.25).

1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.

The amount of these CT Scan expenses is unresolved and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,125.00	$ 22,875.00	$ 7,251.65	$ 3,248.35	$ 79,500.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,675.00**	**$ 22,875.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 158,050.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**	**$ -**	**$ 488,360.00**

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 *****

C. Medical Monitoring Program Only Expenses ****						
Third Party Administrator Fees and Expenses	$ -		$ 12,866.76	$ 5,763.62	$ 18,630.38	
Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,942.98**	**$ 129,522.17**	**$ 328,465.15**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,002.44**	**$ 1,143.75**	**$ 10,938.61**	**$ 6,793.21**	**$ 49,878.01**	
TOTAL of A, B, C, D and E	**$ 651,051.19**	**$ 24,018.75**	**$ 229,710.82**	**$ 142,657.40**	**$ 1,047,438.16**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

DECEMBER 2011 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 46,000.00	$ 10,500.00	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 114,550.00**	**$ 10,500.00**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 13,747.32	$ 6,158.06	$ 19,905.38

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 ***

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 199,823.54**	**$ 129,916.61**	**$ 329,740.15**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 30,996.19**	**$ 525.00**	**$ 10,982.64**	**$ 6,812.93**	**$ 49,316.76**	
TOTAL of A, B, C, D and E	**$ 650,919.94**	**$ 11,025.00**	**$ 230,635.41**	**$ 143,071.56**	**$ 1,035,651.91**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JANUARY 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interested Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses ***					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00		$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00		$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 12,866.76	$ 5,763.62	$ 18,630.38
Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,942.98**	**$ 129,522.17**	**$ 328,465.15**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Claims Administrator Office Vehicle 1 Year Warranty	$ 1,125.00		$ 375.00		$ 1,500.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 18,138.75**	**$ -**	**$ 6,046.25**	**$ -**	**$ 24,185.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,577.44**	**$ -**	**$ 10,957.36**	**$ 6,793.21**	**$ 49,328.01**	
TOTAL of A, B, C, D and E	**$ 663,126.19**	**$ -**	**$ 230,104.57**	**$ 142,657.40**	**$ 1,035,888.16**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

FEBRUARY 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($18,138.75), B, Medical Monitoring (Pre-Implementation Date) ($1.00) and C, Medical Monitoring (Post Implementation) ($6,046.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Property Soil and House Testing Check Preparation	$ 3,550.00	$ -			$ 3,550.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 65,000.00	$ -			$ 65,000.00
Total Claims Administrator Fees and Expenses	**$ 125,050.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 145,550.00**
B. Property Program Only Expenses * **					
Property Program Soil Clean-up Annoyance and Inconvenience Claimant Payments	$ 263,500.00	$ -	$ -		$ 263,500.00
Property Program Soil and House Testing Payments	$ 199,860.00	$ -	$ -		$ 199,860.00
Property Clean-up Technical Advisor	$ 25,000.00	$ -	$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 488,360.00**	**$ -**	**$ -**		**$ 488,360.00**
C. Medical Monitoring Program Only Expenses ** **					

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 ***

Third Party Administrator Fees and Expenses	$ -	$ -	$ 11,082.34	$ 4,964.29	$ 16,046.63	
Medical Provider Medical Monitoring Expenses	$ -	$ -	$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -	$ -	$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.56**	**$ 128,722.84**	**$ 325,881.40**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 31,521.19**	**$ -**	**$ 10,849.39**	**$ 6,753.24**	**$ 49,123.82**	
TOTAL of A, B, C, D and E	**$ 661,944.94**	**$ -**	**$ 227,837.18**	**$ 141,818.11**	**$ 1,031,600.22**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MARCH 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implemenation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -		$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00		$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,962.89	$ 5,358.74	$ 17,321.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 ***

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 198,039.11**	**$ 129,117.29**	**$ 327,156.40**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,893.42**	**$ 6,772.97**	**$ 75,167.07**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 228,761.76**	**$ 142,232.28**	**$ 1,578,508.47**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

APRIL 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00				$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00				$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00				$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**	**$ -**	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,082.34	$ 4,964.29	$ 16,046.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.56**	**$ 128,722.84**	**$ 325,881.40**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,849.39**	**$ 6,753.24**	**$ 75,103.32**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 227,837.18**	**$ 141,818.11**	**$ 1,577,169.72**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

MAY 2012 ***

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
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The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 11,082.34	$ 4,964.29	$ 16,046.63

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

Medical Provider Medical Monitoring Expenses	$ -		$ 182,326.22	$ 122,508.55	$ 304,834.77	
Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 197,158.56**	**$ 128,722.84**	**$ 325,881.40**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	[1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
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Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
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Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
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Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
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Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
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Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 10,849.39**	**$ 6,753.24**	**$ 75,103.32**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 227,837.18**	**$ 141,818.11**	**$ 1,577,169.72**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JUNE 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**		**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 9,578.14	$ 4,290.49	$ 13,868.63
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 50,444.70	$ 125,520.20

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 88,403.64**	**$ 55,985.19**	**$ 144,388.83**
D. Common Expenses Shared by Both Settlement Programs					
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00
Audit and Income Tax Return	$ 40,000.00	$ 33,333.34	$ 6,666.66		$ 80,000.00
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00
Web Hosting	$ 18.75		$ 6.25		$ 25.00
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00 [1]
Office Cleaning	$ 18.75		$ 6.25		$ 25.00
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00
Office Insurance	$ 150.00		$ 50.00		$ 200.00
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00
Telecopies	$ 187.50		$ 62.50		$ 250.00
Postage	$ 375.00		$ 125.00		$ 500.00
Federal Express	$ 187.50		$ 62.50		$ 250.00
Office Supplies	$ 375.00		$ 125.00		$ 500.00
Office Equipment	$ 187.50		$ 62.50		$ 250.00
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00
Total Common Expenses	**$ 57,013.75**	**$ 33,333.34**	**$ 12,337.91**	**$ -**	**$ 102,685.00**
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 59,500.69**	**$ 1,666.67**	**$ 5,744.98**	**$ 3,116.36**	**$ 70,028.69**
TOTAL of A, B, C, D and E	**$ 1,249,514.44**	**$ 35,000.01**	**$ 120,644.51**	**$ 65,443.57**	**$ 1,470,602.52**

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

JULY 2012 *****

** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhbit E.
***** For this month, common overhead expenses (excluding Audit and income Tax Return) are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25). Audit and Income Tax Return expenses were split as follows: (1) 50% (or $40,000) charged to the Property Remediation Fund and 50% (or $40,000) charged to the Medical Monitoring Fund; and (2) for the Medical Monitoring Fund, its portion of Audit and Income Tax Return expenses were further split, assessing Medical Monitoring (Pre-Implementation Date) with 8/12 (January 2011 through August 2011) of these expenses and dividing the remaining 4/12 (September 2011 through December 2011) equally between Medical Monitoring (Pre-Implementation Date) and Medical Monitoring (Post-Implementation).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Expense Category	(APPROVED BY THE COURT ON AUGUST 31, 2011) A. PROPERTY REMEDIATION SETTLEMENT FUND	(APPROVED BY THE COURT ON AUGUST 31, 2011) B. MEDICAL MONITORING SETTLEMENT FUND - ADDITIONAL START-UP AND CLAIMANT REGISTRATION (PRE-IMPLEMENTATION DATE) EXPENSES FROM INITIAL DUPONT FUNDING *	C. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE EXPENSES (EXCLUDING CT SCAN INCREMENTAL EXPENSES) **	D. MEDICAL MONITORING SETTLEMENT FUND - POST SEPTEMBER 1, 2011 IMPLEMENTATION DATE CT SCAN INCREMENTAL EXPENSES#	TOTAL
A. Claims Administrator Fees Based on Detail in Appendix A					
Claims Administrator Legal Fees (Claims Office and General Case Administration Services, Database Loading and Programming, and Tax and Accounting Support)	$ 56,500.00	$ -	$ 7,251.65	$ 3,248.35	$ 67,000.00
Claims Administrator Legal Fees for Medical Monitoring Provisioning	$ -	$ -	$ 6,906.33	$ 3,093.67	$ 10,000.00
Claims Administrator Legal Fees for Property Program Oversight ***	$ 96,000.00	$ -	$ -		$ 96,000.00
Total Claims Administrator Fees and Expenses	**$ 152,500.00**	**$ -**	**$ 14,157.98**	**$ 6,342.02**	**$ 173,000.00**
B. Property Program Only Expenses ***					
Property Program Interior Residential Cleaning Expenses	$ 396,125.00		$ -		$ 396,125.00
Property Program Soil Replacement Expenses	$ 311,750.00		$ -		$ 311,750.00
Property Program Project Administration Expenses	$ 247,625.00		$ -		$ 247,625.00
Property Clean-up Technical Advisor	$ 25,000.00		$ -		$ 25,000.00
Total Property Program Only Expenses	**$ 980,500.00**	**$ -**	**$ -**	**$ -**	**$ 980,500.00**
C. Medical Monitoring Program Only Expenses ****					
Third Party Administrator Fees and Expenses	$ -		$ 8,697.58	$ 3,896.05	$ 12,593.63
Medical Provider Medical Monitoring Expenses	$ -		$ 75,075.50	$ 50,444.70	$ 125,520.20

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

Guardian Ad Litem Fees (20 hours per month @ $250/hr)	$ -		$ 3,750.00	$ 1,250.00	$ 5,000.00	
Total Medical Monitoring Program Only Expenses	**$ -**	**$ -**	**$ 87,523.08**	**$ 55,590.75**	**$ 143,113.83**	
D. Common Expenses Shared by Both Settlement Programs						
Finance Committee Fees (20 hours each per month @ $250/hr)	$ 7,500.00		$ 2,500.00		$ 10,000.00	
Printing Costs	$ 750.00		$ 250.00		$ 1,000.00	
Web Hosting	$ 18.75		$ 6.25		$ 25.00	
Claims Office Rent	$ 525.00		$ 175.00		$ 700.00	1
Office Cleaning	$ 18.75		$ 6.25		$ 25.00	
Copy Machine Rental	$ 300.00		$ 100.00		$ 400.00	
Office Insurance	$ 150.00		$ 50.00		$ 200.00	
Photocopies	$ 1,875.00		$ 625.00		$ 2,500.00	
Telecopies	$ 187.50		$ 62.50		$ 250.00	
Postage	$ 375.00		$ 125.00		$ 500.00	
Federal Express	$ 187.50		$ 62.50		$ 250.00	
Office Supplies	$ 375.00		$ 125.00		$ 500.00	
Office Equipment	$ 187.50		$ 62.50		$ 250.00	
Telephone Service	$ 937.50		$ 312.50		$ 1,250.00	
Westlaw Legal Research	$ 112.50		$ 37.50		$ 150.00	
Vehicle Insurance and Repairs	$ 150.00		$ 50.00		$ 200.00	
Claims Administrator Residence Rent	$ 450.00		$ 150.00		$ 600.00	
Utilities for Claims Administrator Residence	$ 93.75		$ 31.25		$ 125.00	
Airfare (2 round trips from Alabama)	$ 2,325.00		$ 775.00		$ 3,100.00	
Airport Vehicle Storage (@ $12/day)	$ 270.00		$ 90.00		$ 360.00	
Claimant File Storage Monthly Rent	$ 225.00		$ 75.00		$ 300.00	
Total Common Expenses	**$ 17,013.75**	**$ -**	**$ 5,671.25**	**$ -**	**$ 22,685.00**	
E. FASB 5 Contingency Reserve (5% of above accounts)	**$ 57,500.69**	**$ -**	**$ 5,367.62**	**$ 3,096.64**	**$ 65,964.94**	
TOTAL of A, B, C, D and E	**$ 1,207,514.44**	**$ -**	**$ 112,719.93**	**$ 65,029.41**	**$ 1,385,263.77**	

