

**PERRINE DUPONT SETTLEMENT CLAIMS OFFICE  
ATTN: EDGAR C. GENTLE, CLAIMS ADMINISTRATOR  
C/O SPELTER VOLUNTEER FIRE DEPARTMENT OFFICE**

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April 24, 2017

**VIA HAND DELIVERY**

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

**Re: The Perrine DuPont Settlement Remediation Program (the  
"Remediation Program") - Report Respecting Use of Remediation Program  
Second Surplus; Our File No. 4609-1 {DD-89}, 4609-1{GG-25} and  
4609-1{GG-26}**

Dear Judge Bedell:

I hope this letter finds the Court well.

As the Court may recall, your Settlement Administrator projects a surplus in the Remediation Program of approximately \$600,000. The purpose of this Report is to present the detailed proposal of the Medical Advisory Panel and Settlement Administrator "on the possible uses of the remaining funds for medical monitoring, including possibly an epidemiological or health study and possible Claimant participation incentive payments, and disabled Claimant transportation, and to present it to the Court and the Parties," as ordered in the Court's Order entered March 9, 2017. In making this Report, we are aware that the Claimants voted in our town hall meetings to issue a second dividend from all of the surplus. With the recommendations below, we are sensitive to the recommendations of the Claimants as we suggest that half of the surplus go to the Claimants in the form of a dividend and half the surplus to help the Medical Monitoring Program to the benefit of the Claimants. This Report addresses the Court's instructions in two parts: claimant participation incentives and transportation; and scientific research, which might include a health study.

**A. Recommended Incentive Payments and Transportation**

The Panelists and your Settlement Administrator recommend that Claimants participating in the Medical Monitoring Program be given a Walmart gift card valued at \$25 for each round of testing. Assuming 500 participants with 12 more rounds of testing, the cost of the Walmart gift card incentive program would be \$150,000, which we recommend be paid from the remediation surplus.

The Panelists, who join in the submission of this report, first note that there has been a significant drop in participation among registered claimants. We believe an incentive program such as this might increase the claimant participation rate.

A survey of incentives offered in similar programs found that the VA, for example, offers travel reimbursement for mileage from the patient's door to the facility. In some cases, the VA will reimburse food costs.

In some clinical trial programs, participants are paid only after they complete the process, which may be the practice here.

In the administration of a settlement in the *Mingo County Coal Slurry Litigation*, in the Circuit Court of Mingo County, West Virginia, Case Number 10-C-5000, supervised by Mr. Gentle, as Settlement Administrator, participants were originally given \$10 in cash at testing and \$10 in cash once the results were received. However, the Mingo program has been amended to give a \$20 Walmart gift card when tested and a \$20 Walmart gift card when the Claimant returns for the results. In the Mingo County case, the Settlement's Medical Monitoring Plan provides free screenings once every two years during a thirty-year period, based upon the effects of the slurry contamination of the water supplies in Mingo County. An Environmental Protection Agency report stated that the main risks associated with "ingestion and exposure based upon contaminants found in Mingo County are liver damage, cancer, kidney problems, blood issues, reproductive disorders and problems with the nervous system."

Based upon the survey of other similar programs, for those registered participating claimants, your Settlement Administrator and the Panelists also propose that transportation be provided to those needing such. The Spelter Volunteer Fire Department is agreeable to accepting the contribution of the Settlement vehicle, in exchange for providing Medical Monitoring transportation for Claimants needing it.

The Settlement's suggested donation of its vehicle to the Spelter Fire Station with the understanding that it will be used to transport Claimants to their Medical Monitoring appointments as needed should provide needed transportation help for the Medical Monitoring Program.

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**B. Recommendations Concerning Scientific Research<sup>1</sup> Which May Include an Epidemiology<sup>2</sup> or Health Study**

The Panelists and your Settlement Administrator recommend the use of some of the surplus for a seed scientific research grant in order to review Claimant and related data for scientific trends and findings, and the results of which may help in future Medical Monitoring testing protocol design. Using the current data in hand may be counterproductive given that more high-powered, detailed data is necessary for some scientific studies. Such scientific research may include the completion of an epidemiology study. We recommend a seed grant from the remediation surplus of \$150,000 for this purpose, with research grant applications to the Settlement to be vetted by the Medical Advisory Panel and the Settlement Administrator and realizing that such research may be more costly, as shown by one estimate in Appendix A.

