

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

WASHINGTON LEGAL FOUNDATION,

Appellee,

v.

No. 99-5304

JANE E. HENNEY, in her official:
capacity as Commissioner, Food
and Drug Administration, and
DONNA SHALALA, in her official
capacity as Secretary,
Department of Health and Human
Services,

Appellants.

Monday, January 10, 2000

Washington, D.C.

The above-entitled matter came on for oral argument,
pursuant to notice,

BEFORE: Circuit Judges Silberman, Williams and Tatel

COURT OF APPEALS FOR THE D.C. CIRCUIT.

APPEARANCES:

William B. Schultz (DOJ)

Bert Rein

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P R O C E E D I N G S

THE CLERK: Case No. 99-5304

Washington Legal Foundation, Appellants

v.

Jane E. Henney, et al.

ORAL ARGUMENT OF William B. Schultz, Esq.

ON BEHALF OF APPELLANTS

MR. SCHULTZ: Thank you. May it please the Court, the Federal Food and Drug and Cosmetic Act regulates the development in marketing of drugs in order to achieve the vital goal of attaining public health through drugs that are safe and effective. Thus, a manufacturer must prove a drug, safe and effective for each use for which it is marketed. This means that a manufacturer may not market or promote a drug for any use until the FDA has approved that particular use. It does not matter whether the promotion is done by describing the new use on the label, by describing the new use in advertisement, or other promotional means to physicians. And, until 1997, FDA construed this prohibition against promotion to bar manufacturers from distributing articles upon unapproved uses to doctors, such distribution

1 is plainly promotion. As the District Court recognizes, when
2 a manufacturer gives through a detail person and article
3 through a physician about that manufacturer --

4 THE COURT: A detail person?

5 MR. SCHULTZ: Well, the way drugs are typically --

6 THE COURT: I didn't understand the term, detail.

7 MR. SCHULTZ: Well, detail sometimes they just call it a
8 detail man, but it's an employee of the drug company who goes
9 to the physicians office to try and promote --

10 THE COURT: Sales rep.

11 MR. SCHULTZ: Sales rep. And, when the sales rep is
12 handing the physician an article about his company's drug,
13 and about an unapproved use of that drug, that as the
14 District Court recognized is plainly advertising or
15 promotion. In the --

16 THE COURT: Can we step back a moment. Suppose you have
17 a drug with respect or a device with respect which is known
18 that the off-label uses are substantial. Right? In those
19 cases the FDA does not or does it, on a showing that that's
20 the case, does the FDA swing in action to stamp out the off-
21 label uses?

22 MR. SCHULTZ: The analysis, if I may, is whether the
23 off-label uses, what's called an intended use, because --

24 THE COURT: Suppose it's known to everybody who follows
25 the fate of this drug that that's the way it's being used?

1 MR. SCHULTZ: If the FDA --

2 THE COURT: That's among the way it's being used, and
3 represents a non trivial portion of the purchases.

4 MR. SCHULTZ: If the FDA can show that the manufacturer
5 intends this use --

6 THE COURT: Wait a minute.

7 THE COURT: Suppose the manufacturer knows --

8 THE COURT: Yeah.

9 THE COURT: -- that this is the case?

10 MR. SCHULTZ: If the manufacturer knows it's the case,
11 then the FDA can swing into action, as you say.

12 THE COURT: Does it? Does it?

13 MR. SCHULTZ: It rarely --

14 THE COURT: Are there any cases of it doing it?

15 MR. SCHULTZ: It rarely has done that.

16 THE COURT: I thought the question was whether the
17 manufacturer is intentionally promoting it for the off-label
18 use.

19 MR. SCHULTZ: The --

20 THE COURT: I mean, what difference would it make if the
21 manufacturer knew about it, but wasn't doing anything to
22 promote it?

23 MR. SCHULTZ: Well, I think that's --

24 THE COURT: Why would the FDA go after that?

25 MR. SCHULTZ: That's very helpful. The way the FDA in

1 virtually every case proves intent is through the promotion.
2 They prove it --

3 THE COURT: So, it's only when it's accompanied with the
4 speech that the sales under circumstances where it is obvious
5 what's going on are pursued.

6 MR. SCHULTZ: Not necessarily. I mean if you, I mean
7 I'm relying on the statute in the regulations. The statute
8 talks about intent. The regulations define intent and they
9 say one way to do it is through advertising. But intent can
10 be proven through other methods as well. I mean --

11 THE COURT: But, the practice, is there any practice in
12 a case where there is no visible use of speech by the
13 pharmaceutical company to go after well known off-label uses?

14 MR. SCHULTZ: The FDA --

15 THE COURT: Which presumably are intended. Right? I
16 mean the drug company isn't ignorant of them.

17 MR. SCHULTZ: Well, the practice, the FDA has on
18 occasion taken actions. It recently, in the last few years
19 it did it with the so-called Morning After Pill where it was
20 aware of how it was being used, and it issued a notice
21 basically saying that that use ought to be put on the label.
22 That's the kind of action it's taken. But, you were right
23 that --

24 THE COURT: That ought to be put on a label, what
25 happens then?

1 MR. SCHULTZ: Well, the --

2 THE COURT: You can't force the manufacturer --

3 MR. SCHULTZ: That's right. That's correct.

4 THE COURT: There's awkwardness. You can't force the
5 manufacturer to come and ask for an approved use.

6 MR. SCHULTZ: That's correct. The Agen--

7 THE COURT: So, then what do you do?

8 MR. SCHULTZ: Well, in that case it was really more an
9 invitation. Where the off-label is a problem the FDA can --

10 THE COURT: Yeah, but will they come? It reminds of
11 MacBeth.

12 MR. SCHULTZ: That's true. That's true. Where the off-
13 label use is a problem the FDA can require labeling. It has
14 said if it is a public health problem, it can require that
15 the product be withdrawn. But very typically, what the FDA -
16 -

17 THE COURT: Well, Judge Williams' question goes to this
18 awkwardness of the phrase intended use. It's very troubling.
19 I can't quite understand what the, because let's suppose we
20 have, let's put a concrete example. Suppose we have a New
21 York Times story that points out that drug x is used 70
22 percent in the United States for an unapproved use and only
23 30 for an approved use. Long story about that, long
24 statistical analysis. Then what happens? And is the company
25 engaged in illegal behavior if it continues to sell that

1 drug?

2 MR. SCHULTZ: I don't know that the FDA in a situation
3 like that has gone and intended to prove intent, but it
4 certainly --

5 THE COURT: No, but I'm asking is it illegal? Is it
6 illegal? That's a straight question.

7 MR. SCHULTZ: It depends on the manufacturer's intent.

8 THE COURT: I would have thought your answer would be
9 that if all, as I understand your theory of this case, is it
10 the mere fact that the manufacturer is selling a drug that's
11 being used for an off-label purpose? That is the doctors are
12 prescribing it for that purpose? Doesn't make the
13 manufacturer liable. Isn't that your theory? It's that the
14 manufacturer has to be affirmatively promoting it. In fact,
15 the statute allows the manufacturer to respond to a doctor's
16 request for information about an off-label use. Doesn't it?

17 MR. SCHULTZ: That's all correct. The --

18 THE COURT: So then, what difference does it make? I
19 thought the answer to Judge Silberman's question, then,
20 should have been no, of course not.

21 MR. SCHULTZ: Well, I'm just trying to be true to the
22 regulations and --

23 THE COURT: I thought by contrast that the entire theory
24 of your case --

25 MR. SCHULTZ: Excuse me?

1 THE COURT: I thought that the entire theory of your
2 case was that you had a class of introductions in the
3 commerce which were illegal because of the intended destiny
4 of the drug for an off-label use, and that at least
5 initially, and perhaps even after the new statute, the
6 expressions by the pharmaceutical were relevant solely as a
7 matter of the intent.

8 MR. SCHULTZ: That --

9 THE COURT: Presumably the intent, presumably you can
10 have the intent without the promotional activity where as in
11 Judge Silberman's hypo, it's perfectly plain to anyone who
12 can read and write that the sales could, don't be anywhere
13 near the volume they are in the absence of the off-label
14 uses.

15 MR. SCHULTZ: Yes, I agree with all of that, and let
16 me -- the confusion here --

17 THE COURT: Wait a minute. Who are you agreeing with,
18 Judge Williams or Judge Tatel? -- opposite positions, now
19 would you help me and choose which one you agree with.

20 MR. SCHULTZ: When a drug company advertises a drug for
21 a use that's not approved, that establishes the intent.

22 THE COURT: No, no, you didn't answer the question. You
23 didn't answer the question. Which one are you agreeing with,
24 Judge Williams or Judge Tatel?

25 MR. SCHULTZ: Well, I would like to agree with both, and

1 I think that's possible. I don't --

2 THE COURT: Well, Judge Tatel is saying, look, I read
3 this statute as dealing only with promotion. Judge Williams
4 says, no, wait a minute. The statute says intended use and
5 it doesn't necessarily limit itself to promotion. Therefore,
6 if the manufacturer sells into a market which he and the
7 whole world knows and the undisputed evidence to that effect
8 that 70 percent of the use will be for unapproved and 30
9 percent for approved, you have a per se violation of the
10 statute. That's Judge Williams' proposition.

11 MR. SCHULTZ: Right.

12 THE COURT: Is that correct?

13 MR. SCHULTZ: Yes. Well, I don't know if it's -- Judge
14 Williams is correct that this is not just promotion. The
15 statute does not just deal with promotion.

16 THE COURT: Well let's deal with intent. I guess maybe
17 you should express a theory of intent that we can get our
18 hands around.

19 THE COURT: That's right. That's right. That's where
20 the problem is, isn't it?

21 MR. SCHULTZ: The intent --

22 THE COURT: The case you're sounding like making is that
23 it is only the speech that creates the crime only.

24 MR. SCHULTZ: Well, I don't think that's correct.

25 THE COURT: No, it's not like a case like Wisconsin v.

1 Mitchell, where speech is introduced on an issue of intent,
2 but the intent could be proven by all kinds of other things.
3 Right? But here, it's pure speech.

4 MR. SCHULTZ: Here, I would, here the intent can be
5 proven by things other than speech. The speech is one way to
6 prove it.

7 THE COURT: Okay. And what are they?

8 MR. SCHULTZ: There is caselaw, for example, saying that
9 the Agency can look to consumer use or to the way the product
10 is used, either the way it's prescribed or used by consumers.

11 THE COURT: Well, now, you're really --

12 MR. SCHULTZ: And that if it's nearly exclusive for one
13 use, then that can establish intent.

14 THE COURT: Okay. And the closest you've come to an
15 example of this ever happening in the real world is something
16 about the Morning After Pill.

17 MR. SCHULTZ: Well, there is caselaw about dietary
18 supplements, for example. Vitamins which were used to treat
19 diseases and when the Court looked at that, the statute's
20 since been changed, but when the Court looked at that, the
21 Court said, this is the Second Circuit, one way FDA can show
22 intent is through consumer use. In the Ash case, a case of
23 this Court involving tobacco, this Court said looking at the
24 FDA's regulation, said intent can be shown through labeling,
25 advertising or other relevant sources. And so I think it's

1 quite clear that the FDA has always taken the position it can
2 look at other sources, and on occasion it does.

3 THE COURT: But you're not, you're, I thought I
4 understood this case until just now. I thought you were
5 acknowledging that the manufacturers' speech, namely, the
6 distribution of an article through a detail person, whatever
7 it is can be used as evidence of an intent to promote a drug
8 for an off-label purpose.