PERRINE-DUPONT ADMINISTRATION BUDGET NO. 2

AUGUST 2012 *****

* Register means to prove Class Membership, it does not require participation in the Medical Monitoring Program. These expenses are in addition to the $50,000 contingency approved by the Court in the first budget. These additional expenses are the result of unforeseen complications in proving claimant residency in the Class Area, such as the difficulty in matching the stated addresses with a physical location.
** To be funded by an additional contribution by DuPont.
*** Based on the detailed budget developed by the Claims Administrator and the Property Technical Advisor in Exhibit A contemplating that, during the budget period, (i) Class Member registration for the 227 soil parcels in Zone 1A, and the 2,752 houses in the Class Area, will be completed, the resulting $227,000 ($1,000 x 227) in inconvenience payments prior to testing for Zone 1A soils will be made and the $275,200 ($100 x 2,752) in inconvenience payments prior to testing for Class Area house inconvenience payments will be made; (ii) soil and house testing will be completed, with one-third of soils and one-third of houses being contaminated, with the other two-thirds receiving their $608,000 ($4,000 x 152) in soil inconvenience payments and $734,000 ($400 x 1,835) in house inconvenience payments; and (iii) soil remediation for the positive testing soil parcels is one-third completed. The Property budget reflects the best estimate of the costs for testing the class area soil and houses at this time, and the best estimate of the cost of
remediating the contaminated soils in Zone 1A. After testing is completed, which we project to be March 31, 2012, we will revisit the Property budget per the Court's June 27, 2011 Property Remediation (Clean-Up) Program Order.
**** See Exhibit E.
***** For this month, common overhead expenses are split on a 75:00:25 basis between A, Property Remediation ($17,013.75), B, Medical Monitoring (Pre-Implementation Date) ($0.00) and C, Medical Monitoring (Post Implementation) ($5,671.25).
1. Due to the increase in utility costs at the Fire Station, the Claims Office rent is projected to increase from $500 to $700 per month. Substantiation for this adjustment is attached in Exhibit D.
The amount of these CT Scan expenses is unresolved, and is to be briefed by DuPont, Class Counsel, and other interestd Parties, then decided by the Court.

SCHEDULE OF APPENDIX AND EXHIBITS

Appendix A:	Suggested Fees Appendix
Exhibit A:	Detailed Property Program Budget Developed by Claims Administrator and Property Technical Advisor
Exhibit B:	Non-Binding Medical Monitoring Program Third Party Administration Budget Dated October 6, 2011*
Exhibit C:	Medical Monitoring Program Medical Providers Budget Developed by Third Party Administrator*
Exhibit D:	Claims Office Rent Adjustment Substantiation
Exhibit E:	Third Party Administrator and Medical Provider Medical Monitoring Fees and Expenses

* Assumes 4,000 Medical Monitoring claimants.

APPENDIX A

SUGGESTED FEES APPENDIX

A. Claims Office and General Case Administration Services
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)), and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A (Property Remediation Settlement Fund) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation))]

Legal Assistant/Receptionist at Office $50/h x 145	= $ 7,250
Associate Attorney $150/h x 110	= $16,500
Partners $200/h x 15	= $ 3,000
Claims Administrator $250/h x 25	= $ 6,250
	$33,000

B. Database Loading and Programming

1.	$ 80 (blended) /h x 625	= $50,000	[Sep '11 thru Nov '11] 50% to A (Property Remediation Settlement Fund) and 50% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
2.	$ 80 (blended) /h x 468.75	= $37,500	[December 2011] 67% to A (Property Remediation Settlement Fund) and 33% to B (Medical Monitoring Settlement Fund (Pre-Implementation))
3.	$ 80 (blended) /h x 150	= $25,000	[Jan '12 to August '12] 100% to A (Property Remediation Settlement Fund)

C. Tax and Accounting Support
[September 2011 to January 2012 = 50% to A (Property Remediation Settlement Fund), 25% to B (Medical Monitoring Settlement Fund (Pre-Implementation)) and 25% to C (Medical Monitoring Settlement Fund (Post Implementation)); February 2012 to August 2012 = 75% to A and 25% to C]

$150 (blended) /h x 60 = $ 9,000

D. Property Program Soil and House Testing Class Member Checks
4,965 checks for 7 months (September 2011 to March 2012)
@ $5.00/check[1] = $24,825

E. Medical Monitoring Registered Class Member Checks
1,000 checks for September, 500 checks
For October and 250 checks for
November @ $5.00/check[1] = $8,750.00

F. Medical Monitoring Monthly Provisioning

Legal Assistant
$50/h x 7 = $ 350

Accountant
$80/h x 5 = $ 400

Associate Attorney
$150/h x 15 = $ 2,250

Partner
$200/h x 20 = $ 4,000

Claims Administrator
$250/h x 12 = $ 3,000
$10,000

[1] This amount represents the Claims Administrator's estimated costs related to the issuance of a Class Member Property Program Soil and/or House testing check and a Class Member Medical Monitoring check, which includes, but is not limited to, check stock, envelopes, preparation time, postage, and printing. Not included in this amount is the cost of issuing a Federal Form 1099-MISC if the check amount exceeds $600. The Claims Administrator will bill the actual costs; if the actual costs are less than $5 per check, the Claims Administrator will bill the lesser amount.

G. Property Program Oversight (September 2011 Through March 2012)[2]

Legal Assistant	
$50/h x 250	= $ 12,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 200	= $ 30,000
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 65,000

H. Previously Approved Contingency for Final Determination of Medical Monitoring Class Membership and Payment of Balance of Medical Monitoring Cash (October 2011)

Issuance of 5,000 Checks @$5/check	= $25,000
Accountant/Attorney	
$125 (blended) x 100	= $ 12,500
Claims Administrator	
$250/h x 50	= $ 12,500
	$ 50,000

I. Property Program Oversight (April 2012 Through August 2012[2])

Legal Assistant	
$50/h x 370	= $ 18,500
Construction Supervisor	
$100/h x 100	= $ 10,000
Associate Attorney	
$150/h x 250	= $ 37,500
Partner	
$200/h x 100	= $ 20,000
Claims Administrator	
$250/h x 40	= $ 10,000
	$ 96,000

[2] Under the Property Program, Claimant registration is projected to be from July 2011 through October 10, 2011. Soil and house testing is projected to be from August 2011 through March 2012. Soil remediation is projected to be from April 2012 through March 2013. House remediation is projected to be from April 2013 to March 2015.

EXHIBIT A

Terry D. Turner Jr.

Subject: Perrine Zone v1A; 4609-1-dd

This budget estimate for the Zone 1A Spelter Remediation work is very preliminary. So far we have: Testing, Interior Residential Cleaning, Soil Replacement, and Remediation Project Administration.

1. Testing - 227 homes expending $5,500.00 each for testing and inconvenience has an estimated cost totaling $1,249,000.00

2. Interior Residential Cleaning – 227 homes expending 13,959.58 for Cleaning, additional sampling, and temporary relocation for an estimated cost totaling $3,169,000.00

3. Soil Replacement – Time, materials, for collection, replacement, and disposal has an estimated total cost of $7,482,000.00

4. Project Administration for Zone 1A – Including Project Management. Supervision, Record Keeping, Information Databases, Administration, Bonding and Insurances, and a contingency at an estimated total of $3,410,000.00

The total estimated cost for Zone 1A is $15,308,000.00.

Some detail breakdowns are available, but they have not yet been put into a presentable form.

How detailed do you want to tie these figures down. The Cleaning and soils work is provided by Mr. Marc Glass. The overhead figures are based on percentages, not detailed information. They include 5% Project Management, 4% Supervision, 1% Record Keeping, 1% Informational Databases, 2% Administration, 10% Bonding and Insurance, and a 3% contingency.

Bill Sublett
2853 Avenida De Soto
Navarre, Florida 32566
Phone (850) 485-2643
E-Mail: Sublett01@AOL.com

Preliminary Cost Estimation Zone 1A
Interior Residential Cleaning and Soil Replacement
Perrine Class Area

I. Zone 1A Interior Cleaning

Zone 1 Interior Clean/Home	12,559.58
Zone 1A Homes	227
	$2,851,024.66
Pre/Post (90-day) Sampling	1,200.00
	$272,400.00
2-day Relocation for Res/Pets	$200.00
	$45,400.00
Total Avg. per Home	$13,958.58
Sub-Total	$3,168,824.66

II. Zone 1A Soil Replacement

Data:

Pre-Qualification Sampling, Excavation 6-inch soil from Residential Lots, Replace, Site Restoration, Post Sample

Number Zone 1A Residential Lots	227
Avg. sq. ft. Residential Lot	9120
Avg. cu. Ft. Residential Lot (6-inch)	4560
Avg. cu. Yd. Residential Lot (6-inch deep)	168.8888889 cubic yard/residential lot
1.35 tons per cubic yard	228 tons soil to remove/replace/residential lot
Total Zone 1A Cubic yard	38,337.7778
Total Zone 1A Tons	51,756.0000 tons soil to remove/replace

Per Res. Lot Time and Material Calculation

Soil transport/disposal	$13,741.56
Soil Backfill Placement	$13,148.76
Labor/Site Restore	$4,912.80
Pre/Post (90-day) Sampling	$1,155.00
Avg. Res. Lot	$32,958.12
Sub-Total	$7,481,493.24

*Estimated Zone 1A On-Site Remediation $10,650,317.90

*On-site estimates based on average per property remediation time and material estimates and are not inclusive of overall project management/supervision, recordkeeping, informational databases, or administration.