Another case to consider is that of the Fernald, Ohio Uranium Plant Medical Monitoring Program. In this case, 11,000 people were exposed to radiation in uranium dust from a plant that converted uranium ore to metal for use in nuclear plants and for nuclear weapons. A \$78 million settlement fund was established for a medical monitoring program and administered by the University of Cincinnati, with detailed testing being conducted annually to identify disease if present. The database and archived biospecimens represented a rich resource for future research of both health effects related to the environmental exposure, and a wide range of non-exposure questions. As suggested in the *Fernald* case, one purpose of medical monitoring is to determine if there is linkage between the toxic substance or the dangerous product and disease. Five grant-funded studies were completed at Fernald: (i) Estimation of radon exposures to workers at the Fernald Feed Materials Production Center 1952-1998 (2008); (ii) Retrospective smoking history data collection for deceased workers; completeness and accuracy of surrogate reports (2002); (iii) Mortality among a cohort of white male workers at a uranium processing plant: Fernald Feed Materials Production Center. 1951-1989 (1995); (iv) Uranium dust exposure and lung cancer risk in four uranium processing operations (1995); and (v) Mortality among workers exposed to external ionizing radiation at a nuclear facility in Ohio (1991).

The Medical Panel notes that an epidemiologic study of the existing Medical Monitoring data is unlikely to be informative. There is a significant risk the study is underpowered due to the high dropout rate and the seemingly high number of cancers needed to show a difference between controls. The control group may also be less than ideal. Thus, we recommend a grant from the Remediation surplus of \$150,000 as seed money for a scientific research study related to the Settlement, instead, with the possible scientific research not being limited to data only collected through the Medical Monitoring Program.

Although the Medical Advisory Panel and Settlement Administrator are sensitive to the

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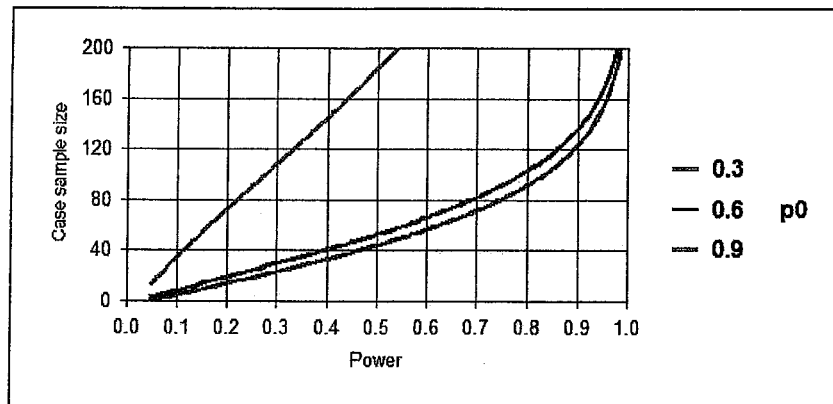
<sup>1</sup> Scientific research is the systematic investigation of scientific theories and hypotheses. A hypothesis is a single assertion, a proposed explanation of something based on available knowledge, for something yet to be explained. It is therefore more flexible than an epidemiology study.

<sup>2</sup> Epidemiology is the study and analysis of the patterns, causes, and effects of health and disease conditions in defined populations. It is the cornerstone of public health, and shapes policy decisions and evidence-based practice by identifying risk factors for disease and targets for preventive healthcare. Major areas of such studies include disease causation, transmission, outbreak investigation, disease surveillance, forensic epidemiology and screening, biomonitoring, and comparisons of treatment effects such as in clinical trials.