9 MR. SCHULTZ: We, we, I know --

10 THE COURT: Isn't that your theory?

11 MR. SCHULTZ: -- acknowledge that. That's at the heart
12 of our case.

13 THE COURT: So, what difference does it make that
14 there's non speech evidence also? Your whole case rests on -
15 -

16 MR. SCHULTZ: I don't know that it does. I'm simply
17 trying to be accurate about the statute, but --

18 THE COURT: And the other thing is I don't understand
19 how the use of the drug can be evidence of the manufacturers'
20 motive. I thought that it was perfectly lawful for a doctor
21 to use a drug, to prescribe a drug for an off-label use.
22 Isn't it?

23 MR. SCHULTZ: That is true. That is correct.

24 THE COURT: Okay. So, what you're trying --

25 THE COURT: But it is also unlawful for the manufacturer

1 to sell for that use.

2 THE COURT: So you're trying, what the statute's trying
3 to do, as I understand, is draw a line between those. Right?
4 Namely the doctors lawful right to prescribe for an off-label
5 purpose.

6 MR. SCHULTZ: In the ordinary --

7 THE COURT: So, if hundreds of thousands of doctors are
8 prescribing it for an off-label purpose, how can that
9 possibly be evidence of the manufacturer's intent?

10 MR. SCHULTZ: I'm not suggesting that that necessarily
11 would be. In the ordinary --

12 THE COURT: But you did.

13 MR. SCHULTZ: -- practice of medicine --

14 THE COURT: You're not dismissing it either because you
15 want to preserve the right to go --. Isn't your answer to
16 both my colleagues here that the real difficult case deals
17 with the hypothetical of their raising, where you have the
18 market behavior which the manufacturer is aware of, and he or
19 she continues to sell into that market, and that intended use
20 problem then becomes very difficult. But your basic argument
21 is that, and this is a legitimate point to say. In this case
22 you're dealing with the promotional activity, and so it
23 doesn't represent anywhere near that statutory difficulty
24 that arises where there is no promotional activity, but an
25 obvious and predictable for non approved purposes. Right?

1 MR. SCHULTZ: Yes.

2 THE COURT: Okay.

3 THE COURT: But you're also in the position of arguing
4 that the illegal non speech act to which this is attached is
5 to a large extent a phantom. Right? Because there is never
6 in the real world enforcement where there is only the act
7 without the promotional activity.

8 MR. SCHULTZ: I --

9 THE COURT: Assuming that's a correct characterization
10 of what we're dealing with here.

11 MR. SCHULTZ: I don't think I agree with the never, but
12 I think that I don't want to step too far away from the point
13 that what we are dealing with here with is advertising,
14 promotion or speech. And what this statute does is it
15 converts an ordinary product into a drug based generally on
16 how it's talked about. What's put on the label. There's a,
17 take the issue of, take the orange juice, for example.
18 There's an ordinary consumer product, but if a company to
19 decides, and it's legal to buy it. Obviously it's legal to
20 buy it and use it. The consumer can use it for whatever he
21 or she wants. But, if a company takes orange juice and
22 markets it to cure the cold or to cure cancer, it has just
23 through speech admittedly turned orange juice into a drug.
24 And, it doesn't matter whether we're talking about orange
25 juice or some new AIDS drug, it is turning a product that's

1 available and legal into an unapproved new drug that requires
2 FDA approval.

3 And the implication of the District Court's opinion is
4 to really upset that entire protection. It's to allow
5 companies to promote. And, I would submit there's no
6 difference between journal articles and advertising and
7 labelling that would allow companies to promote products for
8 uses that have never been approved.

9 THE COURT: Okay. Judge Williams has --

10 THE COURT: Okay. Yeah. Suppose that the certain
11 states which go full limit on the issue of abortion as
12 permitted by Casey and others that don't, and Planned
13 Parenthood, the national organization wants to distribute,
14 disseminate information, let's say scholarly studies showing
15 that the sorts of prohibition which are permitted by Casey
16 and enforced by some states are incredibly unsound and
17 produce terrible effects. Planned Parenthood is a supplier
18 of abortion services. Right? Are there promotional or are
19 these disseminations of scholarly studies statements made
20 entirely to, what is the magic language of Pittsburgh Press,
21 to promote a commercial transaction?

22 MR. SCHULTZ: I don't know. I think maybe not there,
23 but I think that is the ana-- the right analysis is to look
24 at the advertising or whatever the activity is and say is it
25 commercial speech under the caselaw?

1 THE COURT: All right. That's very important. I wanted
2 you to get it. You think this is a commercial speech case?

3 MR. SCHULTZ: Yes.

4 THE COURT: Well, why are you talking about an illegal
5 transaction? Because if it's an illegal transaction it's not
6 a commercial speech case.

7 MR. SCHULTZ: We have alternative arguments, Judge
8 Silberman.

9 THE COURT: All right.

10 MR. SCHULTZ: And, maybe we should turn to Central
11 Hudson, so, I'll feel badly if I sit down without mentioning
12 it.

13 THE COURT: Yeah, I implicitly, I think you have
14 abandoned, well, at least prudently for oral argument, you
15 abandoned the illegal transaction notion and you switched to
16 Central Hudson. All right. Now, analyze this under Central
17 Hudson.

18 MR. SCHULTZ: Okay. Thank you. The first question is
19 what is the Government's issue? Is it a substantial
20 government interest?

21 THE COURT: What's the Government interest?

22 MR. SCHULTZ: And here there are three that Congress
23 really looked at sort of in a bundle. One is the entire drug
24 approval system and the interest in getting research done
25 about drugs and getting information about whether drugs are

1 safe and effective before they're promoted and used. So one
2 is --

3 THE COURT: As we said, excuse me. As we said in
4 Pearson, the question of the Government's interest can be
5 described at such a level of generality as to make it not
6 very useful for analysis, or it can be more specific.

7 MR. SCHULTZ: It's public health. Right.

8 THE COURT: And, you've got into some confusion down in
9 the District Court as to what your interest was, and Court of
10 Appeals, and your adversaries are claiming you're shifting
11 somewhat, but I'm not sure it's all that significant. But
12 any event, your point is down below you seemed to suggest
13 that the Government's interest was trying to induce
14 manufacturers to go through the approval process, which runs
15 into certain problems because sometimes it doesn't make any
16 sense for the manufacturer to go through the approval
17 process, and you don't really want them to do it anyway.
18 Right? So that's not, can't be your real interest.

19 MR. SCHULTZ: I want to be careful here, Judge
20 Silberman.

21 THE COURT: You've been very careful all the way
22 through. So careful that it's hard to get an answer out of
23 you.

24 MR. SCHULTZ: I'm sorry. But I mean you're right that
25 obviously not every use and every drug is going to be

1 researched and approved, but --

2 THE COURT: I don't know why you didn't state it, and
3 I'll ask the other side is why you didn't state it more
4 concretely, your interest? Your interest is in protecting a
5 statutory scheme of regulation and your argument, I think, is
6 that promotional devices which go outside the direct
7 labelling would undermine your statutory scheme.

8 MR. SCHULTZ: Would completely undermine the statutory
9 scheme, and the key to the statutory scheme is to get new
10 uses of drugs studied for safety and efficacy so physicians
11 when they're prescribing drugs can know whether they're safe
12 and effective.

13 THE COURT: This sounds to be very like the purpose that
14 was found inadequate in Tornillo because you want better
15 speech, balanced speech. You prohibit unbalanced speech.
16 And, of course, it's true at the margin some prohibitions of
17 unbalanced speech may generate some better balanced speech,
18 but on the other hand, what seemed to drive the Court in
19 Tornillo was that the flat prohibition could not be justified
20 on that incentive ground.

21 MR. SCHULTZ: Well, I mean, I think what may come forth
22 is --

23 THE COURT: In fact, it took the form of a mandate to
24 have the balance, but --

25 MR. SCHULTZ: But I don't think this has to be viewed in

1 terms of speech. This is viewed in terms of a regulatory
2 system --

3 THE COURT: This isn't, publication of articles isn't
4 speech?

5 MR. SCHULTZ: No, no, no, I'm talking about when a
6 company does the research to find out whether a drug is safe
7 and effective and it files an application with the FDA
8 submitting its scientific studies, and then it gets an
9 approval that allows it to market the drug for that use,
10 that's the Government interest that the District Court, I
11 think adopted and that we advocated below.

12 Now, what was tricky in the statute and I mean this is
13 where it gets difficult, but I want to explain this. There's
14 also an interest in that the information be balanced. But,
15 what was tricky in this statute is that it's adopted against
16 a background where physicians are permitted to prescribe
17 approved drugs for uses that haven't been approved.

18 THE COURT: Right.

19 MR. SCHULTZ: And I would submit that when you look at
20 it in that context that the approach that Congress adopted is
21 not just a reasonable fit, but really it's quite focused,
22 because what it does is it preserves the statutory scheme.
23 It preserves the incentive to do the research. It doesn't
24 mean everybody's going to do it every time. But it's very
25 important. And yet it retains the sort of background where

1 in the ordinary practice of medicine physicians have this
2 flexibility.

3 THE COURT: Now, incidently, in the briefs, the
4 Appellees point out certain examples of implementation of
5 your policy over the last few years, some of which might even
6 be troubling under your theory. Do you necessarily agree
7 with all those things that they actually happened?

8 MR. SCHULTZ: I think I, you'd have to tell me what --

9 THE COURT: Well, I'll wait and see. But they'll
10 certainly bring it up.

11 MR. SCHULTZ: Okay. I --

12 THE COURT: Go ahead, Judge Tatel.

13 THE COURT: Can we just go back to an answer you gave to
14 Judge Silberman to make sure I understand it. Are you,
15 you're not, are you conceding now that this is, there's not
16 an underlying illegal act to which the speech is connected?
17 Is that what you said?

18 MR. SCHULTZ: No.

19 THE COURT: You're not doing that.

20 MR. SCHULTZ: No --

21 THE COURT: This is just your alternative argument.

22 MR. SCHULTZ: Yes, we have two arguments.

23 THE COURT: Your basic position is still that the
24 illegal act here is the intentional promotion of the drug for
25 an off-label use. Right?

1 MR. SCHULTZ: Yes. We still believe --

2 THE COURT: And that that, and that your analysis is, as
3 I understand it that under, that it's commercial speech which
4 because of that has no First Amendment protection. Right?

5 MR. SCHULTZ: Yes, under Pittsburgh Press and Wisconsin
6 v. Mitchell.

7 THE COURT: Okay.

8 THE COURT: Well, I don't understand how you deal with
9 the, what is it 44 case? I mean, if you're saying what makes
10 this illegal is the speech, aren't you, as counsel said on
11 the other side, isn't this a circular argument? That takes
12 it right out of commercial speech doctrine altogether --

13 MR. SCHULTZ: Well --

14 THE COURT: -- and it does not make nonsense out of
15 Central Hudson?

16 MR. SCHULTZ: What makes it illegal is the intent. This
17 is, I'm afraid I'm going to get back into where we started
18 which I know wasn't --

19 THE COURT: Now, you're going to fall.

20 THE COURT: What's the it?

21 MR. SCHULTZ: What makes distributing the journal
22 articles illegal, that's the it. Is the intent, is that it
23 establishes the intent by the manufacturer to sell a drug for
24 an unapproved use. It absolutely establishes it. That was
25 the situation before the 1997 statute and then it's actually

1 codified in the statute.