EXHIBIT B

October 6, 2011 DRAFT

Projection of CTI Administrators Administrative Fees for the Perrine DuPont Medical Monitoring Program

Description of Fee Component	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Initial Set-Up Fee [1]	$ 6,500	$ 0	$ 0	$ 0	$ 0	$ 6,500
Provider Negotiations of Fees Schedules [2]	$ 0	$ 10,000	$ 0	$ 10,000	$ 0	$ 20,000
Communication Materials [3]	$ 10,805	$ 10,805	$ 10,805	$ 10,805	$ 10,805	$ 54,025
Production/Distribution of Plastic ID Cards [4]	$ 9,160	$ 916	$ 916	$ 916	$ 916	$ 12,824
Administrative Fee per Active Claimant [5]	$ 92,640	$ 91,656	$ 90,539	$ 102,900	$ 101,259	$ 478,994

[1] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Based on Fee Pricing Schedule provided by CTI Administrators.

[2] This is in addition to the initial Provider network design expenses, which are capped at $50,000 in the Agreement. Estimated utilizing blended hourly rates for approximately 48 hours of services with an estimated three service providers from the Fee Pricing Schedule. This is based upon CTI Administrators renegotiating fees every two years.

[3] Based on 26.67% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 4,000 claimants in the Medical Monitoring Program. Dr. Michael Brookshire's May 23, 2007 study of costs for the Medical Monitoring Program utilized a 5% attrition rate each year for claimants, but this was offset by a projected 5% increase each year in materials cost.

[4] Based on 4,000 claimants receiving their ID cards in year one, with the Fee Pricing Schedule showing a cost of $1.85 per claimant and adding $0.44 for postage, and assuming 10% need to be replaced each year.

[5] Based on Fee Pricing Schedule per active claimant and incorporating Dr. Brookshire's 5% attrition rate each year for claimants.

Projection of CTI Administrators Administrative Fees for the Perrine DuPont Medical Monitoring Program

Scheduling/Appointment Reminder Letters [6]	$ 11,040	$ 10,773	$ 10,505	$ 10,239	$ 9,969	$ 52,526
Central Repository for Possible Scientific Research Concerning Test Results [7]	$ 48,323	$ 38,086	$ 37,307	$ 36,509	$ 39,424	$ 199,649
Quarterly Meetings [8]	$ 5,100	$ 5,355	$ 5,623	$ 5,904	$ 6,199	$ 28,181
Consulting Services [9]	$ 14,000	$ 14,700	$ 15,435	$ 16,207	$ 17,017	$ 77,359
Totals	**$ 197,568**	**$ 182,291**	**$ 171,130**	**$ 193,480**	**$ 185,589**	**$ 930,058**

[6] Based on Fee Pricing Schedule, which includes up to three letters to a claimant every other year, with one and a half letters being used for projection purposes each year. This expense also incorporates Dr. Brookshire's 5% attrition rate each year for claimants.

[7] These expenses would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. Based on Fee Pricing Schedule per test per claimant. The expense also utilizes Dr. Brookshire's May 23, 2007 study to determine the approximate amount of claimants that would participate in each of five different tests each year, which include urinary, lungs, plumbism, skin and gastro intestinal.

[8] Based on a combination of the Fee Pricing Schedule and yearly average of travel costs experienced in the Tolbert Healthcare Project, with travel costs being increased by 5% each year. The Court, CTIA, and the Claims Administrator, after consulting with the Finance Committee, may review the need to have quarterly in-person meetings from time to time.

[9] These are described in Agreement Section II, I, on page 15. Based on 50% of yearly average of CTI Administrator invoices for the Tolbert Healthcare Project, which contained an average of 15,000 claimants as opposed to the 4,000 claimants in the Medical Monitoring Program. It is estimated that consulting services would still be an essential part of the Medical Monitoring Program, thus this cost was not reduced strictly in accordance with the ratio of claimants. Since this expense contains travel expenses, it was also increased by 5% each year.

EXHIBIT C

Assumptions used in budget estimate.

The seven tests, clinical procedures, and number of tests recommended were extracted from the report, Estimate of the present value of medical monitoring costs per 1,000 persons, 2008-2046 by Michael L. Brookshire, Ph.D. dated May 23, 2007. We have outlined the tests to reflect the manner that we believe to be the most effective and least costly.

The cost estimates were made assuming an initial population of **4,000** participants. The population can be adjusted by changing the Number of Participants field (cell L1) in the worksheet "Adult's Testing Protocol". This will also change the "Child Testing Protocol" worksheet calculations.

Estimates for CT Scans also can be adjusted by changing the Estimated Participation cell (cell FGH75) to the percentage thought to be most accurate. I have started with 37.5%. Just replace 37.5% with the % you think to be the most appropriate.

Clinical Procedure Codes (CPT) were derived from the Physicians' Fee Reference PFR 2011, 28th Edition. Dr. Brookshire's report did not include CPT codes so we used our best judgment as to the procedure codes we thought to be most appropriate.

Targeted Fees are the fees we hope to negotiate with the clinics, facilities, and laboratory (Lab Corp). We have a good idea about the various discounts are available in the Spelter area and have an ongoing discount arrangement with LabCorp.

Costs were adjusted for Geographic area. The Geographic Multiplier for the Spelter/Morgantown area is .91.

Details of each test are shown in two separate worksheets; one for the adults & one for the children.

Estimated Costs are for payments to providers of service and do not include administration fees.

Revised First year claim budget projections using above assumptions are:

Children	$106,979	
Adults	$2,403,425	Estimated adult CT Scans @ 56.3%

Claim expenses do not include administration fees.

ADULT TESTING PROTOCOL (age 18 & above)

Number of Participants **4,000** ← Change as desired

Initial Testing

1. The first visit to the Clinic will be for the purpose of collecting a urine sample and drawing blood. There will be collection of urine & blood samples. There will be a charge for a 5 minute office visit for established patients and a 10 minute office visit for new patients. Patients will also be given a stool hemocult card that will be sent directly to Lab Corp.

1.a. Urinary System Tests will be given to age 18 and above.

1.b. Plumbism Tests will be given to age 18 and above.

1.c Urine & blood samples will be sent to LabCorp with

1.d Stool sample cards will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.

2. LabCorp will perform 6 separate procedures for each participant and send the test results (via EDI) to the Physician & to CTI.

3. CTIA will contact participant to obtain release to maintain test results for subsequent analysis.

3.a If release to maintain data is not obtained, CTIA will delete test results from it's data base. Test results will still be maintained for/by physician.

4. Subsequent Redos are also accounted for in this spreadsheet.

Procedure Code	Description	Count Including Redos	Targeted Fee	Targeted First Year Cost
99201	10 Minute OFFICE VISIT OP NEW	1,878	$60.00	$112,664
99211	5 Minute OFFICE VISIT OP ESTABLISHED	1,878	$32.00	$60,087
99000	SPECIMEN HANDLING	3,873	$12.00	$46,477
36415	ROUTINE VENIPUNCTURE	3,745	$10.00	$37,453
81001	URINALYSIS, NONAUTO W/SCOPE	3,873	$3.50	$13,556
82274	OCCULT BLOOD, FECES	3,745	$20.00	$74,907
82232	ASSAY OF BETA-2 PROTEIN	3,745	$20.00	$74,907
82565	ASSAY OF CREATININE	3,745	$2.50	$9,363
84520	ASSAY OF UREA NITROGEN	3,991	$2.50	$9,977
83655	ASSAY OF LEAD	3,745	$10.00	$37,453
			Total	**$304,093**

First Consultation by Primary Care Physician	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. The consultation will consist of a Physical Exam, review of laboratory findings, Physical Examination, explanation of the pros & cons of having a CT Scan, and scheduling of additional testing on an as needed basis.	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	1,814	$135.00	$244,890
1.a Some of the initial laboratory tests will have to be redone. Costs for these are included in the Initial Testing.	99243	40 Minute Office Visit Physical Exam, CT Scan	1,814	$170.00	$308,380
1.b. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be repeated.					
1.c. Adults testing positive to the Urinary system tests will require two follow-up consultations with a urologist. These tests will include Cystoscopy with biopsy, and CT Sans of the Abdomen and Pelvis. Some of these tests will have to be redone					
1.d. Adults testing positive to the Urinary system tests will require two follow-up consultations with a Urologist. These tests will					
1.e. Adults testing positive to the Urinary system tests or the BUN/Creatinine tests will require two follow-up consultations with a Nephrologist. These tests will include repeat Urine-Beta-2 and BUN/Creatinine.				**Total**	**$553,270**

Adult Skin Test with Dermatologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require a Skin Test. Some of these tests will have to be redone.	99242	Consultation with Dermatologist	108	$140.00	$15,120
1.c Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	11100	BIOPSY, SKIN LESION	36	$110.00	$3,960
2. LabCorp will perform tests and send the test results (via EDI) to the Physician & to CTI.	88304	TISSUE EXAM BY PATHOLOGIST	36	$45.00	$1,620
				Total	**$20,700**

Follow-up with Urologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with an Urologist. Half of these patients will require additional testing.	99242	Consultation with Urologist	108	$140.00	$15,120
1.a. Two consultations will be required for each of the patients and two more for each of those requiring additional tests.	88112	CYTOPATH, CELL ENHANCE TECH	108	$32.00	$3,456
1.b Each patient will require a Cytopathology with Biopsy	52000	CYSTOSCOPY	108	$250.00	$27,000
1.c There will be an Outpatient Facility Charge for the Cytopathology	81001	URINALYSIS, NONAUTO W/SCOPE	108	$3.50	$378
1.d There will be a Charge for the Anesthesia	OP Facility	Out Patient Facility Charge	108	$850.00	$91,800
1.e CT Scan of Abdomen & CT Scan of Pelvis	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	108	$350.00	$37,800
1.f Reading of CT Scan of Abdomen & CT Scan of Pelvis	74176	CT Scan Abdomen & Pelvis	108	$350.00	$37,800
1.g CT Scan of of Pelvis	74176.26	Radiologist	108	$110.00	$11,880
1.h Reading of CT Scan of of Pelvis	72192	CT PELVIS W/O DYE	72	$300.00	$21,600
1.i Biopsy will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	72192.26	Radiologist	72	$100.00	$7,200
1.j CT Scan will be sent to Radiologist with instructions to send test results via EDI to Urologist & to CTIA.					
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.					
3. Radiologist will read CT Scans and send the test results (via???) to the Urologist & to CTI.				**Total**	**$254,034**

