UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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MOMS AGAINST MERCURY et al,
Plaintiffs Civil Action No. 04-334

v.

ANDREW VON ESCHENBACH, et al.,

Defendants,

----------X Washington, D.C.
Friday, May 16, 2008
10:30 A.M.

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE ELLEN SEGAL HUVELLE
UNITED STATES DISTRICT JUDGE

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Proceedings recorded by mechanical stenography, transcript produced by computer.

P R O C E E D I N G S

THE DEPUTY CLERK: This is civil action 07-2332. Mom's against Mercury et. al. versus Andrew Von Eschenbach, et. al.

I am going to ask counsel to please identify themselves for the record.

MR. BROWN: Your Honor, I'm Charles G. Brown, counsel for plaintiffs, Mom's against Mercury, et al.

THE COURT: Good morning.

MR. CUTINI: I'm Drake Cutini from the Justice Department, for the defendants. With me is Wendy Vicente and Jeffrey Senger from the Food and Drug Administration.

THE COURT: We are here now on two motions. One is a motion to dismiss for jurisdiction and lack of standing brought by the defendants; and then, a motion for preliminary injunction.

The plaintiffs are asking me to take this device off the market, the amalgam that is used for fillings, pending the outcome of this case.

Let me say to begin with, maybe this will help us move along. For jurisdictional purposes, and I think the government really knows this deep down, I have jurisdiction under 706-1. It is clearly a proper

suit for a failure to act. That is what it is.

I don't have jurisdiction independently under the various FDA statutes that are cited at this time any way, because they have not done it. This is a, the ultimate issue that gets decided here and the Circuit has given me a lot of help on this in a sense.

There is only one issue before me, ultimately. The bottom line is has the FDA been unreasonable in its delay in terms of acting on classifying this dental amalgam which the acronym is E. A. A. D. M. in caps, which is encapsulated amalgam alloy and dental Mercury. Everybody agrees that it includes Mercury used for fillings. Plaintiffs take the position that it should be classified as a class three device. The FDA has not actually classified the amalgam even though its component parts are classified as a class one and/or class two.

So it is regulated as a class two, but they have not done, and we all agree it has been 32 years. Those facts are not particularly disputed. But so, one, that's where the Court's jurisdiction is. It does not rest anywhere else. I'm here under a 706 APA claim for unreasonable failure to act.

Once we get the contours established, this is not a NEPA type claim. Or this is not an arbitrary

capricious action because they have not acted. This is your classic failure to act. There are two cases. Both of them are rather recent from the D. C. Circuit.

It would be nice if people would actually read the governing law.

Everybody would like the Court to decide that this is a harmful device or not a harmful device or pull it off the market, or not pull it off the market.

That's not the Court's jurisdiction. I don't have the power to decide those things.

All I can decide at the end of the day is whether there has been an unreasonable delay in the resolution of such a decision.

It has clearly been defined actually quite recently under the D. C. Circuit's case. It is called Mashpee Wampanoag W. A. M. P. A. N. O. A. G. Tribal Council versus Norton. That is reported at 356, F3d, 1094. That's the Circuit 2003.

That is one. And since then, there has actually been a more recent case that just came down called Kauffman versus Mukasey, that's 2000 Westlaw, 2774 at page two.

When an agency is compelled to, by law to act but the manner of its action is left to the agency's discretion, the Court can compel the agency to act.

Although it has no power to specify what the action must be.

They're telling me that at the end of the day, the plaintiffs, the best that they can get from a Court is an order to act. That may be fine. That is their remedy. So, but that is what this case is.

I'm actually amazed at how I've had pages and pages of pleadings. And we don't really seem to be focusing on the real issues here and the power of the Court, which is limited by the APA.

I don't have the power to pull this drug off the market. I simply do not. I might think you should have it off the market or as a class three, but it is irrelevant if I think that. The best you can win here at the end of the day is FDA act. What that means in practical terms is something else. But in any case, so, let's address the standing. But I would like to at least define what the legal contours, parameters are of the case.

We are proceeding under 706-1, if you, once defined as such can figure out why they don’t have standing, I’m happy to hear it.

I have jurisdiction. It is a proper case to say here, you have not acted, you should act. That is the classic, unreasonable delay case.

I cannot under the law pull the drug. I couldn't do it even if you won the lawsuit. I don't have that power. There is not a case that you have given me that gives me that power. The D. C. Circuit is very clear. The notion that judges can do whatever they well please is just a fallacy.

It is a fallacy that appears to be engaged in by the political arena, as well. We don't operate that way. There are rules of jurisdiction. There are rules under the APA. So I want to make it clear it has nothing to do with what I think about the harmfulness of this amalgam, nothing. As soon as everybody would proceed to understand what the contours of the case are, we might be able to do something useful. But we're on a side show right now.

You can address the standing issue, but I've never understood your arguments, frankly, sir. I think you are missing the main issue here.

MR. CUTINI: May it please the Court, I am Drake Cutini on behalf of the defendants.

Respectfully, Your Honor, the APA is not a grant of jurisdiction.

THE COURT: Well, I understand. But it is 1331 coupled with 706-1. I have jurisdiction to decide a case of unreasonable delay.