2 THE COURT: And that's a criminal act. Right?

3 MR. SCHULTZ: That's potentially a criminal act, yes.

4 THE COURT: That's a criminal act. Right.

5 THE COURT: What's the role of 331(z) in this?

6 MR. SCHULTZ: Well, that's why I say it was codified.

7 THE COURT: Which appears to be a direct --

8 MR. SCHULTZ: No, I no --

9 THE COURT: -- characterization of the dissemination not
10 in conformity with this section as a prohibitive act.

11 MR. SCHULTZ: Here's the way I would view it. If you
12 look at the situation, if you agree with me that before 1997,
13 before that section was passed into law, that it was illegal
14 for a drug company to distribute journal articles for
15 unapproved use because basically what they're doing is
16 selling a new drug. That's before --

17 THE COURT: I think --

18 MR. SCHULTZ: I'm sorry.

19 THE COURT: -- the fudge of language you use is
20 critical.

21 MR. SCHULTZ: Okay.

22 THE COURT: See.

23 MR. SCHULTZ: In other words --

24 THE COURT: What I thought the Government's basic
25 position was being that the distribution for an unapproved

1 use is illegal, is pre-1997.

2 MR. SCHULTZ: With intent, yes.

3 THE COURT: With the wrong intent.

4 MR. SCHULTZ: Yes.

5 THE COURT: And the promotional activity comes in
6 entirely on the issue of intent.

7 MR. SCHULTZ: Yes --

8 THE COURT: The trouble is 331(z) seems to play havoc
9 with that and it also plays havoc with the argument that the
10 '97 Act is just a safe harbor.

11 MR. SCHULTZ: Well, let me see if I can explain.
12 Assuming that it was illegal before 1997, what the '97 --

13 THE COURT: What's it?

14 MR. SCHULTZ: Assuming that it was illegal to --

15 THE COURT: (z) is very clear that it's talking about
16 dissemination of information. Okay.

17 MR. SCHULTZ: Pardon?

18 THE COURT: (z), 331(z) --

19 MR. SCHULTZ: Yes, assuming --

20 THE COURT: -- it's very clear it's talking about
21 dissemination of information.

22 MR. SCHULTZ: Assuming it was illegal to disseminate
23 information about an unapproved use before 1997 because that
24 established the intent to sell an unapproved new drug.

25 THE COURT: Suppose --

1 THE COURT: Suppose it's before a single doctor has ever
2 had a dream of prescribing the drug. Right?-

3 MR. SCHULTZ: I think that's even more --

4 THE COURT: That's more so?

5 MR. SCHULTZ: Well, no doctor has had a dream about it
6 and now the drug company is giving the doctor an article
7 basically saying here's something new you can --

8 THE COURT: Yeah, I know, but where is the distribution?
9 I would think that unless sales pick up or something
10 reflecting the new use, you don't have any indication of
11 distribution. Distribution in excess of the uses specified.

12 MR. SCHULTZ: In each case you look to see whether this
13 is marketing. And we can conjure up hypotheticals where it
14 might not be marketing, but --

15 THE COURT: Not so hard to do in light of Bigelow, is
16 it?

17 MR. SCHULTZ: It's not so hard to do. It happened in
18 all the moot courts I did. You know there are certainly
19 hypotheticals where it might not be marketing, but where it
20 is marketing, which is I think what we have at issue here,
21 what Congress did in 1997 is they said to the drug companies,
22 we are now going to let you do something that you could not
23 do before. We're going to, if you want to take advantage of
24 this new statute and comply with its rules, then you may
25 distribute these journal articles. And the rules basically

1 say you have to, in general, commit to do the research and
2 the information has to be, you have to give them all the
3 information, not just some of it and --

4 THE COURT: Excuse me, Mr. Schultz. I want to take you
5 back to this illegality because I'm very confused about that.

6 MR. SCHULTZ: Judge Silberman, could -- I just wanted to
7 --

8 THE COURT: Yes, sir.

9 THE COURT: I think he should finish on (z). I believe
10 he is.

11 MR. SCHULTZ: -- just this one. And what 331(z) --

12 THE COURT: Well, if you would directly respond to his
13 question I wouldn't --

14 MR. SCHULTZ: Yeah, I apologize. I just --

15 THE COURT: You're answering the question about (z)?

16 MR. SCHULTZ: Yeah. What it does is it says, and all it
17 does, if you choose to take advantage of this new statute
18 that allowed you to disseminate information, but you violate
19 some provision of it, then you're in violation of the law.

20 THE COURT: In other words if you submit --

21 MR. SCHULTZ: And that's all it does.

22 THE COURT: In other words if you submit something
23 pursuant to the 60 day and you get approval to distribute a
24 peer review piece, but you include in it a non peer review
25 piece, then you're violating --

1 MR. SCHULTZ: Yes.

2 THE COURT: -- the terms of your agreement.

3 MR. SCHULTZ: Yes.

4 THE COURT: Regard --

5 THE COURT: In other words it's not a --

6 THE COURT: Regardless of distribution in excess of the
7 permitted uses. Right?

8 MR. SCHULTZ: Well, if you chose --

9 THE COURT: It's got to be regardless or (z) is
10 surplusage.

11 MR. SCHULTZ: Regardless of, I'm just afraid you don't
12 understand.

13 THE COURT: You point to 331(a) and (d) as forbidden
14 kinds of distribution and your argument has run generally
15 that these statements are ancillary to those forbidden uses
16 which gets you into the promoting an illegal transaction
17 category which you want to be in. But, when you don't have,
18 for whatever reason, enforcement is unpromising under (a) and
19 (d), and therefore you turn to 331(z). You're going alone on
20 the promotion regardless of intent to distribute.

21 MR. SCHULTZ: But you'd have to, as Judge Tatel's
22 pointed out, you'd have to show a violation of --

23 THE COURT: I understand. But --

24 MR. SCHULTZ: -- this new statute.

25 THE COURT: No, I didn't point it out. I was just

1 trying to understand what you said, and I understood you
2 saying that the only, the only time (2) is triggered --

3 MR. SCHULTZ: Right.

4 THE COURT: -- and I'm not quite sure I understand why
5 is if you violate the terms of your agreement with the
6 Secretary, and how do you get that from that? Is that
7 because of the reference to 360?

8 MR. SCHULTZ: Yes, and because 360, it basically says
9 the manufacturer may distribute journal articles if it
10 complies with all the sections here.

11 THE COURT: Okay. So, in other words, if you've agreed
12 with the Secretary to do certain things, but under that
13 agreement yo do more, that's a separate violation, has
14 nothing to do with underlying crime of -- in fact, that's not
15 even a criminal offense. Isn't it? (2)?

16 MR. SCHULTZ: I think --

17 THE COURT: These are all prohibitions.

18 THE COURT: These are all just prohibitions, yeah.

19 MR. SCHULTZ: Yes, but if you're subject to a
20 prohibition, then the other sanctions generally kick in, and
21 the criminal statute kicks in, although I think there's some
22 special provision about criminal law for this section. But,
23 the prohibitions are then tied into the sanctions which are
24 injunction penalties and can in some cases be criminal.

25 THE COURT: Can I come back to my illegality again?

1 MR. SCHULTZ: Yes, I apologize.

2 THE COURT: Yes, I want to -- excuse me, Judge Tatel.
3 Let me just see if I can get this one. Your opponents point
4 out, they make the point, they make the argument that your
5 argument is circular in claiming there's an illegal
6 transaction here, because the only illegality is the
7 promotion, or the promotion possibly connected with other
8 kinds of practices which would reflect a bad intent. The
9 more I hear the argument that the whole word intent has an
10 interesting use in this statute and Congress seems to move
11 around it. I'm not sure it's really a clear intent statute.
12 But, any event, my understanding of your position is if you
13 argue that this is an illegal transaction you're out of
14 commercial speech altogether. Right.

15 MR. SCHULTZ: You're out of First Amendment right.

16 THE COURT: Yeah, that's right. You're out of any kind
17 of protection.

18 MR. SCHULTZ: Yeah, out of the First Amendment.

19 THE COURT: So, well, that's right. So, that forces us
20 to think very hard. Are you really arguing here that the
21 underlying transaction is illegal? And when the Supreme
22 Court does that, they're not talking about the speech you're
23 trying to restrict, because that is circular.

24 MR. SCHULTZ: Right.

25 THE COURT: If the speech you're trying to restrict

1 makes the speech illegal and therefore you're outside of
2 First Amendment, then there is no First Amendment. So, I
3 don't understand your position on the underlying illegality.

4 MR. SCHULTZ: Okay. And I am not arguing this isn't
5 tricky and difficult, but let me try and see if it's
6 persuasive.

7 THE COURT: You're going to run it up the flag pole and
8 see if it waves?

9 MR. SCHULTZ: Yeah. I've got a couple of different flag
10 poles, but in, if you think about Pittsburgh Press, certainly
11 the employer can give speeches saying look, you know, I
12 believe in hiring only men. There's nothing illegal about
13 that. But when the employer, when the newspaper accepts an
14 ad which indicates that the employer's going to discriminate,
15 going to basically, in the employer's mind he's going to hire
16 only men, then all of a sudden that father, that speech
17 becomes illegal. It's illegal discrimination. And, we
18 think, I'm not, we think that that caselaw has some bearing
19 on what's at issue here. And it may be a little easier to
20 see if you imagine a drug that hasn't been approved at all.
21 We have a case, a substance called Aloe Vera which is used in
22 soap, and a physician in Maryland says, this is a public
23 record. It's a criminal case. Is giving it to cancer
24 patients to take orally and for injection. And he's
25 advertising that. I mean he's promoting that.

1 THE COURT: He's also doing it, I take it.

2 MR. SCHULTZ: He's, yes, he's also doing it.

3 THE COURT: He's doing it.

4 THE COURT: But that's lawful. Isn't it?

5 MR. SCHULTZ: It's, no. None of it's lawful.

6 THE COURT: Wait a minute. I thought it was okay for a
7 doctor to prescribe a drug for an off-label use.

8 MR. SCHULTZ: It is okay only if the drug is approved
9 for some reason.

10 THE COURT: Oh, you mean this thing isn't approved at
11 all?

12 MR. SCHULTZ: This isn't approved at all.

13 THE COURT: Oh, I misunderstood you.

14 MR. SCHULTZ: But --

15 THE COURT: So what's that got to do with this case?

16 THE COURT: Nothing. You know the problem with the
17 Pittsburgh case, the problem with the Pittsburgh case, I
18 grant you that that, I think it leads you down a blind alley
19 of arguing that this is evidence of intent, and therefore it
20 can be banned as evidence of intent. That doesn't make any
21 sense because suppose it was, as counsel points out, suppose
22 it was equivocal evidence. It could suggest either way. And
23 you're saying it could be banned anyway. I think the better
24 way to analyze Pittsburgh is to say it wouldn't matter if the
25 employer in that case had an absolute positive intent. If in

1 fact, he put that ad in which showed discrimination on its
2 face, it would be arguably banned, it could be prohibited.

3 MR. SCHULTZ: If a drug company sells Aloe Vera, it's
4 not, drug company's not putting it in patients, it's simply
5 selling it --

6 THE COURT: Right.

7 MR. SCHULTZ: -- to cure cancer without ever getting
8 approval. We are going to use that speech as evidence of
9 it's intent that the drug be used as an unapproved drug and
10 not get approval.