Follow-up with Nephrologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the Urinary system tests will require follow-up with a Nephrologist to test for kidney failure.	99242	Consultation with Nephrologist	288	$140.00	$40,320
1.a. Two consultations will be required for each of the 108 patients.	99000	SPECIMEN HANDLING	144	$12.00	$1,728
1.b Each patient will require a Urinalysis	36415	ROUTINE VENIPUNCTURE	144	$10.00	$1,440
1.c Urine & blood samples will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	81001	URINALYSIS, NONAUTO W/SCOPE	144	$3.50	$504
	84520	ASSAY OF UREA NITROGEN	144	$2.50	$360
1.c. Miscellaneous lab work to determine cause for kidney failure	misc	misc lab work to determine cause of kidney failure	144	$125.00	$18,000
2. LabCorp will perform tests and send the test results (via EDI) to the Urologist & to CTI.				**Total**	**$62,352**

Follow-up with Gastroenterologist & Proctologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the stool sample tests will require follow-up with a Gastroenterologist followed by some patients with a Proctologist.	99242	Consultation with Gastroenterologist	181	$140.00	$25,387
1.a. A consultation with a Gastroenterologist will be required for each patient.	82274	OCCULT BLOOD, FECES	181	$20.00	$3,627
1.b Each patient will require another Stool Sample Test	99242	Consultation with Proctologist	27	$160.00	$4,267
1.c. A consultation with a Proctologist will be required for some patients.	82274	OCCULT BLOOD, FECES	27	$20.00	$533
1.d Each patient will require another Stool Sample Test & an Upper GI Endoscopy.	43239	UPPER GI ENDOSCOPY, BIOPSY	27	$350.00	$9,333
	OP Facility	Out Patient Facility Charge	1	$850.00	$826
2. LabCorp will perform tests and send the test results (via EDI) to the Gastroenterologist, Proctologist, & to CTI.	00910	ANESTH, BLADDER SURGERY (3base @$70 + time)	1	$350.00	$340
				Total	**$43,973**

Follow-up with Toxicologist & Psychologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. Adults testing positive to the lead blood tests will require follow-up with a Medical Toxicologist followed by some patients with a Psychologist.	99242	Consultation with Toxicologist	283	$140.00	$39,573
1.a. Four consultations with a Medical Toxicologist will be required for each patients.	36415	ROUTINE VENIPUNCTURE	71	$10.00	$707
1.b. Each patient will require a complete blood count, lead, and zinc test.	85025	COMPLETE CBC W/AUTO DIFF WBC	71	$4.00	$283
1.c. Four one-hour tests with a Psychologist will be required for each of the 131 patients & 33 retests. (856 hours)	84202	ASSAY RBC PROTOPORPHYRIN	71	$10.00	$707
	83655	ASSAY OF LEAD	71	$10.00	$707
2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.	96118	NEUROPSYCH TST BY PSYCH/PHYS	1,141	$100.00	$114,133
				Total	$156,109

Adult CT Scans with Cardiologist, & Pulmonologist	Estimated Participation (change as desired)		Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
	56.25%	←	Change as desired				
1. There are 67% adults in the population of participants over age 35. The percentage of CT Scans will be as indicated in the cell Estimated Participation. 1.a. 40% of the initial CT Scans will need to be repeated 1.b. Each patient will require a complete blood count, lead, and zinc test. 1.c. Four one-hour consultations with a Pulmonologist will be required for each patient. 2. LabCorp will perform tests and send the test results (via EDI) to the Cardiologist & Pulmonologist, & to CTI.			71250	CT THORAX W/O DYE	1,508	$300.00	$452,250
			71250.26	CT THORAX W/O DYE	1,508	$100.00	$150,750
			71250	Repeat CT Scan of Chest	603	$300.00	$180,900
			71250.26	Repeat CT Scan of Chest	603	$100.00	$60,300
			99242	Consultation with Pulmonologist	151	$140.00	$21,105
			99242	Consultation with Cardiologist	75	$140.00	$10,553
			99242	Consultation with General Surgeon	26	$140.00	$3,693
			32095	BIOPSY THROUGH CHEST WALL	26	$425.00	$11,212
			OP Facility	Out Patient Facility Charge	26	$850.00	$22,424
			00910	ANESTH, (3base @$70 + time)	26	$350.00	$9,233
			99242	Consultation with Pulmonologist	49	$140.00	$6,859
			32095	BIOPSY THROUGH CHEST WALL	49	$425.00	$20,822
			OP Facility	Out Patient Facility Charge	49	$850.00	$41,645
			00910	ANESTH, (3base @$70 + time)	49	$350.00	$17,148
						Total	$1,008,894

cap Using Targeted Fees	
Initial Testing	$304,093
First Consultation by Primary Care Physician	$553,270
Adult Skin Test	$20,700
Follow-up with Urologist	$254,034
Follow-up with Nephrologist	$62,352
Follow-up with Gastroenterologist & Proctologist	$43,973
Follow-up with Toxicologist & Psychologist	$156,109
Adult CT Scans with Pulmonologist, Cardiologist, & Pulmonologist	$1,008,894
CT Scan participation estimated at 56.25%	**$2,403,425**

Procedure Code	Number of Procedures Every Other Year
81001	4,125
82270	0
82232	3,745
82565	3,745
84520	4,135
83655	3,816
88304	36
88112	108
85025	71
84202	71

CHILD TESTING PROTOCOL			4,000		
Initial Testing	**Procedure Code**	**Description**	**Count Including Redos**	**Targeted Fee**	**Targeted First Year Cost**
1. The first visit to the Clinic will be for the purpose of collecting urine & blood samples. There will be a charge for a 5 minute office visit for established patients and a 10 minute office visit for new patients.	99201	10 Minute OFFICE VISIT OP NEW	294	$60.00	$17,640
1.a. Plumbism Tests will be given to age 18 and below.	99211	5 Minute OFFICE VISIT OP ESTABLISHED	294	$32.00	$9,408
1.b. Urine Tests will be given to age 15 -18.	36415	ROUTINE VENIPUNCTURE	588	$10.00	$5,880
1.b Blood samples will be sent to LabCorp with instructions to send test results via EDI to Physicians & to CTIA.	81001	URINALYSIS, NONAUTO W/SCOPE	118	$3.50	$412
2. LabCorp will perform 3 separate procedures for each participant and send the test results (via EDI) to the Physician & to CTI.	83655	ASSAY OF LEAD	588	$10.00	$5,880
3. CTIA will contact participant to obtain release to maintain test results for subsequent analysis.	82232	ASSAY OF BETA-2 PROTEIN	588	$20.00	$11,760
3.a If release to maintain data is not obtained, CTIA will delete test results from it's data base. Test results will still be maintained for/by physician.	82565	ASSAY OF CREATININE	588	$2.50	$1,470
4. Subsequent Redos are also accounted for in this spreadsheet.					
				Total	**$19,522**

First Consultation by Primary Care Physician	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1. The consultation will consist of a Physical Exam, review of laboratory findings, & and scheduling of additional testing on an as needed basis. There will be no consultation regarding CT Scans.	99242	30 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	294	$135.00	$39,690
1.a Some of the initial laboratory tests will have to be redone. Costs for these are included in the Initial Testing.	99243	40 Minute Office Visit Physical Exam, CT Scan Pros & Cons, review of	294	$170.00	$49,980
				Total	**$49,980**

Follow-up with Toxicologist & Psychologist	Procedure Code	Description	Count	Targeted Fee	Targeted First Year Cost
1.Children testing positive to the lead blood tests (53) will require follow-up with a Medical Toxicologist followed by another 131 patients with a Psychologist.	99242	Consultation with Toxicologist	224	$135.00	$30,240
1.a. Four consultations with a Medical Toxicologist will be required for each of the 42 patients. (212 total)	36415	ROUTINE VENIPUNCTURE	56	$10.00	$560
1.b. Each patient will require a complete blood count, lead, and zinc test.	85025	COMPLETE CBC W/AUTO DIFF WBC	56	$4.00	$224
1.c. Four one-hour tests with a Psychologist will be required for each of the 8 patients & 2 retests. (10 hours)	84202	ASSAY RBC PROTOPORPHYRIN	56	$10.00	$560
	83655	ASSAY OF LEAD	56	$10.00	$560
2. LabCorp will perform tests and send the test results (via EDI) to the Toxicologist & Psychologist, & to CTI.	96118	NEUROPSYCH TST BY PSYCH/PHYS	53	$100.00	$5,333
				Total	$37,477

Child Testing Recap Using Targeted Fees	
Initial Testing	$19,522
First Consultation by Primary Care Physician	$49,980
Follow-up with Toxicologist & Psychologist	$37,477
Total	**$106,979**

Procedure Code	Number of Procedures Every Other Year
81001	118
82272	0
82232	588
82565	588
84520	0
83655	644
88304	0
88112	0
85025	56
84202	56

EXHIBIT D

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 0B150 2

Amount Due $240.29

Due Date MAY 13, 2010
Rate Code/Schedule 003/E Check Digit 0801

port an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related ions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present APR 22, 2010 - Actual Reading	30105
Previous MAR 18, 2010 - Estimated Reading	27531
Total KWH Used for 35 Days	2574

Allegheny Power

Balance Last Bill	347.87
Payment - MAR 25, 2010	347.87 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 2574 KWH	230.71
Environmental Control Charge	9.58
Current Charges	$240.29

TOTAL AMOUNT DUE $240.29

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2009	03/18/2010	04/22/2010
	35	29	35
	4700	3767	2574
ıg Type	Actual	Estimated	Actual
ily Usg	134	130	74
ımp	45	33	50
ily Cost	$11.48	$12.00	$6.87
hly Usg	5276	4880	4697
ıth Usg	63049	58256	56130

ıeter reading will be estimated, see back of provide a customer reading between 6, 2010 and MAY 17, 2010.

Paid 4-26-10 CK# 3123

AlleghenyPower
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number	3 10 10 454 08150 2
Amount Due	$347.33
Due Date	JUN 08, 2010
Rate Code/Schedule 003/8	Check Digit 0825

Page 1 of 1

ort an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related ons, call weekdays from 7:00 a.m. until 8:00 p.m.

Important Information

average cost per day is higher than your ious bill. This may be due to temperature ge, estimated reading or customer controlled e change.

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present MAY 18, 2010 - Estimated Reading	33866
Previous APR 22, 2010 - Actual Reading	30105
Total KWH Used for 26 Days	3761

Allegheny Power

Balance Last Bill	240.29
Payment - APR 27, 2010	240.29 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3761 KWH	333.34
Environmental Control Charge	13.99
Current Charges	$347.33

TOTAL AMOUNT DUE $347.33

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	05/18/2009	04/22/2010	05/18/2010
	26	35	26
	4069	2574	3761
ng Type	Estimated	Actual	Estimated
ally Usg	157	74	145
emp	58	50	57
ally Cost	$13.42	$6.67	$13.36
thly Usg	5215	4897	4666
nth Usg	62422	56130	55822

neter reading is scheduled for JUN 17, 2010.