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value of information gleaned from epidemiological studies utilizing the carefully constructed and interrogatable database (see B above), there was an overall sense that a one-time cross sectional retrospective study (as proposed by Translational Technologies International – see Appendix A – study objectives A,B) would not necessarily be informative for assuring that components of medical surveillance were focused on health outcomes of individuals of the claimant cohort (addressing their risk of disease from exposure to lead, arsenic and/or cadmium). A cross sectional observational health survey is not likely to replace reviewing emerging literature on harmful effects of these agents, individually or in combination, in situations where exposure is well documented and adjusting components of medical surveillance. Furthermore, the extensive drop off rate in participation (see A above) of the claimants will significantly detract from conclusions made in any longitudinal (Appendix A – study objective C) or case-control (Appendix A- Study objective D) studies. The latter will also be hampered by concerns of population size and statistical analyses. The Medical Advisory Panel and Settlement Administrator felt that determinants of clinical assessment (physical examination, laboratory tests including biomarkers, imaging and pathophysiological phenotypic measurements, etc) will continue to rely on evidence based epidemiological studies in peer reviewed medical journals depicting risks and modalities for early detection and potential prevention of disease in carefully controlled relevant cohorts. In particular:

A cross sectional study by nature is descriptive and provides data on entire population under study. Capturing health outcomes (and behaviors and risk factors) for variety of chronic diseases from original cohort of 4100 persons from Perrine WV who entered medical surveillance in 2011 will indeed quantify prevalence of any particular disease outcome (number of cases in this group normalized to these 4100 persons). Nonetheless the associative nature of the analysis and the uncertainty of exposure precludes cause and effect. A higher level observational study is required that includes a control group with similar demographic and potentially confounding features but void of the attribute (e.g. exposure to metal toxicants from zinc smelter plant). If we just consider cancer (combined lung, bladder and skin cancer), then in entire state of West Virginia, the average annual age-adjusted incidence (per 100,000) is 81, 21 and 24, respectively (2016 West Virginia Cancer Burden Report; <http://dhhr.wv.gov/oeps/cancer/Documents/burdenreport2016.pdf>) and thus there would be an expected 3 lung, 1 bladder and 1 skin cancer (in presumptive largely unexposed population). In the case of lung cancer, utilizing a case-control study in Chile on effect of ingesting arsenic (Smith AH et al, J Expos Sci Environ Epidemiol 2009) odds ratios ranged from 0.7-7.1 for developing lung cancer across increasing exposure to arsenic. A power analysis (<http://biostat.mc.vanderbilt.edu/wili/Main/PowerSampleSize>) performed with assumption that the odds ratio for developing lung cancer with a moderate arsenic exposure is 2.0 and the probability of exposure among controls ( $p_0$ ) was 0.3, we would need 60 cancer cases to have a study with a 60% power (See figure below). This number would increase if odds ratio for lung cancer was lower or the probability that the control group ( $p_0$ ) was exposed was higher; conversely it would decrease if odds ratio was higher and probability of misassignment were lower. \_



Thus, this type of analysis could be done for a myriad of medical outcomes derived from the rich data accumulated in the initial cohort of 4100 in a reasonable period of time for a modest investment as described by Translational Technologies International. The difficulty in assuring the control group was not exposed may be challenging and the distinct likelihood that the study may be underpowered detracts from the likelihood of arriving at associations between disease endpoint and exposure that would be useful in medical surveillance.

Attempting to identify and describe disease trends in the community through the survey year (2017) is fraught with concerns about drop out of approximately 50% every two years. It is imperative and quite challenging to evaluate the diminishing cohort with respect to reasons for dropout that may confound such a longitudinal analysis and bias results of disease outcomes with time. There is nothing in the current design of such an epidemiological study that will identify a causal link between exposures to the community and identified outcomes. This requires a gradient of exposures over space and time that is not empirically apparent in the data potentially at hand although it is possible that remediation, per se, provides a point in time where exposure is abruptly decreased.

The Medical Advisory Panel is currently in the process of reviewing the breadth and specificity of the nature of surveillance for the members of the initial cohort of potentially exposed individuals and assuring best practices based on emerging medical and toxicological science is utilized.

It is possible that information gleaned from research grants described in section B above may be useful in designing interventional studies that may be of benefit in documenting exposure, identifying useful biomarkers and clinical assessments and help focus on a subgroup of original cohort that may be particularly at risk. A multicenter double blind placebo-controlled randomized 10 year long trial showed that among stable patients with a history of myocardial infarction, intravenous chelation therapy (with disodium EDTA) modestly reduced the risk of adverse cardiovascular outcomes (Lamas et al, J Am Med Assoc 309: 1241- 1250) that was reduced even more in subgroup of post myocardial infarction patients with diabetes mellitus (Escolar E et al, Circ Cardiovasc Qual Outcomes 7: 15-24, 2014). This latter observation is currently in a replicative phase that will attempt to establish whether removal of toxic metals (lead, cadmium) from the body as demonstrated by Waters et al (Biol Trace Elem Res 83:

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207-221, 2001) is a plausible mechanism for the benefit of such therapy (Lamas et al, J Amer Coll Cardiol 67: 2411-2418).