11 THE COURT: Does this statute ban these activities as
12 evidence of an unlawful act? That's not an accurate
13 description of the statute. Is it?

14 MR. SCHULTZ: Does this statute --

15 THE COURT: Does this statute ban the distribution of
16 non peer reviewed documents because they are, they could be
17 evidence of an illegal act?

18 MR. SCHULTZ: I think that in the first argument, not
19 the Central Hudson argument, but the first argument, I think
20 that is one way to characterize what we're arguing.

21 THE COURT: Well, wait a minute. See now I totally
22 don't understand your case. I completely don't understand
23 it. I thought your whole explanation of this statute and the
24 guidance was that they have established a procedure for
25 manufacturers who distribute certain materials regarding off-

1 label uses in such a way that they will not be used as
2 evidence against them in a prosecution under the misbranding
3 provisions. I thought that's what this was about. And that
4 I thought that any manufacturer could distribute anything
5 they wanted, if they wanted to take a chance of ending up a
6 defendant in a mislabeling case. Isn't that right?

7 MR. SCHULTZ: That's all correct. That's all correct.

8 THE COURT: That's all correct.

9 MR. SCHULTZ: Yes.

10 THE COURT: So this Act, setting aside (z) for a minute,
11 doesn't ban anything. Right?

12 MR. SCHULTZ: I don't believe it does. I don't believe
13 this Act bans anything.

14 THE COURT: It doesn't ban a thing. In other words if
15 I'm a drug manufacturer and if I want to distribute non peer
16 reviewed articles, if I want to sponsor a conference about a
17 non label use I can go ahead and do so without going through
18 any of these 60 day provisions. Right?

19 MR. SCHULTZ: I believe that's correct.

20 THE COURT: And the only risk I take is that they might
21 use that someday against me as evidence that I intended to
22 distribute the product for a non-label use. Right?

23 MR. SCHULTZ: Yes, that's correct. And in fact this
24 case was brought before the statute, so, that's correct.

25 THE COURT: All right.

1 MR. SCHULTZ: It's all correct, that --

2 THE COURT: That's the right understanding of it.

3 MR. SCHULTZ: That is --

4 THE COURT: So, let's go back to (2) for a minute.

5 Okay? So I can understand (2). I understood what you said,
6 but then at page 32 of your brief, you say this. The
7 treatment of the dissemination of off-label information as a
8 separate violation of the misbranding provisions is
9 consistent with the First Amendment. So, I was with you all
10 the way up to that sentence and then I fell off the
11 reservation. I don't get it. I thought you were saying that
12 you were not treating these things as an independent
13 violation, but only as evidence of intent.

14 MR. SCHULTZ: You said, the treatment of these --

15 THE COURT: Here, I'll read it to you again. Page 32.

16 MR. SCHULTZ: Right.

17 THE COURT: The treatment of the dissemination of off-
18 label information as a separate violation of the misbranding
19 provisions is consistent with the First Amendment.

20 MR. SCHULTZ: If you, if companies choose to go through
21 the new 1997 statute, which is a practical matter, is the
22 only way FDA is going to permit them to disseminate these
23 articles. If they choose to do that then the fact that
24 331(2) says that if you violate the deal in the new statute,
25 that's a prohibitive act --

1 THE COURT: Okay. So this sentence doesn't --

2 MR. SCHULTZ: -- doesn't violate the First Amendment.

3 THE COURT: This sentence then doesn't mean anything
4 more than (z).

5 MR. SCHULTZ: No, I don't think it does.

6 THE COURT: All right. And (z), I just want to make
7 sure I get it. (z) you say is not treating this information
8 as an independent violation of the misbranding provision, but
9 rather as a violation of your deal with the Secretary.

10 MR. SCHULTZ: And all (z) says is --

11 THE COURT: Is that right?

12 MR. SCHULTZ: Yes, it's prohibited to disseminate
13 information in violation of Section 551 which is the new
14 statute.

15 THE COURT: Which is the deal part of it.

16 MR. SCHULTZ: It's the deal.

17 THE COURT: Could Congress pass a statute barring --
18 well, let me take a step back. You're not, you don't
19 normally argue NLRP cases before us. But, let me give you a
20 background. It is generally illegal for an employer to
21 intentionally promise a wage benefit or any other kind of
22 benefit leading up to an election. And it also, and these
23 cases often turn on what the intent is and they're very
24 complex and very difficult because employers often speak
25 about wages. Suppose Congress passed a law barring employers

1 from every speaking about wages and for some period of time
2 prior to an election, and it was defended on the grounds that
3 sometimes that would be evidence of a bad intent. Sometimes
4 it wouldn't, sometimes it would. But, we banned it.
5 Constitutional?

6 MR. SCHULTZ: No.

7 THE COURT: Then aren't you conceding?

8 MR. SCHULTZ: No, no because here the speech is illegal
9 only if --

10 THE COURT: Well that's the circular --

11 MR. SCHULTZ: -- wait a minute. Only if --

12 THE COURT: It's never illegal.

13 MR. SCHULTZ: It's gotta be promotional. It's gotta be
14 evidence of the unlawful intent. If it can be done in a way
15 that's not promotional --

16 THE COURT: But your brief argued if it can be evidence
17 it can be banned. And that's, you sailed right into his
18 torpedoes because they say, wait a minute, you can't ban
19 speech on the grounds that it might be bad evidence, evidence
20 of a bad intent.

21 MR. SCHULTZ: If a drug company wants to convene a
22 conference of scientists who you know, aren't practicing
23 physicians, and wants to distribute journal articles about
24 its drug to discuss study design or so on, this statute
25 doesn't get at that. This statute gets at the behavior only

1 when the company is promoting its product.

2 THE COURT: Yeah, but suppose the company --

3 THE COURT: So, then you're, that implicitly abandons
4 the underlying illegality of the transaction. You're
5 focusing, as Judge Williams said in the beginning on the
6 promotion, on the speech. That is part of -- as it relates
7 to a transaction.

8 MR. SCHULTZ: Pittsburgh Press and Wisconsin v. Mitchell

9 --

10 THE COURT: Yeah.

11 MR. SCHULTZ: -- are, you know, are still implicated.

12 But I --

13 THE COURT: Let me give you a hypothetical on the drug
14 company. My drug is used for proper purpose A and being
15 promoted, being used by doctors for B. Okay? I get together
16 with somebody and I sponsor a big conference on off-label use
17 B. All right. I fund it. I do everything. It violates all
18 12 of these standards in the guidance. Okay? Flat out
19 inconsistent. Right? Now, is that conference independently
20 illegal or is it only useable by the Government as evidence
21 in a criminal prosecution that I intended to market the drug
22 for an off-label use?

23 MR. SCHULTZ: I would say it's useable as evidence that
24 you intended to market the drug for the off-label use.

25 THE COURT: So there are no circumstances under which

1 the Department could stop that conference or punish the
2 manufacturer for participating and funding the conference?

3 MR. SCHULTZ: Only --

4 THE COURT: Independent --

5 MR. SCHULTZ: The only argument the Government would
6 have is that the manufacturer is selling an unapproved new
7 drug.

8 THE COURT: Forget (2). Right. Okay.

9 MR. SCHULTZ: And the conference is evidence of the
10 intent. And then I should stress the criminal prosecution
11 would be way down the line. The first thing the Agency would
12 do is send the company a letter.

13 THE COURT: I'm trying to recall. Does the '97 statute
14 use intent or is it really amending the prior statute which
15 uses the word?

16 MR. SCHULTZ: It's the prior statute. It's in the drug
17 definition.

18 THE COURT: Right. That's what I thought. And the '97
19 statute doesn't refer to intent.

20 MR. SCHULTZ: No.

21 THE COURT: No. So, I think that, my concern is that
22 Congress may have been legislating against a framework which
23 doesn't exactly fit with the framework they used in '97. Let
24 me go, well, on the illegality point, I think you see what's
25 so troubling. Perhaps we should leave you, sit down for a

1 moment --

2 THE COURT: There is one question hanging and that is
3 why is the circulation of a peer reviewed article relating to
4 an off-label use more, well, it has to be more, more
5 promotional than the advertisement in Bigelow?

6 MR. SCHULTZ: I'd have to go back and remember Bigelow,
7 but I think under --

8 THE COURT: It appears to be assumed by the Court --

9 MR. SCHULTZ: That was to the general public.

10 THE COURT: -- although it's a little obscure, but it
11 appears to be assumed that the persons placing the
12 advertisement are running a service which either through
13 reciprocal fees or something they will receive for
14 remuneration. So it --

15 MR. SCHULTZ: Well --

16 THE COURT: It's hard for me to see that it is, that
17 circulating a peer reviewed article is more promotional than
18 that which was held not to be promotional.

19 MR. SCHULTZ: Well, I mean --

20 THE COURT: Would you like --

21 MR. SCHULTZ: -- there's a lot that's happened since
22 Bigelow, but --

23 THE COURT: Mr. Schultz, would you like to think about
24 Bigelow and then come back on rebuttal? Because I can't
25 remember Bigelow either, and you can tell the fact, you can

1 talk about the facts on that when you come back.

2 MR. SCHULTZ: Sure, I'd be happy to. Thank you.

3 THE COURT: Yeah. Judge Williams you wouldn't mind?

4 Let him go.

5 THE COURT: That's all right. No, all the time in the
6 world.

7 ORAL ARGUMENT OF Bert Rein, Esq.

8 ON BEHALF OF APPELLEE

9 MR. REIN: Good morning, Your Honor, may it please the
10 Court, my name is Bert Rein and I am here on behalf of the
11 Appellee, WLF. I want to assure the Court I'm not going to
12 ask to dismiss the Government's appeal, though I am going to
13 ask to affirm the judgment below.

14 I think that I'd like to go, come directly to the points
15 that you were addressing with Government counsel, because I -
16 -

17 THE COURT: They made a, they actually made an implicit
18 argument we should dismiss your appeal on grounds you don't
19 have standing. But, I won't even get into that.

20 MR. REIN: Well, I think we answered that in our brief,
21 Your Honor, and I think we meet the three-part test for
22 standing that the Courts have used.

23 THE COURT: I don't want to go into it.

24 MR. REIN: I think the central issue that's bothering
25 the Court is is the Government here seeking to impose a

1 prophylactic ban on speech itself as 331(z) certainly appears
2 to do --

3 THE COURT: Well, let me tell you why, let's just put
4 aside for a moment the Government's argument, which I frankly
5 regard as labored. That there's an underlying illegal
6 transaction or that the problem here is that the speech is
7 evidence that can or cannot be evidence of bad intent and
8 therefore we can ban it because it might be evidence of bad
9 intent. That doesn't make much sense to me either. But what
10 does make sense, which to me at least, is the Government's
11 argument which they sort of dance around, but they make it
12 sufficiently. Is look, we have a regulatory scheme here
13 which requires that drug manufacturers bring uses to the FDA
14 for approval. We also recognize that doctors can prescribe
15 unapproved uses, but we do not want the drug manufacturers to
16 be touting those unapproved uses. You concede implicitly
17 that they have every legal right to do that because you
18 concede they can prevent labeling which includes all the
19 information that you would send out with the drug
20 manufacturing. Labelling which would include unapproved
21 uses. Right?