Paid
5-21-10
CK# 3140

Allegheny Power
an Allegheny Energy company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number	3 10 10 454 08150 2
Amount Due	$703.68
Due Date	JUL 15, 2010
Rate Code/Schedule 003/S	Check Digit 0816

iport an emergency or outage, call 24 hours a day at 1-800-Allegheny (1-800-255-3443). For account related
tions, call weekdays from 7:00 a.m. until 8:00 p.m.

Important Information

ir average cost per day is higher than your
vious bill. This may be due to temperature
nge, estimated reading or customer controlled
ge change.

I now have the option of enrolling in PowerPay,
direct payment plan, by signing the back of the
stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2010 - Actual Reading	41578
Previous MAY 18, 2010 - Estimated Reading	33866
Total KWH Used for 35 Days	7712

Allegheny Power

Balance Last Bill	347.33
Payment - MAY 22, 2010	347.33 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 7712 KWH	674.99
Environmental Control Charge	28.69
Current Charges	$703.68

TOTAL AMOUNT DUE **$703.68**

Corrected Bill

Paid 6-27-11 CK # 3161

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	06/22/2009	05/18/2010	06/22/2010
	35	26	35
	6620	3761	7712
ling Type	Actual	Estimated	Actual
Daily Usg	189	145	220
Temp	66	57	68
Daily Cost	$16.08	$13.36	$20.11
Mthly Usg	5307	4866	4758
onth Usg	63685	55822	58914

meter reading will be estimated, see back of
> provide a customer reading between
17, 2010 and JUL 16, 2010.

MonPower
A FirstEnergy Company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number	3 10 10 454 08150 2
Amount Due	$360.42
Due Date	MAY 16, 2011

Rate Code/Schedule 003/B Check Digit 0810 Page 1 of 1

port an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call days from 7:00 a.m. until 6:00 p.m.

Important Information

now have the option of enrolling in PowerPay, direct payment plan, by signing the back of the stub when submitting payment.

Usage Information Meter # 34863187

Present APR 18, 2011 - Estimated Reading	83798
Previous MAR 18, 2011 - Estimated Reading	79990
Total KWH Used for 31 Days	3808

Mon Power

Balance Last Bill	285.90
Payment - MAR 25, 2011	285.90 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 3808 KWH	347.36
Environmental Control Charge	13.06
Current Charges	$360.42

TOTAL AMOUNT DUE $360.42

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	04/22/2010	03/18/2011	04/18/2011
	35	24	31
	2574	3020	3808
ng Type	Actual	Estimated	Estimated
ally Usg	74	126	123
emp	50	41	47
ally Cost	$6.87	$11.91	$11.63
thly Usg	4897	4392	4544
nth Usg	56130	52459	54288

neter reading will be estimated, see back of provide a customer reading between 6, 2011 and MAY 17, 2011.

Paid
4-27-11
CK # 3347

MonPower
A FirstEnergy Company

SPELTER VOL FIRE DEPT
55 B ST
SPELTER WV 26438

Non-Residential

Account Number 3 10 10 454 08150 2

Amount Due $529.51

Due Date JUN 08, 2011

Rate Code/Schedule 003/S Check Digit 0841

port an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call
lays from 7:00 a.m. until 6:00 p.m.

Important Information

' average cost per day is higher than your
ious bill. This may be due to temperature
ge, estimated reading or customer controlled
e change.

now have the option of enrolling in PowerPay,
irect payment plan, by signing the back of the
tub when submitting payment.

Usage Information Meter # 34863787

Present MAY 18, 2011 - Estimated Reading	89440
Previous APR 18, 2011 - Estimated Reading	83798
Total KWH Used for 30 Days	5642

Mon Power

Balance Last Bill	360.42
Payment - APR 28, 2011	360.42 CR
Balance Remaining	$0.00
Current Charges:	
Base Charge for 5642 KWH	510.16
Environmental Control Charge	19.35
Current Charges	$529.51

TOTAL AMOUNT DUE **$529.51**

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
	05/18/2010	04/18/2011	05/18/2011
	28	31	30
	3761	3808	5642
Type	Estimated	Estimated	Estimated
ly Usg	145	123	188
np	57	47	58
ly Cost	$13.36	$11.63	$17.65
ily Usg	4686	4544	4636
n Usg	55822	54288	55574

ster reading is scheduled for JUN 17, 2011.

Paid 5-25-11
CK# 3367

MonPower
A FirstEnergy Company

Name	SPELTER VOL FIRE DEPT	**Account Number**	3 10 10 454 08150 2
Service Address	65 B ST SPELTER WV 26438	**Amount Due**	$865.21
	Non-Residential	**Due Date**	JUL 13, 2011
		Rate Code/Schedule 003/B	Check Digit 0962

To report an emergency or outage, call 24 hours a day at 1-800-255-3443. For account related questions, call weekdays from 7:00 a.m. until 6:00 p.m.

Important Information

Your average cost per day is higher than your previous bill. This may be due to temperature change, estimated reading or customer controlled usage change.

You now have the option of enrolling in PowerPay, our direct payment plan, by signing the back of the bill stub when submitting payment.

Usage Information Meter # 34863187

Present JUN 22, 2011 - Actual Reading	98723
Previous MAY 18, 2011 - Estimated Reading	89440
Total KWH Used for 35 Days	9283

Mon Power

Balance Last Bill	529.51
Payment - MAY 24, 2011	529.51 C
Balance Remaining	$0.00
Current Charges:	
Base Charge for 9283 KWH	833.37
Environmental Control Charge	31.84
Current Charges	$865.21

TOTAL AMOUNT DUE $865.21

Paid 6-17-11 CK# 3388

Comparing Your Usage (Usg)

	Last Year	Last Bill	Current
Date	06/22/2010	05/18/2011	06/22/2011
Days	35	30	35
KWH	7712	5642	9283
Reading Type	Actual	Estimated	Actual
Avg Daily Usg	220	188	265
Avg Temp	86	56	67
Avg Daily Cost	$20.11	$17.65	$24.72
Avg Mthly Usg	4758	4636	4788
12 Month Usg	56914	55574	57145

Next meter reading will be estimated, see back of bill to provide a customer reading between JUL 17, 2011 and JUL 18, 2011.

EXHIBIT E

THIRD PARTY ADMINISTRATOR AND MEDICAL PROVIDER MEDICAL MONITORING FEES AND EXPENSES

The Third Party Administrator (the "TPA") and the Medical Provider Medical Monitoring fees and expenses are based on the assumption that there will be 4,000 Medical Monitoring claimants, based on the non-binding projection attached as Exhibit B. The Medical Provider Medical Monitoring fees and expenses for the Budget period are projected by the Third Party Administrator at $2,510,404 for 4,000 Medical Monitoring claimants, and we have adjusted the Medical Monitoring Medical Provider fees and expenses projection downward from $3,813,654 (based on our September 1, 2011 draft Budget projection) to $2,510,404, with these amounts being projected utilizing the following assumptions: (1) Dr. Michael L. Brookshire's Expert Report estimated that only 75% of the Medical Monitoring claimants would show up for their tests; (2) we are estimating that of the 75% of Medical Monitoring claimants that may be eligible to have a CT scan, only 75% of those CT scans may be considered diagnostically medically necessary; and (3) 67% of the adult population is 35 or older (acquired by reviewing the Medical Monitoring Registration Forms received to date) and may be eligible for CT scans. Our estimate for the projected number of CT scans is predicated on Section 3(c) of the Memorandum of Understanding (the "MOU") that no routine CT scans shall be performed as part of the medical monitoring program, although the Defendant shall provide CT scans that are diagnostically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in the litigation. In accordance with Section 3 of the MOU between the Parties, the Defendant shall provide a medical monitoring program for all enrolled Plaintiffs on a pay-as-you-go basis, paying a sum certain each calendar year that reasonably secures such medical monitoring expenses for each such calendar year and, if the sum certain is not sufficient for payment of anticipated medical monitoring expenses, the Defendant shall make an additional payment to reasonably secure such medical monitoring expenses for the calendar year. It is estimated that the additional Third Party Administrator and Medical Provider fees and expense for each additional Medical Monitoring claimant over 4,000 total claimants per year would equal $677.03 per claimant[1].

Medical Provider Medical Monitoring Expenses: Because the TPA projects dividing the Medical Monitoring claimants into 4 groups for testing during the months of November 2011 through February 2012, we have allocated the projected Budget period Medical Provider Medical Monitoring Expenses of $2,510,404 as follows: (i) 5% of the total (or $125,520.20) allocated to November 2011 (the beginning of testing); (ii) 5% of the total (or $125,520.20) each to July 2012 and August 2012; and (iii) the remaining 85% (or $2,133,843.40) was allocated evenly among the months of December 2011 through June 2011.

The Medical Provider Medical Monitoring Expenses include estimated CT scan and consultation expenses totalling $1,008,894. The budgeted amount for CT scan expenses is in dispute among the Parties, thus, we have separated these CT scan expenses and the related administrative expenses into a separate Budget column, column D.

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[1] Of this amount, $252.22 represents the additional testing cost per Medical Monitoring claimant per year related to CT scans.

Third Party Administrator Fees and Expenses: Included within Third Party Administrator Fees and Expenses are $48,324 in expenses during the Budget period for a Central Repository for Scientific Research Concerning Test Results and would only be for the purpose of collecting and maintaining the test results, and not to do research, which may be performed by an independent researcher. For the Budget period, these Central Repository expenses were allocated based upon the same method as Medical Provider Medical Monitoring Expenses, discussed above.

As for the remaining Third Party Administrator Fees and Expenses: (i) those expenses that are claimant sensitive (Communication Materials, Production/Distribution of ID Cards, and Scheduling/Appointment Reminder Letters) were allocated during the Budget year with 75% of the Budget year expense split evenly among the first 6 months, and 25% of the Budget year expenses shared evenly among the remaining six months; (ii) the Administrative Fee Per Active Claimant and Consulting Services expenses were allocated evenly each month throughout the Budget year; and (iii) the Quarterly Meetings expenses were allocated quarterly during the months of October 2011, January 2012, April 2012, and July 2012.

VIII. Proposed Working Order on Paper and Electronic Media

[PROPOSED WORKING ORDER FOR OCTOBER 17, 2011 10:00 A.M. HEARING]
[PROVIDED ON PAPER MEDIUM, PDF, WORD AND WORDPERFECT]

IN THE CIRCUIT COURT OF HARRISON COUNTY, WEST VIRGINIA

LENORA PERRINE, et al., individuals residing in West Virginia, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

Case No. 04-C-296-2
Thomas A. Bedell, Circuit Judge

E. I. DUPONT DE NEMOURS & COMPANY, et al.,

Defendants.

ORDER RESOLVING PENDING MEDICAL MONITORING PROGRAM ISSUES IN PREPARATION FOR NOVEMBER 1, 2011 IMPLEMENTATION DATE

Presently before the Court are the unresolved issues described below and related to the November 1, 2011 implementation of the Medical Monitoring Program.