Please let us know if the Court has any questions regarding our Report.

Thank you for the Court's consideration.

Yours very truly,



Ed Gentle, III  
Claims Administrator

Joined by:

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Bruce R. Pitt, PhD  
Perrine Medical Monitoring Program Panel  
Chair

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Maria M. Kolar, MD  
Perrine Medical Monitoring Program Panel  
Internal Medicine Expert

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Peter L. Perrotta, MD  
Perrine Medical Monitoring Program Panel  
Pathology Expert

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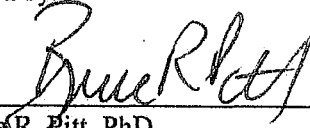
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Ed Gentle, III  
Claims Administrator

Joined by:

 21 Apr 2017  
\_\_\_\_\_  
Bruce R. Pitt, PhD  
Perrine Medical Monitoring Program Panel  
Chair

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Maria M. Kolar, MD  
Perrine Medical Monitoring Program Panel  
Internal Medicine Expert

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ECGIII/jcs

April 24, 2017

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Ed Gentle, III  
Claims Administrator

Joined by:

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Bruce R. Pitt, PhD  
Perrine Medical Monitoring Program Panel  
Chair

---

Maria M. Kolar, MD (Signed by ED)  
Perrine Medical Monitoring Program Panel  
Internal Medicine Expert

Date with  
permission)

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Peter L. Perrotta, MD  
Perrine Medical Monitoring Program Panel  
Pathology Expert

ECGIII/jos



**Amanda Williams**

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**From:** Ed Gentle <escrowagen@aol.com>  
**Sent:** Monday, April 24, 2017 3:33 AM  
**To:** Amanda Williams  
**Subject:** Fwd: The Perrine Medical Monitoring Program

Pls print n out on my chair thanks ed

Ed Gentle  
Gentle, Turner, Sexton & Harbison, LLC  
501 Riverchase Parkway East, Ste. 100  
Hoover, AL 35244  
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(205) 960-2533 cell

Sent from my iPhone

Begin forwarded message:

**From:** Ed Gentle <escrowagen@aol.com>  
**Date:** April 24, 2017 at 3:31:00 AM CDT  
**To:** "Kolar, Maria" <mkolar@hsc.wvu.edu>  
**Subject:** Re: The Perrine Medical Monitoring Program

Maria I will just sign for you no problem Ed

Ed Gentle  
Gentle, Turner, Sexton & Harbison, LLC  
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(205) 960-2533 cell

Sent from my iPhone

On Apr 23, 2017, at 9:50 PM, Kolar, Maria <mkolar@hsc.wvu.edu> wrote:

I'm sorry for the delay in getting this to you. I am having difficulty with my home computer. I should be able to sign and return to you in the morning. Or, if you think it would be better to sign for me, that would be fine too.

Thanks.

Maria

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I hereby certify that I have served a copy of the foregoing upon the following individuals by email:

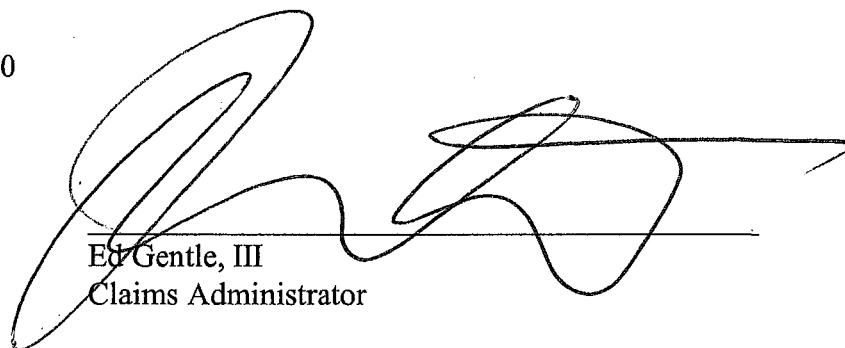
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Ed Gentle, III  
Claims Administrator