22 MR. REIN: I think, let me tell you what we do and don't
23 concede to.

24 THE COURT: No, no. Do you concede that or not?

25 THE COURT: I think he's trying to give a -- stance.

1 MR. REIN: I do not concede that, Your Honor, because I
2 can explain I think with some clarity where we do believe
3 they have enforcement rights that are not only in the
4 statute, but preserved by the injunction. To wit, if a
5 manufacturer makes claim of a use that has not been approved
6 as safe and effective in shifts with that claim, that is a
7 violation of 505 and it's enforceable under 331. That's a
8 case that's not before us.

9 THE COURT: Wait a minute.

10 MR. REIN: That --

11 THE COURT: For constitutional purposes it is. Thinking
12 about what, because then if the manufacturing would send out
13 the drug with the article --

14 MR. REIN: I think you're making the assumption that
15 merely transmitting the article in itself is a claim without
16 regard to the facts and circumstances.

17 THE COURT: Let's suppose, well that's a fair point.
18 Suppose they send it out with a letter to the doctor saying
19 here's our new super duper drug and this is the label we have
20 on it. And, by the way look at this article that describes
21 this unapproved use.

22 MR. REIN: I think --

23 THE COURT: And that's all one package that comes to the
24 doctor.

25 MR. REIN: Right. And that's a case that's like Bolger

1 in which one might argue that in no circumstance, in the
2 totality of that mailing to the doctor they were claiming
3 that this use, which is not approved is an appropriate use of
4 the drug. And I think that --

5 THE COURT: And so that would be banned.
6 Constitutionally, there you have no --

7 MR. REIN: No, and I think ban is the wrong word, Judge
8 Silberman. What could happen there is the Government could
9 choose to act against the conduct. The Government could say
10 that shipment was an unlawful shipment. There --

11 THE COURT: Which included that bad speech.

12 MR. REIN: It's not a question of whether -- it's the
13 shipment --

14 THE COURT: No, but you're agreeing that it doesn't
15 ban --

16 MR. REIN: -- not the speech.

17 THE COURT: You're agreeing that it doesn't ban the
18 speech. Right?

19 MR. REIN: I don't think that 505 bans the speech as
20 such.

21 THE COURT: The statute doesn't ban the speech.

22 MR. REIN: 331(z) I believe does ban the speech. That's
23 what the fight was about below. The guidance that the
24 Government had --

25 THE COURT: Well, the Government says that only applies

1 where you violate your deal with the Secretary.

2 MR. REIN: Well, under that construction, which is
3 somewhat novel and I'm not sure it's accurate, there really,
4 the case is almost moot because the Government is now saying
5 they have no right to prohibit the manufacturer from going
6 out and distributing the articles. All they have is the
7 right to bring substantive cases for shipping in violation of
8 the statute or having a misbranded drug on the market.

9 THE COURT: All right. That's what I understood.

10 MR. REIN: And no one is quarreling about that because
11 the District Court's injunction does not deal with the
12 Government's ability to bring prosecutions under the (a) and
13 (d) of 331. So, that issue isn't even before this Court.
14 The Government is arguing about a non issue.

15 THE COURT: No, Government counsel just said in response
16 to one of my questions that the only, that this bans nothing,
17 unless you violate your deal with the Secretary.

18 MR. REIN: I understand that the Government --

19 THE COURT: That's all, that's what he said.

20 MR. REIN: Judge Tatel --

21 THE COURT: Yeah.

22 MR. REIN: If that is all that 331(z) does, if it --

23 THE COURT: Then this case isn't even ripe. Is it?

24 MR. REIN: Then I think, no, I think the injunction
25 below is properly taken because the Government in ~~terrores~~

1 had taken a much broader view and continued to take it under
2 its guidances which were also at issue.

3 THE COURT: Well, if it's retreated this late before
4 us --

5 MR. REIN: Well, if the Government is now prepared to
6 concede that the Court's injunction, that is the conduct
7 preserved by the injunction below which is the right to
8 distribute these articles without threat of illegality as
9 such, and that so manufacturers are now free to allow our
10 position members to receive this information, leaving in
11 place the remedies that have existed under this statute
12 historically for situations where the manufacturer's conduct
13 might be deemed to create a violation, then there's nobody
14 arguing about anything because we're supporting the Court's
15 injunction which the Government fought below. If the
16 Government no longer believes that the injunction has an
17 operative effect because they agree that the very conduct
18 supported by the injunction is permissible, then I agree.
19 We're not engaged in much of a fight here. Surprise, that
20 they, you know, maybe you should dismiss their appeal under
21 this.

22 THE COURT: Well, wait a minute. I didn't read the
23 Government, I didn't understand the Government as saying what
24 you're describing them as saying.

25 MR. REIN: Well, Judge Silberman, I think the question

1 is this --

2 THE COURT: I must say there is a little confusion, more
3 than a little confusion. Let's assume, however, let's assume
4 and let's make it crystal clear. The Government is in effect
5 banning the distribution of promotional material in this non
6 peer review article for unapproved use. Let's assume there's
7 a ban of that.

8 MR. REIN: Then I think we're into the question, is this
9 ban supportable --

10 THE COURT: Right.

11 MR. REIN: -- under the First Amendment?

12 THE COURT: And, I thought you conceded that the
13 Government would be able to ban directly by regulation or
14 whatever under this statute, the sending of that material
15 with the drug as part of the transaction.

16 MR. REIN: No, Your Honor, I did not. I said that if
17 the Government sought to bring a case --

18 THE COURT: Yes.

19 MR. REIN: -- a case of improper shipment or a case of
20 misbranding, those are substantive violations and they
21 address the conduct.

22 THE COURT: All right.

23 MR. REIN: All right.

24 THE COURT: Let's assume they issued a regulation which
25 said if you send out the promotional material with the drug,

1 we regard that as part of the labeling and that will be
2 illegal.

3 MR. REIN: We would not believe that they could do that.
4 That would not be constitutional.

5 THE COURT: Why?

6 MR. REIN: Because that is a broad prophylactic approach
7 which attempts to characterize without evidence --

8 THE COURT: Well, now wait a minute. Wait a minute,
9 counsel. You're saying that the conduct can be barred, but
10 you can't do it by rule. You have to do it by case-by-case?
11 That doesn't make any sense as a matter of constitutional
12 law.

13 MR. REIN: Judge Silberman, the conduct is shipping the
14 drug.

15 THE COURT: Right.

16 MR. REIN: All right. And not --

17 THE COURT: With the promotion, with the promotional
18 material could be regarded as the label. Could it not?
19 Under this --

20 MR. REIN: The word labelling has been interpreted quite
21 broadly.

22 THE COURT: Right. So the promotional material could be
23 included as part of the labeling. And, if a manufacturer
24 sent out the drug with the "label" i.e. including the
25 promotional material for unapproved use, the Government can

1 prohibit that.

2 MR. REIN: But, Your Honor, when you're saying the
3 Government can prohibit that, I want to be precise about what
4 the injunction addresses. It addresses only certain kinds of
5 materials. We're talking about peer reviewed articles
6 which --

7 THE COURT: Let me work my way up to that.

8 MR. REIN: Because we're not on a slippery slope.

9 THE COURT: No, Mr. Rein, wait a minute. I work my way
10 up to it. I want to try and get, see if I can understand
11 where there is an agreement as to the Government's
12 constitutional position, even under your view. My
13 hypothetical where they issued a regulation that precluded
14 that, you would not have any argument that that was
15 unconstitutional.

16 MR. REIN: Yes, I would, Your Honor, because the
17 regulation --

18 THE COURT: Which is your constitutional argument?

19 MR. REIN: -- sweepingly characterizes all these
20 transmittals of this kind of material.

21 THE COURT: No, my hypothetical, where you --

22 MR. REIN: In your hypothetical, I'm trying to address
23 that. If that regulation reached out to the class of
24 materials that are in the injunction, peer reviewed articles,
25 textbooks, independently produced by third parties --

1 THE COURT: Right.

2 MR. REIN: -- our view would be those are not on a
3 prophylactic basis to be deemed promotion --

4 THE COURT: So now your argument, now you have shifted
5 to an argument that you did not make below, and you did not
6 make in your brief which is even if this material were sent
7 out with the drug shipment, it is constitutionally protected.

8 MR. REIN: I don't believe we -- we did make that
9 argument below because we said two things. One, this
10 material itself is core speech. It's scientific material and
11 it --

12 THE COURT: No, but you never made the argument that I'm
13 -- did you ever make that argument that even if this material
14 --

15 MR. REIN: We, it's in our brief, Your Honor.

16 THE COURT: -- even if this material is sent out, it's
17 clearly promotional material with the drugs. That it
18 couldn't be banned because it's pure speech.

19 MR. REIN: We certainly did not attribute any importance
20 to whether it's with the drug or not with the drug. We --

21 THE COURT: I'll tell you why I think it's important.
22 First of all, I think that position that there would even be
23 a constitutional question about that is not serious. Because
24 as I read the statute, the Government clearly could do that
25 as part of the proposed transaction. That is to say ban the

1 promotional material as part of the deal. The problem that
2 bothers me is if they can do that then I don't understand why
3 they can't do this because this would be necessary to event
4 the circumvention of my hypothetical.

5 MR. REIN: And I think, what I'm trying --

6 THE COURT: This being the practice.

7 MR. REIN: And I'm trying to respond to your
8 hypothetical, Judge Silberman, by pointing out that what
9 we're talking about is a specific class of materials that are
10 covered by the injunction. One, we have argued and it's
11 below and in our briefs that these materials are for speech.
12 They are not commercial speech. They are circulated freely
13 by journals and textbooks. They're recognized --

14 THE COURT: You certainly are not suggesting that a
15 scholarly article can not be thought of as promotional
16 material for a commercial transaction. As part of that.

17 MR. REIN: Your Honor, what I am suggesting is an
18 article of that type, a scholarly is --

19 THE COURT: Can be, can be.

20 MR. REIN: -- no, is pure speech.

21 THE COURT: Under no circumstances --

22 MR. REIN: -- is pure speech. It can be used in
23 connection with other materials and in a context where the
24 overall activity might be deemed to be promotion. But that
25 doesn't make the article promotion.

1 THE COURT: All right.

2 MR. REIN: What it says is the activity viewed in
3 context and overall is promotion. And what I'm telling you
4 is that our position has been steadily, these materials in
5 isolation --

6 THE COURT: If Lexus sends out a flyer to all proposed
7 buyers of Lexus which includes an article in consumer reports
8 which indicates Lexus, according to consumer's reports, Lexus
9 was the most reliable SUV. Is that promotional material?

10 MR. REIN: If we're talking about an independent peer
11 reviewed article in Consumer Reports, the answer to that,
12 Your Honor, is it depends on the context in which it's
13 furnished to the consumer. I can't make that judgment a
14 priori. I don't think you could ban Consumer Reports from
15 publishing that article because Consumer Reports is
16 commenting on a matter of --

17 THE COURT: Well, that's a non sequitur, is it. That's
18 not, we're not asking about whether you can ban the article.
19 The question is whether you can ban the manufacturer from
20 distributing the article in connection with its sell of the
21 product.

22 MR. REIN: Well, Your Honor, and I'm saying that there
23 is a conduct remedy here. If the manufacturer's method of
24 distributing that article, taken in context, whether it's by
25 the proximity to the shipment, whether it's by the totality

1 of the message amounts to a claim for a use that the
2 manufacturer has not established in the statute to where
3 remedy lies. That's not what the case is about. This case
4 is not about Wisconsin v. Mitchell.