In order to allow the Parties to be heard on these issues and all other issues related to the implementation of the Medical Monitoring Program, this matter came on to be heard on October 17, 2011, at 10:00 o'clock a.m., and said hearing was held before the Honorable Thomas A. Bedell, Judge of the Circuit Court of Harrison County, West Virginia, in the Division 2 Courtroom located on the 4th Floor of the Harrison County Courthouse, 301 West Main Street, Clarksburg, West Virginia.

At the Hearing, the Claims Administrator submitted his Report respecting the recommended resolution of the issues, while presenting the alternative positions of the Parties. Also appearing was Dr. Jubal Watts, an expert sponsored by the Claims Administrator, to address the CT Scan issue.

The Claims Administrator and Dr. Watts subjected themselves to cross-examination by the Parties, with the Claims Administrator, as a neutral for the Court, then resting. Class Counsel, the Guardian ad Litem for Children and DuPont then presented their positions for the Court's consideration.

After a careful review of the Claims Administrator's submission and the submissions of the Parties, and having weighed the evidence and the presentations made at the October 17, 2011 hearing, and in consideration of the applicable law, the Court ORDERS the following:

1. The Medical Monitoring Program is a primary plan for medical testing benefits, with DuPont being responsible for all costs thereof.

2. To facilitate the collection of Medical Monitoring Plan data for possible future scientific and medical research, the Court hereby approves the use by the Medical Monitoring Plan of the final Optional Data Collection Consent Form submitted by the Claims Administrator in Attachment II to his October 10, 2011 Report, with Claimants being allowed to complete and sign the Form, at their option, during their initial Medical Monitoring Provider visit.

3. The Court has carefully considered the positions of the Guardian ad Litem and DuPont on how to handle "No" box minor Medical Monitoring Claimants, whose parent or guardian checked the "No" box and therefore did not choose Medical Monitoring, when these minor "No" box Claimants become adults. The Court further considered their positions on when an "Inactive" Medical Monitoring Claimant (a Claimant who signed up for Medical Monitoring but then fails to use it) may become "Active" again. The Guardian ad Litem suggests that the Medical Monitoring Plan is a right which cannot be waived through a lack of use by a Claimant, while DuPont argues that the Medical Monitoring Plan is a right that can be waived by a Claimant through lack of use.

Although this is a difficult issue, the Court makes the following determination:

[ALTERNATIVE A: CANNOT BE WAIVED]

The Medical Monitoring Plan is a right of a Claimant that cannot be waived, with such a waiver not being reflected anywhere in the Settlement Memorandum of Understanding ("MOU") or any related Orders. The Court therefore decides that the Claims Administrator's suggested procedures to notice these Claimants, with the procedures being contained in Attachment III to the Claims Administrator's October 10, 2011 Report, are well taken and are hereby approved.

[ALTERNATIVE B: CAN BE WAIVED]

The Court finds that a Claimant who has registered for Medical Monitoring has a duty to avail himself of the benefit or else it will be waived. Minor Claimants whose parents or guardians checked the "No" box shall be reminded of their Medical Monitoring benefit three times by the Claims Administrator after they reach adulthood. If they still do not then use the benefit, they will be deemed to have waived it, and will not be provided further notice. Likewise, an active Claimant that is ripe to be medically monitored shall be provided three notices to set up an appointment to begin the process. If the active Claimant does not participate after three notices, the active Claimant will be deemed to have waived his Medical Monitoring right, and will be classified as inactive, and will not receive further notice.

4. In connection with CT Scans, the Court has carefully reviewed the proposed CT Rule and CT Scan Verification Form provided by the Claims Administrator in his October 10, 2011 Report. The Court understands that DuPont supports the Claims Administrator's suggested approach to CT Scanning and these related forms, but the Guardian ad Litem for Children and Class Counsel suggest that there first be baseline CT scanning made available to all CT Scan eligible Claimants during their first round of Medical Monitoring, and for younger Claimants as they reach age 35, with the CT Rule

and the CT Scan Verification Form suggested by the Claims Administrator then being implemented thereafter.

After careful consideration of the submission of the Claims Administrator and the positions of DuPont, the Guardian ad Litem for Children and Class Counsel in this matter, the Court hereby makes the following determination:

[ALTERNATIVE A: CT RULE AND CT SCAN VERIFICATION FORM APPROVED]

The approach suggested by the Claims Administrator best carries out the terms of the MOU which provide that:

> "The program shall provide those examinations and tests set forth in the Court's Order of February 25, 2008 with the exception that no routine CT Scans shall be performed as part of the Medical Monitoring Program. The Defendant does agree to provide CT Scans that are diagnostically medically necessary as determined by a competent physician as relevant to possible exposure to the heavy metal contamination at issue in this litigation." [Emphasis added].

That is, CT Scans cannot be baseline or routine even at the commencement of Medical Monitoring. However, as suggested by all Parties, the Claims Administrator's CT Rule and CT Scan Verification Form vouchsafes the diagnosis of a CT Scan by the attending physician for a decision. Exposure to heavy metals and not a specific diagnosis are all that is required to diagnose a CT Scan.

[ALTERNATIVE B: APPROVES MY UNDERSTANDING OF GUARDIAN AD LITEM AND CLASS COUNSEL POSITION]

Although the Claims Administrator and DuPont correctly state that the MOU at Paragraph C on page 2 does not allow routine CT Scanning under the Settlement, the Court finds it appropriate to have baseline CT scanning at the commencement of the Medical Monitoring Plan, and as younger Claimants reach age 35, in order for physicians to make an early determination of disease and

thereby save lives. Thereafter, the Claims Administrator's CT Rule and CT Scan Verification Form will be utilized by the Medical Monitoring Plan.

5. The Claims Administrator has submitted his proposed Budget for Medical Monitoring implementation from November 1, 2011 through August 31, 2012, which is divided into (i) a separate Medical Monitoring Implementation Budget without incremental CT Scan Costs totaling $1,977,207.41 and (ii) an incremental CT Scan Costs Budget, in an effort to ensure the timely commencement of Medical Monitoring on November 1, 2011 even if the CT Scan issue is further litigated.

The two major objections by DuPont to the finalization of the Budget at this time are that the number of Medical Monitoring Participating Claimants is unknown and the Medical Monitoring Medical Provider prices are not finalized.

However, as suggested by the Claims Administrator in his Report and in his Budget and supporting documentation in Attachment VII thereto, a materially accurate projection of the number of Medical Monitoring Participating Claimants was provided on October 3, 2011, and totals 4,000. In addition, Medical Monitoring Provider contracts are in the process of being finalized, with a letter containing the prices, that was previously vetted with the Parties, having been submitted to the Providers on October 6, 2011, and with Medical Provider contracts, after vetting with the Parties, having been submitted to the Providers for review and possible signature.

The Court also understands that the Medical Monitoring prices that were ably negotiated by CTIA, the Third Party Administrator, are substantially below that originally budgeted on August 19, 2011. The Court therefore finds that these two variables have been reasonably established so that

setting a Budget now, funding it by October 31, 2011, and commencing the Medical Monitoring Program on November 1, 2011 are appropriate.

Respecting the second component of the Medical Monitoring Budget, the amount of funding necessary to fund CT scans, the Claims Administrator reports that the amount of funding required depends on (i) whether the CT Rule and CT Scan Verification Form suggested by the Claims Administrator are implemented at the beginning of the Medical Monitoring Plan; or (ii) the baseline CT Scan approach suggested by Class Counsel and the Guardian ad Litem is implemented at the beginning of the Medical Monitoring Plan and as younger Claimants reach age 35; (iii) with the Incremental CT Scan Budget under the Claims Administrator's Proposal being $839,302.10 and with the incremental CT Scan Budget under Class Counsel's and the Guardian ad Litem's proposal being $1,192,414.93.

After carefully considering this matter, the Court makes the following decision:

[ALTERNATIVE A: CT RULE AND CT SCAN VERIFICATION FORM APPROVED]

The Claims Administrator's approach to CT Scans is the correct one, so that the Incremental CT Scan Budget is $839,302.10.

THEREFORE, THE NEW CONTRIBUTION OF DUPONT TO THE MEDICAL MONITORING FUND DUE TO BE PAID OCTOBER 31, 2011 (FOR NON-CT SCAN AND FOR CT SCAN MEDICAL MONITORING) IS $2,789,984.94.

[ALTERNATIVE B: CLASS COUNSEL AND GUARDIAN AD LITEM BASELINE CT SCAN POSITION ACCEPTED]

Class Counsel's and the Guardian ad Litem's baseline approach to CT Scanning is more appropriate, so that the Incremental CT Scan Budget is $1,192,414.93.

THEREFORE, THE NEW CONTRIBUTION BY DUPONT TO THE MEDICAL MONITORING FUND DUE TO BE PAID BY OCTOBER 31, 2011 (FOR NON-CT SCAN AND FOR CT SCAN MEDICAL MONITORING) IS $3,143,097.77.

6. Finally, in his August 24, 2011 and September 1, 2011 Reports to the Court, the Claims Administrator suggested that the Court consider whether DuPont should pay an additional $26,524.57 for expenses incurred by CTIA, the Third Party Administrator for the Medical Monitoring Plan, during September and October 2011, as being post-implementation expenses, or whether these expenses should be paid from old money already contributed by DuPont at Settlement, as pre-implementation expenses. In his October 10, 2011, Report, the Claims Administrator now suggests that these expenses are not materially great and the appropriate payment is debatable. He also reports that approximately half of this amount, or $15,440, is attributed to monthly charges of CTIA under its contract with the Settlement, which are not directly related to actual testing. The other costs are for communications materials, production and distribution of ID cards, and the scheduling of appointments and reminder letters and design consulting services. Although some of these costs are reasonably related to actual testing, there is a reasonable basis to find that none of them deal with testing itself until the testing actually begins.

Therefore, the Court accepts the Claims Administrator's proposal that these Bridge Funding expenses be paid from the old DuPont deposit to the Medical Monitoring Fund.

IT IS SO ORDERED.