**APPENDIX A**



Perrine, WV Preliminary Study Estimate

Study Rationale

Those who live near an environmental hazard site may suffer from harmful health effects linked to exposure to contaminants released into the environment. As is the case in this situation, oftentimes following a class-action litigation suit, monetary resources are set aside to provide the benefit of medical monitoring to the exposed community (Wones et al. 2009). The introduction of unsafe levels of heavy metal contaminants of lead, arsenic, cadmium, and zinc into the water supply has increased the risk of adverse health events such as cancer in those exposed to the metals. There is a strong relationship between exposure to lead, cadmium, mercury, and arsenic and serious health complications, in which high risks have been observed (Jarup 2003). Cadmium exposure is associated with kidney damage, bone fragility, and fractures (ATSDR, CDC 2012). Children are especially susceptible to lead exposure, as its toxicity prevents normal brain development, potentially causing permanent mental retardation. Adults experience suppressed immune systems and generalized increased mortality rates (Brown and Margolis 2012). Since mercury is a neurotoxin, exposure to it can cause brain damage, loss of peripheral vision, muscle weakness, and impairment of speech, hearing, and walking (EPA 2016). Exposure to arsenic in drinking water may lead to cancers, skin lesions, cardiovascular disease, and diabetes (WHO 2016). Early detection and intervention of any health outcomes the contaminants may be linked to is important for the individual patient, their families, and their community. This study will help identify markers and indications of any contaminant-related diseases to allow for early treatment and better final health outcomes for all those affected.

Study Objectives

- A. To identify and recruit approximately 4100 persons from Perrine, WV for participation in a cross-sectional (one-time) epidemiology study;
- B. To obtain medical data on participants as part of Medical Monitoring Program (MMP), including abstraction of medical records and administration of questionnaires to capture health outcomes, behaviors and risk factors for many chronic diseases;
- C. To identify and describe disease trends in the community through the survey year (2017), using data obtained from patient medical records;
- D. To conduct analyses examining the potential causal link between exposures to the community and identified outcomes;
- E. To review and adjudicate medical information from hospital, physician and other records;
- F. To develop innovative hypotheses, perform data analysis, and produce publications from this study;
- G. To provide community education and feedback regarding information from the study itself; to provide information to improve the health of the community in general.

General Proposed Study Methodology / Protocol

\*This is a draft skeleton for budgeting purposes only.



- A. Questionnaires
  - a. General health status and medical history
  - b. Behavioral health and lifestyle factors
  - c. Disability
  - d. TBD
- B. Abstraction of Records from Medical Examinations
  - a. Extent TBD based on final budget
- C. Survey administration – single survey in 2017

**Cost Assumptions**

- Assumes cost for exams is captured separately as part of medical monitoring plan.
- Estimated costs are based on knowledge and experience in conducting studies of similar size and complexity and factor in a margin of error for unknown protocol elements to be determined at a later time; estimates are subject to change once additional data becomes available.
- Protocols may be adapted to accommodate available funding.

**Cost Estimate**

- \$300,000 for the 1-year study period

**References**

Agency for Toxic Substances and Disease Registry (ATSDR). 2012. Toxicological Profile for Cadmium. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

Brown, M.J., Margolis, S. (2012). Lead in Drinking Water and Human Blood Levels in the United States. Morbidity and Mortality Weekly Report (MMWR). Centers for Disease Control and Prevention.

Environmental Protection Agency (EPA), 2016. Health Effects of Exposures to Mercury.

Järup, L. (2003). Hazards of heavy metal contamination. British medical bulletin, 68(1), 167-182.

World Health Organization (WHO). 2016. Arsenic: Fact Sheet.  
<http://www.who.int/mediacentre/factsheets/fs372/en/>

Wones, R., Pinney, S. M., Buckholz, J. M., Deck-Tabbe, C., Freyberg, R., & Pesce, A. (2009). Medical monitoring: a beneficial remedy for residents living near an environmental hazard site. Journal of occupational and environmental medicine/American College of Occupational and Environmental Medicine, 51(12), 1374.