5 THE COURT: But that could be, even a peer reviewed
6 piece could be used in that context. Right?

7 MR. REIN: Right.

8 THE COURT: Even a pure article from the New England
9 Journal of Medicine you concede in a misbrand, in a suit,
10 criminal case against the manufacturer arguing, claiming that
11 they are marketing this for off-label purpose, that article
12 from the New England Journal of Medicine could be used as
13 evidence. You would argue that it isn't. Right? It
14 wouldn't be a First Amendment problem.

15 MR. REIN: We're not claiming the First Amendment
16 precludes it from being used as evidence --

17 THE COURT: Right. Okay.

18 MR. REIN: That is, it is, the fact that you send it out
19 is conduct.

20 THE COURT: No, I understand that. But so, but do you
21 understand the statute differently than I do? As I
22 understand it, the only thing the statute does is say if you
23 come to the department with that New England Journal of
24 Medicine and submit it to us and we approve it, we guarantee
25 now it won't be used as evidence against you.

1 MR. REIN: One aspect of the statute --

2 THE COURT: That's all that statute says. Isn't it?

3 MR. REIN: -- is the so-called safe harbor. The statute
4 also has 331(z).

5 THE COURT: Well no, but let's assume that 331(z) means
6 what the Government told us it meant. That it only means
7 that if you come to the Department and say, and they approve
8 your distribution of the New England Journal of Medicine
9 article, but you include within it another article that they
10 didn't approve, that that's what violates (z).

11 MR. REIN: Your Honor, if we read (z) as contractual and
12 --

13 THE COURT: Yeah.

14 MR. REIN: -- then the question is why then, is there
15 any problem with the injunction entered by the District Court
16 which --

17 THE COURT: I think that's a really good question.

18 MR. REIN: -- simply says the Government, the
19 Government.

20 THE COURT: I don't understand either. Because the --

21 MR. REIN: Well, if the Government shouldn't interfere
22 with other distribution, and the answer to that is the
23 Government is not accepting the injunctive relief. They must
24 have some reason to believe they can prohibit the speech --

25 THE COURT: Well --

1 THE COURT: Now wait a minute. Wait a minute. The
2 District Judge held the statute unconstitutional. That's the
3 grounds in --

4 MR. REIN: No, he did not. He's only insofar --

5 THE COURT: Wait a minute. When in his reconsideration
6 he most certainly did.

7 MR. REIN: He said only, his injunctive order is very
8 clear. It's constitutional insofar as it conflicts with the
9 injunction. The injunction is intended to establish
10 boundaries for a First Amendment right to distribute and to
11 the extent that the statute conflicts with it it's held
12 unconstitutional. Now, if the Government says it doesn't
13 conflict because the statute doesn't ban any of the
14 activities that are permitted by the injunction, then we have
15 an abstract statement without an actual conflict. Certainly
16 before the District Court, the District Court understood the
17 Government to be taking the position that the matters that he
18 authorized by the injunction were in conflict with the
19 statute. That is why he held it unconstitutional to the
20 extent it conflicted.

21 But the District Court did not say I'm sweeping away --
22 it is not our position that it's swept away. The safe harbor
23 is still available. So, a manufacturer --

24 THE COURT: Well, I thought you were -- unless you want
25 to get into a ripeness question which I'm sure would appall

1 you at this point. But, my understanding is you claim the
2 Government as a matter of practice is adopting the policy
3 with which I described exactly, of banning promotional
4 material, banning the distribution of non peer reviewed
5 articles as promotional material for drugs.

6 MR. REIN: That is what the Government's guidance said
7 that if you distribute, a manufacturer distributed the
8 material, that would --

9 THE COURT: Well, that's what the statute specifically
10 precludes. Doesn't it?

11 MR. REIN: Well, the Government is now --

12 THE COURT: Let him finish his sentence. I want to find
13 out instead of paraphrasing.

14 MR. REIN: All right. I think that when this case
15 started we, the statute had not been passed and so the
16 guidance that was then outstanding from FDA indicated that
17 the mere distribution of this peer reviewed article would be
18 a violation. Would constitute the violation without regard
19 to all the facts and circumstances, without regard to 331(a)
20 and (d) that is to say proof that there was a claimed use.
21 And I certainly believe that in this statute, claims are a
22 better word than intent, because intent is too amorphous.
23 And that's where the case started.

24 When the FDAMA was passed, the Government said well the
25 FDAMA supersedes the guidance but it did not say it's no

1 longer unlawful to send this out. Whoopee. The FDAMA has
2 allowed you to do everything that your members, the WLF
3 members want and added yet another and safer means of doing
4 the same thing. I mean Congress clearly created an
5 additional incentive for coming on labeling FDAMA to safe
6 harbor. And that incentive has significance under the
7 constitutional balancing in Central Hudson because it's
8 certainly, again, a lesser, a less sweeping measure and a
9 furthering of the Government's on-label objective by a means
10 that's incentivizing rather than prohibitory. That's true.
11 The Government did not take the position before that the
12 FDAMA swept away the prior guidance and now allows these
13 materials to be distributed so long as the manufacturer's
14 prepared to take the risk under 331(a) and (d).

15 THE COURT: I thought that's exactly what their brief
16 said.

17 MR. REIN: Well --

18 THE COURT: In this Court.

19 MR. REIN: Well, their brief to this Court did not say
20 that, Your Honor. It said this speech was illegal. It was
21 forbidden under Pittsburgh Press --

22 THE COURT: Where does it say that?

23 MR. REIN: Their invocation of Pittsburgh Press --

24 THE COURT: Your brief says, your brief describes the
25 statute as banning speech, but I don't recall the

1 Government's brief, except for that one sentence I asked him
2 about.

3 MR. REIN: Well, Your Honor, I think that --

4 THE COURT: It describes it throughout as a safe harbor.
5 It says if you go through these procedures, then this won't
6 be used as evidence against you. That's what their brief
7 says.

8 MR. REIN: It is a safe harbor. There's no ques-- we're
9 not fighting about whether there is a safe harbor.

10 THE COURT: Yeah, I know, but I'm just re--

11 MR. REIN: The question is whether the Government either
12 through the FDAMA or through its interpretation of pre-
13 existing authorities says this speech is unlawful. This
14 speech meets the test of Pittsburgh Press and Pittsburgh
15 Press --

16 THE COURT: Where does it say that?

17 MR. REIN: Judge Tatel, if I might, just in Pittsburgh
18 Press, which the Government has its principal reliance. In
19 Pittsburgh Press, the Press was accused of aiding and
20 abetting an unlawful scheme, an unlawful hiring scheme by
21 putting columns in that were male and female distinguished,
22 segregated.

23 THE COURT: I know the facts of the case.

24 MR. REIN: And to invoke Pittsburgh Press one has to
25 assume here that the transmittal of the information itself is

1 a violation, otherwise --

2 THE COURT: See, I thought, I could be totally
3 misunderstanding --

4 MR. REIN: -- Pittsburgh Press makes no sense.

5 THE COURT: I could be totally their misunderstanding
6 position, but I thought the Government's position was, and I
7 read the statute as being less intrusive than Pittsburgh
8 Press because it's nothing more than a safe harbor.

9 MR. REIN: The Government's position is that they have
10 the right to ban it, and that Congress has given back some of
11 the flexibility through the statute.

12 THE COURT: Where does it say that in their brief?
13 Well, we can ask the Government about that.

14 MR. REIN: And that is exactly what they say in their
15 brief because they say, the Government's brief says the
16 statute allows more speech, more speech than the pre-existing
17 situation. That could only be true if the pre-existing
18 situation you couldn't do any of it and the statute allows
19 you --

20 THE COURT: It depends primarily what you think of as
21 the pre-existing situation. Say, if you, it's sort of a
22 substantive issue and highly technical issue. Substantive
23 issue is exactly how much, how close the relationship, for
24 example, would be between the speech and the sell --

25 THE COURT: Right.

1 THE COURT: -- for the sell to be rendered illegal by
2 virtue of the speech. Then there's the formal issue, was
3 there before FDAMA any independent ban on the speech alone,
4 and we seem to be hearing from the Government no. There was
5 no such independent ban on the speech.

6 MR. REIN: Judge Williams, as I said, I think that's not
7 --

8 THE COURT: I say, we seem, I understand --

9 MR. REIN: That's not a fair characterization of their
10 position because under that position there would not be more
11 speech allowed under FDAMA than there was prior to it.
12 Because their position was prior to FDAMA --

13 THE COURT: Well, yeah, there is in a way because
14 there's the pre-existing situation plus the safe harbor.
15 Safe harbor may be an empty and dangerous harbor, but it is
16 something. Right?

17 MR. REIN: There is no question, when we are not
18 contending that the Government can't offer a safe harbor
19 because it goes beyond what was available previous to this.
20 Previously if you circulated the materials even under the
21 Court's injunction the Government was not foreclosed from
22 charging a substantive violation, 331(a), 331(d). They could
23 claim that the shipment was in violation of the prohibition
24 on shipping for an unauthorized purpose. They could claim
25 that it was misbranded.

1 Now, the fact is, and I think --

2 THE COURT: Mr. Rein, I'm going to suggest something
3 that's a little unorthodox because I think all of us are a
4 little confused as precisely what the issue is between you
5 and the Government. I'm going to ask you to sit down and
6 after the Government comes up, and please tell us what their
7 position is, what their practice is and what their reading of
8 the statute and prior law is, and then we'll see if we still
9 have a conflict.

10 THE COURT: Can I refine the question slightly?

11 THE COURT: Yes, Judge Tatel wants to refine it, so
12 you're going to sit down for a moment. We're going to give
13 you a chance to come back up.

14 THE COURT: I just have a very specific question. Okay?

15 THE COURT: You can sit down, Mr. Rein.

16 MR. REIN: Well, if Judge Tatel wants to ask a question.

17 THE COURT: No, I want to ask the Government counsel.

18 MR. REIN: Okay. I'm sorry.

19 THE COURT: And then, okay. That's all. Thanks.

20 MR. REIN: I was confused. I thought Judge Tatel wanted
21 to ask me the question.

22 THE COURT: No, no. I understand the answer to your
23 question.

24 THE COURT: You'll get a chance to come back, Mr. Rein.

25 MR. REIN: All right. Thank you, Your Honor.

1 THE COURT: Does this statute do anything more than
2 create a safe harbor?

3 ORAL ARGUMENT OF William B. Schultz, Esq.

4 ON BEHALF OF APPELLANTS -- Rebuttal

5 MR. SCHULTZ: FDAMA does not. The 1997 statute does, we
6 believe creates --

7 THE COURT: And what is the meaning of the prior Act?

8 MR. SCHULTZ: The prior Act --

9 THE COURT: Wait, hold, excuse me.

10 THE COURT: Let Judge Tatel finish.

11 THE COURT: I just want to, so this statute and the
12 guidance, the manufacturers can distribute anything they
13 want, sponsor any meetings they want at their own risk.
14 Right? That is the risk being that it might be used as
15 evidence in a case against them for distributing the product
16 with intent for off-label use. Right? That's all the
17 statute does.

18 MR. SCHULTZ: Well, it's all, but when you say at their
19 own risk, it's a pretty big risk --

20 THE COURT: Well, I understand that.

21 MR. SCHULTZ: But yes.

22 THE COURT: But the statute gives the Government no
23 power other than as Mr. Rein said possibly a contractual
24 arrangement with the Secretary. If a manufacturer tomorrow
25 distributes a million copies of the New England Journal of

1 Medicine article, forget New England Journal, yeah, take New
2 England Journal of Medicine, distributes a million copies for
3 an off-label use, that is not illegal, independently.