Finally, it is **ORDERED** that the Clerk of this Court shall provide certified copies of this Order to the following:

David B. Thomas
James S. Arnold
Stephanie Thacker
Guthrie & Thomas, PLLC
P.O. Box 3394
Charleston, WV 25333-3394

Virginia Buchanan
Levin, Papantonio, Thomas, Mitchell,
Eshner & Proctor, P.A.
316 South Baylen St., Suite 600
Pensacola, FL 32591

Edgar C. Gentle, III
Michael A. Jacks
Gentle, Turner & Sexton
P. O. Box 257
Spelter, WV 26438
Special Master

Meredith McCarthy
901 W. Main St.
Bridgeport, WV 26330
Guardian ad litem

J. Farrest Taylor
Cochran, Cherry, Givens, Smith
Lane & Taylor, P.C.
163 West Main Street
Dothan, AL 36301

ENTER: _____

_____
Thomas A. Bedell, Circuit Judge

IX. Expert Opinion of Dr. Jubal Watts, with Resume and List of Documents He Reviewed

I am a cardiopulmonary radiologist at University of Alabama at Birmingham, the second largest participating site in the National Lung Cancer Screening Trial (NLST). While I was not a primary investigator during the trial (I was a resident physician until the screening portion of the trial was nearly complete), I am familiar with the NLST and my participation was requested by the radiology primary investigator, Dr. Hrudaya Nath, as he could not participate due to a scheduling conflict. I am board certified in diagnostic radiology and have worked as an academic cardiopulmonary radiologist for just over four years. I am currently involved in research projects using data from the NLST.

There are no major professional societies that I am aware of that recommend lung cancer screening for populations with risk profiles outside of those of the NLST population. The data is very preliminary and will require further subset analysis and hopefully better risk stratification with biochemical markers collected at some of the participating sites, before reasonable recommendations can be made.

A few points about the NLST that need to be considered when determining the CT scan guidelines or rules that are being contested.

Over 96% of the positive screens in the CT arm of the NLST were false positives.[1]

The rate of positive screens in the CT arm of the NLST ranged from 16.8% to 27.9% per year with just over 39% of participants in the CT arm having at least one positive screen.[1]

Of these positive screens (the overwhelming majority being false positives) just under 50% subsequently required a diagnostic (typically full dose) chest CT (73% for the baseline T-0 exam). A substantial minority also had a PET or PET-CT (8.3% total and 10.3% for the baseline T-0 exam).[1]

Radiation induced malignancies have a typical lag time in excess of ten years and were not included in the NLST analysis (which had six to seven year follow-up).

Reviewing the report of Dr. Werntz (who is obviously an expert epidemiologist and I am not), if I understand correctly on page 3, he describes the time in each zone of involvement necessary to expose an individual to a 1 in 100,000 risk of developing lung and/or skin cancer. For an example, I will use zone 2, where someone living on the peripheral contour of this area would require 3 years of exposure to these heavy metals to increase the risk of developing lung cancer by 1 in 100,000. Assuming they were exposed for 30 years (one order of magnitude) then the incremental risk of developing lung cancer would be 1:10,000. If I am incorrectly understanding or am mischaracterizing these estimates I hope Dr. Werntz will correct me.

Ignoring the cumulative radiation dose from the additional diagnostic chest CT's (estimated effective dose of roughly 8 mSv per diagnostic chest CT, described in the

NLST paper[1]) or additional PET-CT's (typically substantially higher effective doses than diagnostic chest CT's) required in the work-up of these large number of false positives, the cancer risk from only the radiation involved in the low dose screening exam protocols used in the NLST has been estimated.[2] For an example, a 42 year old female would have an expected radiation induced lung cancer mortality risk of 3 to 5 per 10,000 people screened.[2] Again, if I am understanding Dr. Werntz's report correctly, then screening a 42 year old patient (with the NLST low dose protocol) would increase the risk of lung cancer mortality 3 to 5 times greater than that of a 30 year exposure at the periphery of zone 2 (1:10,000).

Radiation induced breast cancer estimates in women from the NLST protocol also range from 3-6 cases per 10,000 screened.[2]

These risks would increase substantially if the effective radiation dose from the downstream diagnostic exams generated by the false positive screens (roughly 39% in the CT arm of the NLST) were included.

Now I am a proponent of lung cancer screening in high risk populations, like the NLST population with lung cancer mortality risks in excess of 1% (1 in 100). These patients are older and the radiation risks are substantially less than for younger populations. I think the incremental risks associated with the heavy metal exposure are 2 to 3 orders of magnitude lower (1 in 100,000 for 3 years at the periphery of zone 2) than the risks faced by 55+ year old smokers with a 30+ pack year history (the population invited to screen in the NLST). Just the radiation induced lung cancer mortality from the low dose NLST screening protocol (3 to 5 per 10,000 in a 42 year old woman) appears to me greater than the incremental risk of the majority of the population in the class area. Adding the breast cancer risk in women (3-6 cases per 10,000 screened) and downstream risk of higher dose exams required to work-up the false positives leads me to believe that CT screening based solely on the heavy metal exposure for zones 2 and 3 may create more cancers than it would detect and cure.

If you take the zone 1 inner estimates of Dr. Werntz with a 1 in 100,000 risk for an exposure of 0.3 years, living 3 years in the periphery of zone 1 inner is a risk of 1 in 10,000, and living 10 years in the peripheral contour of zone 1 inner would be a risk between 3 and 4 per 10,000 (approximately the risk of inducing lung cancer solely from the radiation dose using the NLST low dose screening regimen in a 42 year old woman - 3 to 5 per 10,000).

These radiation dose risk estimates are based on the National Academy of Sciences 2005 report[3] and are the best data we have to date. While many physicians feel this data overestimates risk, being based on Japanese atomic bomb survivors and not diagnostic medical radiation, there is no better data to my knowledge. The FDA also acknowledges the potential risk in medical radiation.

Excerpts taken from the FDA website on radiation risks from CT

"A CT examination with an effective dose of 10 millisieverts (abbreviated mSv; 1 mSv = 1 mGy in the case of x rays.) may be associated with an increase in the possibility of fatal cancer of approximately 1 chance in 2000. . ."

"It must be noted that there is uncertainty regarding the risk estimates for low levels of radiation exposure as commonly experienced in diagnostic radiology procedures. There are some that question whether there is adequate evidence for a risk of cancer induction at low doses. However, this position has not been adopted by most authoritative bodies in the radiation protection and medical arenas. . ."

"The effective doses from diagnostic CT procedures are typically estimated to be in the range of 1 to 10 mSv. This range is not much less than the lowest doses of 5 to 20 mSv received by some of the Japanese survivors of the atomic bombs. These survivors, who are estimated to have experienced doses only slightly larger than those encountered in CT, have demonstrated a small but increased radiation-related excess relative risk for cancer mortality. . . "[4]

The linear no threshold model used by the National Academy of Sciences is generally accepted and I do not believe deviating from it to discount the radiation risks in lung cancer screening is reasonable with no better validated risk prediction model to date. Future analysis of NLST and other large screening populations may give us more accurate models but we do not have them currently.

The FDA estimates the increase risk in the possibility of a fatal cancer from a CT effective dose of 10 mSv at 1 in 2000. A single diagnostic chest CT (performed in large numbers in the NLST CT screening arm for the 96% false positives) has an effective dose of 8 mSv. Additional tests that were frequently performed, such as PET-CT, would increase the incremental cancer risks well above the risks of living in the peripheral contour of zone 1 inner for 10 years (between 3 and 4 in 10,000). Absent a significant smoking history, I am not certain of more benefit than harm to the patients living in the peripheral contour of zone 1 inner.

I think many physicians are underestimating the radiation risks with lung cancer screening. Physicians' knowledge of radiation risks and radiation doses with medical imaging exams is poor overall, with only a minority of physicians found to be well informed on radiation doses and risks in a recent meta-analysis.[5] The majority of physicians (60 to 87%) in the included trials underestimated CT doses.[5]

Regarding the frequency of screening, any recommendations outside the annual screening as performed in the NLST is not likely to be as beneficial. Clinically significant lung cancers are typically biologically aggressive tumors. Over the three years of screening in the NLST the numbers of lung cancers detected in the T0-baseline scan were 270, compared with 168 in the T1 (second annual screening

exam) and 211 in the T2 exam (third annual screening exam).[1] The prevalence and incidence rates are fairly similar for clinically significant lung cancers and wide screening intervals may miss most significant cancers while detecting most insignificant cancers - overdiagnosis - with resultant unnecessary morbidity. Even with annual screening, there was no real benefit for one of the most aggressive histologic types of lung cancer, small cell carcinoma.[1] It may be that semi-annual screening is necessary to detect the very aggressive type of lung cancers. No one knows the optimum screening intervals at this time and varying from the NLST trial design is unwarranted. We will have a much better idea on appropriate screening intervals in three years and I believe that high risk patients (similar to risk profiles in the NLST), should be screened aggressively, with annual screenings performed as it was in the NLST for three years. After the three annual screens more data will be available and adjustments can be made.

Lung cancer screening is medically justifiable/necessary in high risk populations and, as with any screening exam, is done based on the presence of risk factors alone and not specific signs and symptoms. Accordingly, I do not think the presence of any specific sign or symptom should be a prerequisite to obtaining a lung cancer screening CT.

In summary, we know that lung cancer screening benefits individuals at high risk for lung cancer, patients 55+ years and with 30+ pack year smoking history, and it is reasonable to screen patients with similar risk profiles. Interpreting Dr. Werntz's report to the best of my ability, I am doubtful that the incremental risks of lung cancer in the class area from the exposure to heavy metals would independently elevate an individuals cancer risk to approximate that of the NLST cohort. It would be hard to justify screening any 35 year old (the lower age limit of the involved population eligible for CT screening in the medical monitoring program) with any exposure history or risk factors, based on the radiation risks of screening alone and I do not think that screening people this young is a reasonable extrapolation of the NLST.

That being said, I agree that until more data becomes available it should be up to the patients physician to decide if lung cancer screening is medically necessary based on knowledge of cumulative risk factors, e.g. smoking history as well as duration and degree of exposure to heavy metals. The involved physicians will likely need specific education regarding radiation risks in CT screening, as current understanding of radiation dose and risk by physicians is poor. Specific physician education regarding other aspects of lung cancer screening, including the 39% positive screen rate and the 96+% false positive rate, would also allow physicians to more accurately weigh the risks and benefits.

Lastly, I also would recommend lung cancer screening be performed at institutions similar to the ones involved in the NLST, as the NLST had low diagnostic procedure rates and very low surgical mortality (1% vs 4% previously reported for the general community)[1]. I am not certain how effectively the benefits of lung cancer screening

will translate to the general medical community for the same reasons described in the NLST paper[1].

Sincerely,

Jubal R. Watts Jr. M.D.

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[1] The National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. N Engl J Med 2011;365:395-409

[2] Berrington DE Gonzalez A, Kim KP, Berg CD. Low- Dose Lung Computed Tomography Screening Before Age 55: Estimates of the Mortality Reduction Required to Outweigh the Radiation-Induced Cancer Risk. *J Med Screen* 2008;15:153-158.

[3] National Research Council. Committee to assess health risks from exposure to low levels of ionizing radiation. Health Risks from Exposure to Low Levels of Ionizing Radiation: BEIR VII. Washington DC: National Academy of Sciences, 2005

[4] http://www.fda.gov/Radiation-EmittingProducts/RadiationEmitting ProductsandProcedures/MedicalImaging/MedicalX-Rays/ucm115329.htm

[5] Krille L, Hammer GP, Merzenich H, and Zeeb H. "Systematic review of physician's knowledge about radiation doses and radiation risks of computed tomography. Eur J Radiol. 2010 Oct;76(1):36-41

CURRICULUM VITAE
University of Alabama at Birmingham
School of Medicine Faculty

Date: October 7, 2011

PERSONAL INFORMATION

Name:	**Jubal R. Watts, Jr., M.D.**
Citizenship:	U.S.A.
Home Address:	5004 Altamont Road South Birmingham, AL 35222
Phone:	205-591-8929

RANK/TITLE	**Assistant Professor, tenure-earning**
Department:	Diagnostic Radiology
Business Address:	619 19th St. So., JT N363 Birmingham, AL 35249-6830
Phone:	205-934-5345
Fax:	205-934-5688
Email:	jrwatts@uabmc.edu

HOSPITAL AND OTHER (NON ACADEMIC) APPOINTMENTS:

01/2008 – 02/2009	Assoc Radiologist	Georgia West Imaging Carrollton, GA
2/2009-present	Staff Radiologist	UAB Hospital and Clinics Birmingham, AL

EDUCATION:

Institution	**Degree**	**Year**
Medical College of Georgia Augusta, GA	M.D.	08/1997 – 05/2001
Layola University New Orleans, LA	Undergraduate	08/1993 – 05/1997

LICENSURE:
Alabama, M.D., #25097

BOARD CERTIFICATION:
American Board of Radiology, 2006

ABR Diagnostic Radiology Examination

Diagnostic Section	08/2004
Physics Section	09/2004
Oral Section	06/2006

USMLE Step 1	06/1999
USMLE Step 2	08/2000
USMLE Step 3	08/2002
NIOSH B-Reader Certification	06/2009

POSTDOCTORAL TRAINING:

Year	Program	Institution
07/2001 – 06/2002	Internship Internal Medicine	Cleveland Clinic Foundation Cleveland, OH
07/2001 - 06/2006	Residency Diagnostic Radiology	UAB School of Medicine Birmingham, AL

ACADEMIC APPOINTMENTS:

Year	Rank/Title	Institution
02/2009 – Present	Assistant Professor Diagnostic Radiology	UAB School of Medicine Birmingham, AL
07/2006 – 12/2007	Instructor & Assistant Professor Diagnostic Radiology	UAB School of Medicine Birmingham, AL
11/1996 – 03/1997	Volunteer Pediatric Oncology	Ochsner Foundation Hospital

AWARDS/HONORS:

Alpha Omega Alpha (Member- AOA)
2010 – Elected Fellow of the American College of Chest Physicians
2010 – Dr. Gary T. Barnes Distinguished Faculty Award for Resident Education
2010 – Best Doctors in America
2010 – Top Ten Teacher Award, UAB Department of Radiology
2010 – Top Ten Teacher Award, UAB Department of Radiology
2009 – Top Ten Teacher Award, UAB Department of Radiology
2009 – Top Ten Teacher Award, UAB Department of Radiology
2007 – Top Ten Teacher Award, UAB Department of Radiology
2006 – Top Ten Teacher Award, UAB Department of Radiology
2006 – RSNA Roentgen Resident/Fellow Research Award
2001 – Medical College of Georgia, Clinical Scholar Award, Department of Medicine
2000 – Tanner Medical Foundation Scholarship
1999 – Honors, USMLE Step I, Medical College of Georgia
1998 – American Medical Association Scholarship Award

PROFESSIONAL SOCIETIES / MEMBERSHIPS:

Society of Thoracic Radiology – Senior Member
North American Society of Cardiac Imaging – Active Member
American College of Radiology – Active Member
American Roentgen Ray Society – Active Member
Radiological Society of North America – Active Member
Southern Medical Association – Active Member
American College of Chest Physicians – Active Member
Society of Cardiovascular Computed Tomography – Active Member
Southern Radiological Society – Active Member

UNIVERSITY ACTIVITIES:

UAB Hospital, Department of Radiology

Medical Director, Inpatient Radiology
Resident Education Committee
Diagnostic Radiograph Exam Quality Committee
Trauma Radiology Committee
Radiology Leadership Council

University of Alabama School of Medicine (UASOM)

Blood Utilization and Management Committee
Clinical Rounds Committee
Patient Safety Committee – Radiology Representative

MAJOR RESEARCH INTERESTS:

Imaging of congenital and acquired heart disease including coronary arterial calcification
Imaging of thoracic aortopathies
Lung cancer imaging

TEACHING EXPERIENCE:

Teaching portfolio furnished upon request.

BIBLIOGRAPHY:

Manuscripts already published:

Watts KA, **Watts JR Jr.** Incidental discovery of an anterior mediastinal angiomyolipoma. J Thorac Imaging 2007 May;22(2):180-181. Case Report

Book Review:

Watts JR, Lockhart ME. "Imaging in Oncology, 2nd Ed. Vols I & II". AJR 2005 Aug;185:562.

POSTER EXHIBITS:

1. Malcolm IG, Singh SP, **Watts JR, Jr.** Mediastinal Fibrosis – Revisited. Society of Thoracic Radiology Annual Meeting, Loews Royal Pacific Resort at Universal Studios, Orlando, FL, March 12-16, 2006

2. **Watts JR Jr.**, Singh SP. STR Case of the Day – Massive Mediastinal Pheochromocytoma in a Patient with Multicentric Paragangliomas. Society of Thoracic Radiology Annual Meeting, Red Rock Casino, Resort and Spa, Las Vegas, NV, March 25-29, 2007.

3. Joshi A, **Watts JR Jr.**, Singh SP. Assessment of Motion Degradation of Coronary Artery Segments Throughout the Cardiac Cycle in Coronary CT Angiography. 35th Annual Meeting of the North American Society for Cardiac Imaging, J.W. Marriott Hotel, Washington, DC. , October 5-9, 2007.

4. **Watts JR Jr.**, Singh SP, Nath H, Wade M. Pictorial Review of EKG Gated MDCT Evaluation of Repaired Congenital Heart Disease. 37th Annual Meeting of the NASCI, Orlando, FL, October 3-6, 2009.

5. **Watts, JR Jr.** Pictorial Review of MDCT Imaging of the Preoperative Evaluation of Congenital Heart Disease. Honorable Mention. 37th Annual Meeting of the NASCI, Orlando, FL, October 3-6, 2009.

6. Wade M, Patel B, **Watts, JR Jr.**, Singh SP. Evolving Role of Imaging in Thoracic Aortic Endograft Stent Treatment: Post op Surveilllance. Magna Cum Laude Award. STR Annual Meeting, San Diego, CA, February 28-March 3, 2010.

7. Wade M, Patel B, **Watts, JR Jr.**, Singh SP. Imaging after Open Thoracic Aortic Surgery: Normal Appearance, Pitfalls, and Complications. Cum Laude Award. STR Annual Meeting, San Diego, CA, February 28 – March 3, 2010.

8. **Watts JR Jr.**, Singh SP, Nath H. Comparison of Effective Radiation Dose in Pediatric Cardiovascular CT Angiography. 38th Annual Meeting of NASCI, Seattle, WA, October 2-5, 2010.

9. **Watts, JR Jr.**, Singh SP, Nath H. Optimizing Pediatric Cardiac MDCT – Diagnostic Accuracy: What We Missed and How We Can Improve. 38th Annual Meeting of NASCI, Seattle, WA, October 2-5, 2010.

10. **Watts JR, Jr.**, Singh SP, Simms H, Terry N. The Wayward Catheter: Pictorial Review of Less than Ideal Tube and Catheter Positions. Presented at the Society of Thoracic Radiology, Bonita Springs, FL, March 6-9, 2011.

ELECTRONIC EXHIBITS:

1. Terry NL, **Watts JR, Jr.** Singh SP. The Road Less Traveled: Thoracic venous collateral pathways demonstrated on 64-detector CT – Physiologic vs Pathologic. RSNA, Chicago, IL, November 27-December 3, 2010.

2. Tank KC, **Watts JR Jr.**, Nath H, Singh SP. Cardiac Case of the Day – Monday. RSNA, Chicago, IL, November 27 – December 3, 2010.

MISCELLANEOUS:

VuCOMP investigator for lung nodule computer aided detection.

Jubal Watts, M.D.
Documents reviewed for
Perrine vs. DuPont; Civil Action No.: 04-C-296-2

1	Bedell 9/1/11 Budget
2	Bedell 9/20/11 Consent & CT Scan Form
3	DuPont 9/21/11 Submission: Re CT Scans & MM Budget
4	Exhibit List to Plaintiffs Response to Proposed CT Scan Rule
5	Information Packet for Physicians W Exhibits 9/21/11
6	Plaintiffs Response to Proposed CT Scan Rule
7	Plaintiffs Response to Proposed CT Scan Rule Exhibit 1
8	Plaintiffs Response to Proposed CT Scan Rule Exhibit 2
9	9/21/11 Order - Re: Briefing on CT Scan Physicians Forms
10	Dr. Werntz's Letter/Report With Risks 12/9/2010
11	10/3/11 Exhibits for Response to Def Submission Rect Guidelines
12	10/3/11 Response to Def Submission Rect Guidelines
13	10/4/11 Submission of GAL as to CT Scans & Budget
14	DuPont 10/3/11 Reply Sub Re CT Scan Budget
15	Plaintiff 10/3/11 Exhibits for Response to Def Submission Rect Guidelines
16	Plaintiff 10/3/11 Response to Def Submission Rect Guidelines
17	ACR Practice Guideline for Performing & Interpreting Diagnostic Computed Tomography (CT). Revised 2011 (Resolution 35)
18	Brandt & Others Order Setting Hearing 10/5/11
19	Low-Dose Lung Computed Tomography Screening Before Age 55: Estimates of the Mortality Reduction Required to Outweigh the Radiation Induced Cancer Risk. J Med Screen 2008;15:153-158
20	Dr. McGuire's Letter 8/19/2011
21	Exhibit List to Plaintiffs Response to Proposed CT Scan Rule
22	Better Evidence About Screening for Lung Cancer. N Engl J Med 2011;365:455-457
23	Reduced Lung Cancer Mortality With Low-Dose Computed Tomographic Screening. N Engl J Med 2011;365:395-409
24	Memo 9/26/11 – Perrine-DuPont Settlement - Age Statistics of "Yes" Verified Ripe Claimants; Our file nos. 4609-1 {GG-6}
25	Memo on CT Scan Proposed Protocol from DD to ECG, KH and PO - 8/17/2011