4 Correct?

5 MR. SCHULTZ: I think that's, I believe that's correct,
6 yes.

7 THE COURT: So, I don't understand why this case is
8 here. I mean --

9 MR. SCHULTZ: Well, the case is here --

10 THE COURT: -- your view of the case and their view of
11 the case is your view of the case and their view of the
12 statute is identical. You both agree, you both agree that
13 the distribution could be used as evidence of intent in a
14 prosecution for off-brand marketing.

15 MR. SCHULTZ: I mean understand --

16 THE COURT: And you both also agree that it doesn't
17 independently ban the distribution of the New England Journal
18 of Medicine article. Right?

19 MR. SCHULTZ: We have, I mean, yeah, I think that is
20 right. We have to be --

21 THE COURT: Okay. So, where's the case?

22 THE COURT: And just to clarify the question, this means
23 the total statutory scheme, FDAMA, and the whole statute to
24 which it is an amendment. Right? Or not?

25 MR. SCHULTZ: Well, can I ask, the reason the case is

1 here, I just want to make sure --

2 THE COURT: No, wait, hold on. No, wait. Let me make,
3 let me say one other thing and then we'll get it all out.

4 Okay?

5 MR. SCHULTZ: All right.

6 THE COURT: The difference, I understood you saying when
7 you said this statute allows more conduct than under prior
8 law. Right?

9 MR. SCHULTZ: Yes.

10 THE COURT: I thought what you meant was that under
11 prior law, you could use the New England Journal of Medicine
12 article as evidence of intent, whereas this law gives the
13 manufacturer a process for protecting himself from having
14 that used.

15 MR. SCHULTZ: That is exactly correct.

16 THE COURT: Okay. So, I don't think we have a case.

17 MR. SCHULTZ: Well, the reason we have a case --

18 THE COURT: Just to make absolutely sure you're saying
19 what Judge Tatel believes you're saying and I think you may
20 be saying, the only use of the promotional material not
21 fitting within FDAMA is this evidence that there's been a
22 violation of one of the provisions relating to marketing of
23 drugs, selling drugs, introducing drugs at a commerce for
24 off-label uses.

25 MR. SCHULTZ: That is correct.

1 THE COURT: Or misbranding.

2 MR. SCHULTZ: Or misbranding, that's correct. That's
3 correct. And, we're disadvantaged because we don't have a
4 drug company before us in this Court who's done something.
5 Instead --

6 THE COURT: Well, I know. Unfortunately in the First
7 Amendment area, ripeness requirements are very loose.

8 THE COURT: Is this what you argued in the District
9 Court? I mean, I can go back and look at the briefs, but did
10 you, was this case described to the District Court as a safe
11 harbor and nothing more?

12 MR. SCHULTZ: Well, I think it was. Understand that
13 most of the case was litigated before the 1997 law was even
14 enacted. So, it was litigated under the earlier law, but the
15 District Court --

16 THE COURT: Well, why don't you tell us what
17 specifically you're appealing about? What do you object to
18 in the injunction?

19 MR. SCHULTZ: The injunction says the defendants, that's
20 the Government shall not in anyway prohibit, restrict,
21 sanction or otherwise seek to limit any pharmaceutical or
22 medical device manufacturer, any person from disseminating
23 journal articles and so on. And --

24 THE COURT: But you just told me you wouldn't do that.
25 That that's not what the statute authorizes you to do other

1 than --

2 MR. SCHULTZ: We won't do it directly.

3 THE COURT: No, I don't think so.

4 MR. SCHULTZ: We won't do it directly, but --

5 THE COURT: No, no, you said you wouldn't be prepared to
6 prosecute and your theory is that injunction precludes you
7 from prosecuting.

8 MR. SCHULTZ: Yes, yes. That's a big deal.

9 THE COURT: And that's what I understood too. So, you
10 were giving away much too much of this case earlier I
11 thought. Well, forgive me for saying that. But, you've got
12 an injunction from a District Judge that prevents you from
13 enforcing the statute.

14 MR. SCHULTZ: Yes. And that's why the Government's so
15 excited about the case. That's right.

16 THE COURT: All right. All right. Let me see if we can
17 go back to Mr. Rein and see -- now, I, do we have a clear,
18 isn't that injunction too broad then under anybody's theory?

19 MR. REIN: Your Honor, let me say it obviously raises
20 the question what is the injunction's effect on a prosecution
21 substantively brought under 331(a) or (d). That is to say
22 was this injunction intended to foreclose the Government from
23 pursuing a manufacturer distributor who is making claims of
24 an unauthorized use or failing to --

25 THE COURT: But, as Judge Williams said, in most cases,

1 you know, often depend on how close the promotional material
2 is to the transaction, the shipments and so forth and all
3 these facts that have been very complicated which I was
4 trying to deal with you in hypotheticals, but it's very hard
5 to figure out.

6 MR. REIN: And, certainly, we don't disagree with the
7 fact that --

8 THE COURT: So, but that, the injunction seems to barr
9 the Government from using that promotional material in
10 anyway.

11 MR. REIN: No, the injunction, as we read it, as the
12 Government read it in the District Court, where they said we
13 do not, you know, this injunction may not do you any good
14 because we can still bring cases substantively against the
15 manufacturer which was their position in the District Court.
16 It's different from their position today, but it was their
17 prior position. In our view, having proposed the injunction,
18 the injunction was intended to prevent a prophylactic
19 sweeping prohibition on the distribution of the materials.
20 It did not say --

21 THE COURT: But if the statute doesn't authorize that,
22 then there's no need for the injunction. The Government has
23 just told us --

24 MR. REIN: The Government's --

25 THE COURT: The Government has just told us that this

1 thing is nothing more than a safe harbor. It doesn't ban
2 anything and you agreed with us earlier that if that's all it
3 is, the statute's not unconstitutional.

4 MR. REIN: If the FDAMA is read in the way the
5 Government now read it --

6 THE COURT: Yes.

7 MR. REIN: -- and it is solely a safe harbor, then it
8 does not conflict with the permissive parts of the
9 injunction. So at that point, the Government should --

10 THE COURT: But if it's read the way the Government
11 reads it, is the statute unconstitutional?

12 MR. REIN: The, I think all the injunction says is if
13 one chose to read it more broadly and the language of 331(z)
14 certainly lends itself to different readings, so --

15 THE COURT: But if the statute is not unconstitutional,
16 what's the basis for a District Court injunction at all?

17 MR. REIN: Well, there were also some guidances at issue
18 in this case which had much more sweeping language
19 prohibiting the actual distribution. They targeted the
20 materials. And --

21 THE COURT: Yeah, but aren't they preempted by the
22 statute?

23 MR. REIN: No, they were not. They, if the Government
24 now believes that the guidances --

25 THE COURT: I didn't hear what your answer was.

1 MR. REIN: That's up to the --

2 THE COURT: Actually, I didn't hear Judge Tatel's
3 question.

4 MR. REIN: I'm sorry, Judge Tatel, if the Government now
5 believes that the guidances are withdrawn, and indeed the
6 Government first said they were superseded which meant, as
7 far as we could understand it that 331(2) which has very
8 broad prohibitory language did what the guidances did. Said
9 you can't distribute this material or it will be a violation.
10 Thus it superseded the guidances. If the Government now says
11 no, we withdrew the guidances in light of FDAMA, we somehow
12 with a mystical act that they never reported any place, have
13 now withdrawn those guidances. We no longer object to
14 manufacturers distributing, let's say putting these, let's
15 take a clear example, Judge Silberman, cause I think it will
16 help. Suppose a manufacturer opens a website and says on my
17 website I have all articles that refer to this drug. Anybody
18 can come and look at them. Now the question becomes is the
19 Government saying, yes, fine, terrific, go do it --

20 THE COURT: The Government says that's okay. That's
21 what they just told us.

22 MR. REIN: Well, the Government certainly did not tell
23 the District Court that "that was okay." Suppose the
24 manufacturer mails them out, says --

25 THE COURT: I've never seen anybody try so hard not to

1 win a case.

2 MR. REIN: Well --

3 THE COURT: I mean, it sounds to me like the Government
4 agrees with your interpretation totally.

5 MR. REIN: Well, Your Honor, I think all we're saying,
6 and I'm perfectly prepared to win on the ground that the
7 injunction here preserves forms of conduct which now if the
8 Government is prepared to say we don't contest them, then
9 they should never have appealed this case. They should have
10 said the injunction doesn't trouble us.

11 THE COURT: Yeah, but the District Court declared the
12 law unconstitutional.

13 MR. REIN: They only declared it unconstitutional
14 insofar as the District Court believed the Government's then
15 interpretation which was it replaced the guidances. It
16 reinforced the guidances which said don't do it at all, were
17 in place. Now, if they're not in place, and the Government
18 now chooses to withdraw the guidances because the law doesn't
19 affect the guidances in the Government's view, it --

20 THE COURT: Well, one thing's for sure. The third
21 guidance is still in effect. Right?

22 MR. REIN: Absolutely. That's the CME guidance.

23 THE COURT: And that deals with the seminars.

24 MR. REIN: That's correct.

25 THE COURT: Which we haven't discussed at all.

1 THE COURT: Well, we did. You heard, Mr. Schultz said
2 that a manufacturer could conduct a conference on his own
3 that violated all 12 factors.

4 MR. REIN: And, you know, it --

5 THE COURT: And the Department would have no basis for
6 stopping it.

7 MR. REIN: Well, if they're now going to withdraw the
8 guidance, I mean, Your Honor, I'm somewhat difficult because
9 we're not the Government, and --

10 THE COURT: Well, but I thought they were just saying
11 the 12 factors were a safe harbor. In other words if you
12 came to them and said I want to do this conference and
13 everybody agrees that if you apply the 12 factors then it's
14 clear that the conference is independently, scientifically
15 valid and not a marketing device, that that's the end of it.
16 That they can go ahead and do it and that the Government can
17 never use it as evidence in an unlawful labeling case.

18 MR. REIN: Well, if that is the Government's position,
19 they can never use it in evidence in an off-label case, I
20 don't think, then from the point of view of our members the
21 seminars will flow and the materials will flow. I don't
22 believe that's the Government's position --

23 THE COURT: I can't imagine why the Government appealed.
24 They certainly made it look like it was much more a seninole
25 a case than where we're down to now. Mr. Rein, I appreciate

1 very much your forbearing with us while we shifted around our
2 procedure. I will only say that if there is no issue between
3 you, an injunc-- I don't see how an injunction can stand.
4 There has to -- you can't, you don't allow prophylactic
5 injunctions in case the Government interprets the statute in
6 a bad fashion.

7 MR. REIN: Well, Your Honor, I think that the question
8 here there are a couple of things. It's not moot because the
9 Government has previously threw its guidance interpreted the
10 pre-existing statutes to allow that prohibition. The
11 Government has --

12 THE COURT: Well, not if their view is that whatever the
13 pre-existing guidance, whatever content it had is obviated by
14 the '97 statute.

15 MR. REIN: Your Honor, again, we haven't seen that.
16 It's not in the Federal Register. They didn't withdraw it.
17 If they're now going to take the position that they'll put a
18 notice in the Federal Register that says the pre-existing
19 guidances are withdrawn, all prohibitions are removed --

20 THE COURT: Well, wait, wait, wait, wait. I understand
21 your point. They may not need to do all that. Their
22 representations in this Court are of some importance. Thank
23 you, counsel. Now, I'd like to have Mr. Schultz.

24 Mr. Schultz, we are three mystified judges, I think --

25 MR. SCHULTZ: It sounds like we should have been able to

1 settle the case. The, first of all in terms of the status of
2 the three guidances --

3 THE COURT: Yes.

4 MR. SCHULTZ: There were three. Two of them, the ones
5 dealing with journal articles and textbooks were superseded
6 by the regulations implementing the 1997 statute. The third
7 one which is one that tells --

8 THE COURT: Put aside the third one for a moment.

9 MR. SCHULTZ: Okay.

10 THE COURT: The two that are superseded by regulations
11 implementing the '97 statutes according to what we understood
12 retreat from your interpretations prior to the passage of the
13 '97 statute.

14 MR. SCHULTZ: Well, I mean what I said is the '97
15 statute is a safe harbor. If there's nothing --

16 THE COURT: A safe harbor against what? That's the
17 problem. We're trying to figure out what are the torpedoes
18 here.

19 MR. SCHULTZ: There's nothing in the law that directly
20 prohibits the dissemination of journal articles. But, the
21 FDA will use that as I have said again and again, and that's
22 what this case really is about. The FDA will use the
23 articles or the advertising as evidence that the company is
24 selling -- yes.

25 THE COURT: Don't use the word but. I mean, it doesn't

1 ban anything. Right?

2 THE COURT: Well, I see your point.

3 MR. SCHULTZ: Well, the FDA issues guidance, will issue,
4 what the FDA did before is it issued guidance to the
5 companies. It said --

6 THE COURT: Is that right? It doesn't ban anything.
7 Does it? The statute?

8 MR. SCHULTZ: No, no.

9 THE COURT: Doesn't ban anything.

10 THE COURT: So, the guidance suggests your enforcement
11 posture.

12 MR. SCHULTZ: Yes. It says that the companies --

13 THE COURT: And, but then if you suggest a, all right
14 now, wait a minute. Now, if you suggest an enforcement
15 posture, if you do A, and B, and C, we're going to enforce
16 against you. And, you're in an area of speech, then it seems
17 to me Appellees are correct to say we can go to federal court
18 and get an injunction against that because that's a broad
19 practice. That's not a just a case-by-case, we're going to
20 see it in evidence when we see it. That's a broad
21 generality, and that is designed, they are, you did shield
22 speech. Therefore we're entitled to an injunction.

23 Now, you maybe have a right to kill that speech or not,
24 but that gets us back to the question of whether we have
25 something before us.

1 MR. SCHULTZ: Right. Now, the point --

2 THE COURT: And the answer is we do have your guidance
3 before you.

4 MR. SCHULTZ: Well, the only guidance I believe you have
5 before you is the CME guidance.

6 THE COURT: What?

7 MR. SCHULTZ: The guidance on educational seminars.

8 THE COURT: Okay. So, you've withdrawn the guidance on
9 the first two?

10 MR. SCHULTZ: They've been superseded by the statute,
11 yes.

12 THE COURT: Yeah, but you said superseded by the
13 regulations implementing the statute. You're saying the
14 regulations implementing the statute no longer in anyway go
15 back to the old guidance. Let's go on. So, you're not
16 taking any general position of guidance. Look, if you engage
17 in this conduct, we're going to come after you.

18 MR. SCHULTZ: Yes, now, the Agency will still use the
19 statute, but there's no guidance.

20 THE COURT: Go on to the guidance. Go on to the
21 guidance now. The one that's left.

22 THE COURT: Yes, the seminar.

23 THE COURT: Am I right. That if someone wants to run a
24 conference, it violates all 12 factors they can just go ahead
25 and do it.

1 MR. SCHULTZ: They can run the conference.

2 THE COURT: You can't stop them.

3 MR. SCHULTZ: Can't stop the conference.

4 THE COURT: But you might file an off-labeling
5 prosecution and use it as evidence.

6 MR. SCHULTZ: Yes.

7 THE COURT: Thank you.

8 THE COURT: Now --

9 MR. SCHULTZ: I think the District Court opinion, I
10 mean, it's important to look at the order because --

11 THE COURT: The injunction goes too broad, and in light
12 of what you have just stated, I understand where --

13 MR. SCHULTZ: Yes, I think the injunction declares the
14 statute unconstitutional and it keeps us from bringing the
15 prosecution which is at the heart of enforcing the statute.

16 THE COURT: All right. Thank you. Mr. Rein, will give
17 you another chance again because we're narrowing down. We're
18 getting closer and closer to the level of this dispute.

19 MR. REIN: Well, Your Honor, I come to you a little bit
20 as a marshmallow, but I, let me say this. First, with
21 respect to what the injunction says --

22 THE COURT: You're referring to the Court or the
23 Government that's the marshmallow?

24 MR. REIN: No, I would certainly, I think the reference
25 was clear, Your Honor.

1 THE COURT: The reference --

2 MR. REIN: Let me just say that the injunction says that
3 with respect to the FDAMA and the rules they are contrary to
4 rights secured by the United States Constitution. It doesn't
5 say they're unconstitutional. It's contrary to rights and
6 therefore must be set aside pursuant to 706(2)(b) except
7 insofar as they are consistent with the injunction provisions
8 below. So, if they're totally consistent with the injunction
9 provisions, yes, I, you know, if the Government now would
10 like to construe the rights available as consistent with the
11 injunction that is to say nothing in the injunction is
12 prohibited, then there's no conflict between the two.

13 THE COURT: Well, the real question here, and by no
14 means am I critical of you in bringing the suit because I
15 understand full well why you did it. And, it seems to me
16 that your perception initially as to the Government's
17 position was correct. But, as it now comes down to it, the
18 Government is saying look, we are just preserving the right
19 to prosecute in the event the distribution of promotional
20 material can be used as evidence of a proscribed intent.

21 MR. REIN: I think --

22 THE COURT: You don't deny their ability to do that.

23 MR. REIN: On a case-by-case basis they are entitled to
24 prosecute. Your Honor, I think that the difference in what
25 we said in our brief is and it's almost like banning books.

1 This is a heavy regulated industry. The Government can have
2 an interorum effect. It puts out these guidances. It says
3 if you cross this line --

4 THE COURT: That's right. That's why I said I agreed
5 with your position initially. I mean I think it made a lot
6 of sense to bring this action initially based on that
7 guidance. But now, now that those first two guidances are
8 withdrawn and the third guidance is interpreted in the way
9 Judge Tatel did, then the injunction is inappropriate. Isn't
10 it?

11 MR. REIN: I think though I'm still hearing the
12 Government say as to the third guidance that while you can go
13 ahead and hold the seminar, there's no prior restraint as
14 such. That they will at least take the position that if you
15 do it, they will systematically move against you.

16 THE COURT: No, that's not what he said.

17 MR. REIN: Now --

18 THE COURT: He said, he said only if they file an off-
19 label, is that what you call it, an off-label prosecution.
20 Whatever you call it. Misbranded.

21 MR. REIN: Misbranding or improper shipment.

22 THE COURT: Yeah. Okay. Only if they file such case.
23 And seek to -- let me finish. And seek to prosecute a drug
24 company for that would they use the conducting of that
25 conference as evidence of the manufacturers intent.

1 MR. REIN: Judge Tatel --

2 THE COURT: That doesn't bother you, does it?

3 MR. REIN: I think the fact that they can file such a
4 case is not barred by the injunction. That's not the issue.
5 The question is whether the Government is saying to the
6 world, and it's very important what they are communicating
7 because the manufacturers are a heavily regulated sector.
8 Are members are physicians. They're making lawful
9 prescribing decisions. They want this information. To the
10 extent that the manufacturers are interororum, they are not
11 going to provide the information our members require. That's
12 the interest we're here to represent.

13 THE COURT: I understand.

14 MR. REIN: So, what we're saying is the Government is
15 now under at least some question from the Court, now lurking
16 in the woods saying well, we're not going to say that we can
17 prohibit it directly. But, if you violate the factors we're
18 going to have the ability to prosecute. What they're not
19 saying is that they are going to do this on a case-by-case
20 basis taking into account the full context that is, say, we
21 distinguish between information that facilitates a
22 physician's decision and an advocacy, a claim made by a
23 manufacturer.

24 For example, a manufacturer said send out materials
25 saying here's something from New England Journal of Medicine

1 but out laboratories are not in a position to either confirm
2 or dispute what's in it. It's provided for the interest of
3 the medical community generally. Or put up a website. Those
4 are situations where we would say no prosecution could lie,
5 and the history, Your Honor, the history I think it's
6 important. Before this case was brought, the Government was
7 operating interorum. It didn't go after substantive
8 violations. It hasn't gone after one of them. There's no
9 record that they've been pursuing remedies for misbranding.
10 There's no record that they pursued remedies for false
11 shipment. That's not how they intended to get their way.
12 What they did was put out interorum guidance and --

13 THE COURT: Terror is cheaper.

14 MR. REIN: Cheaper and it got to what, the Government
15 says in it's brief there are two things I just want to point
16 out that were said in the brief, in the reply brief, the last
17 brief the Government filed that are significant.

18 One, to go back to the very first question you asked,
19 Judge Williams, they said, that where a manufacturer sends
20 out the material, in a situation where there's widespread use
21 of material for off-label purposes, that can demonstrate the
22 requisite intent. So, they do have, even without anything
23 going out. They have the authority --

24 THE COURT: But you can argue that -- you don't have any
25 objection to arguing that in an individual specific case.

1 Right?

2 MR. REIN: We're not asking this Court to enjoin the
3 Government for enforcing 331(a) --

4 THE COURT: In other words, it would be perfectly
5 appropriate for the Government to make that argument in a
6 specific misbranding case, and you'll argue that's
7 ridiculous. You can't rely on that. Right?

8 MR. REIN: I'm not trying to prejudge. I'm not asking
9 the Court to prejudge a misbranding case.

10 THE COURT: No, but that --

11 MR. REIN: What I am saying is that where they use that
12 interorum principle and where they have said in their brief
13 that as far as they're concerned, only the FDA has the
14 scientific ability to determine whether use is safe and
15 effective, and physicians generally do not. That's what they
16 say.

17 THE COURT: That's not what they're saying.

18 MR. REIN: That's what they're communi--

19 THE COURT: They're not saying that off-label use is
20 illegal.

21 MR. REIN: It's in their brief. It's in their brief,
22 Your Honor. And the point is they've made it very clear in
23 their own brief and reply brief, they don't like off-label
24 use. They intend to try to crack down on it. They know that
25 they can't prohibit it with the physicians because the

1 Congress told them they couldn't. They're trying to suppress
2 the information and these guidances and their statements are
3 interorum. They're intended to put the regulated sector --

4 THE COURT: So, you should be very grateful that the
5 guidances have been withdrawn.

6 MR. REIN: I am thrilled about it, Your Honor. That's
7 where we started. Thank you very much.

8 THE COURT: Case is submitted.
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C E R T I F I C A T E

DEPOSITION SERVICES, INC., hereby certifies that the attached pages represent an accurate transcript of the electronic sound recording of the proceedings before the United States Court of Appeals for the District of Columbia Circuit in the matter of:

Washington Legal Foundation, Appellants v.

Jane E. Henney, et al.

Case No. 99-5304

By:


Caroline G. Gibson, Transcriber