MR. CUTINI: Respectfully, we disagree and believe that plaintiffs still must show that they have standing under Article III of the Constitution.

THE COURT: I agree.

MR. CUTINI: They have not made sufficient allegations to demonstrate that. Particularly, with respect to the second two prongs of the traditional injury analysis causation and redress ability.

THE COURT: Well, can we get over the injury in fact? Why don't they have a clear case of exposure to enhanced risk? How else could you ever get into Court in a case like this if these people can't do it?

MR. CUTINI: For purposes of this motion, we're not conceding that any of these injuries were, are continuing or caused by dental amalgam, but for purposes of this motion at the pleading stage, we're not going to dispute injury in fact at this point.

THE COURT: Because, as we all admit, it is not for me to decide the merits of the case at this moment. They have an incredibly strong case of standing for purposes of injury in fact, and enhanced risk of exposure to harm. And I would, for the record, I mean, there is D.C. Circuit law. And nobody cited it to me. We have spent our time looking up cases.

I started with the Second Circuit case of Bower versus Veneman and where the injury in fact was far more speculative than here. But just looking at the case law from our Circuit, Mountain States Legal Foundation versus Glickman, certainly.

Public Citizen versus Foreman. A D.C. case from the District Court, Cutler versus Kennedy. They have shown, made ample showing for standing purposes of enhanced risk of exposure to harm, therefore, an injury in fact and the injury is certainly particularized to the plaintiffs. I only have to find there are people, workers and dentists, people who have suffered in fact and are suffering continuing.

So, I don't understand, how is it that a case like this, if they don't have the ability to proceed, how could anybody ever challenge, tell me, who could challenge your unreasonable failure to act if it can't be these people?

MR. CUTINI: I don't know, well, I know that these people cannot. The reasons are and maybe nobody can. The reasons are the uniqueness of the situation here. This product has been regulated as a class two device. It is on the market legally. There is nothing illegal about its current marketing.

THE COURT: But you were supposed to go back

and classify it after, because it was a pre-amendment.

MR. CUTINI: Correct.

THE COURT: And you have not.

MR. CUTINI: That is correct.

THE COURT: So you have not acted. I don't think there is any issue. It is by default that it is a class two.

MR. CUTINI: It's class two because some of the predicate devices, amalgam alloy is class two. But they still have to show that their harm, alleged harm which we are not conceding but not disputing at this point, was caused by FDA's activities with respect to dental amalgam. And further, that the classification would redress that alleged injury.

THE COURT: Well now, let’s go back. You are positing that the only way they could show causation and readdress ability is by showing that they would win ultimately before you, that it would be a class three. Is that what you're saying?

MR. CUTINI: No, no, if they won, we're not saying they have to win to have standing. If they won, there is no showing that any of the alleged injuries would be redressed. In fact, in responding to our motion to dismiss, they describe redress ability principally as an informational injury.

THE COURT: I'm not going to get hung up on all of your, both sides were on complete tangents. This is not an informational standing case. This is a standing case. Think about it in terms of NEPA for a moment. It is the best way to look at it.

You can come in as a plaintiff and say you didn't have notice and comment. You didn't permit us to participate. You didn't act. There was a series of things. The law does not require plaintiff to show that had you acted they would have gotten the kind of relief that would remove the environmental harm. That is not, it's called procedural standing.

They have a right to say I have a right under the APA to participate in the administrative process. However, whatever those rights are, it can be, you know, through the notice and comment, it can be through what is going on here. But to win a case like that on standing purposes, the law does not require them to show, had they had notice and comment, the regulation would have gone their way. So why doesn't that take care of us?

MR. CUTINI: We're not saying that. Under Luhan versus Defenders of Wild Life, I believe it's footnote eight. It said even if the allegation is a procedural injury, they still must show some type of

harm from that procedural injury.

THE COURT: You've already told me that we're moving on from harm. We're going to causation and redress ability.

MR. CUTINI: That's correct for purposes of this motion. They have not shown, what they have alleged the redress will be if the FDA, or if they win this lawsuit, is that there will be better information out there, and maybe they will receive better medical care and --

THE COURT: How about they may receive a classification from the FDA?

MR. CUTINI: That's not an injury. That's simply --

THE COURT: Sir, you keep going back to the injury. They want the following remedy. They want you to classify. They want you to stop dragging your feet and classify it. Then, if you say it is a class two, then they can appeal that. We all know that. They're just saying if you act then we could well get what we want, which is a class three classification. Or we could get at least to pregnant women, as children, whatever; that's what they're saying.

MR. CUTINI: The lack of classification is not an injury. What they alleged some of the

plaintiffs, one of the plaintiffs has alleged she has had miscarriages, that is an injury.

We don't concede that that was caused by dental amalgam, but that is a type of injury. Or another plaintiff alleged some type of physical harm. That is an injury. Simply not classifying this is not an injury. That is a type of procedural injury.

THE COURT: That means no one could come to court. I won't buy that. It is not legally right.

MR. CUTINI: They have to have causation, they have to demonstrate causation and redress ability and they have not alleged.

THE COURT: Go back to NEPA. There is not a person that has to allege that in fact you would make, you would make the environment safer for the snail guarder. You still get to Court.

MR. CUTINI: They didn't get to Court in Luhan versus Defenders of Wild Life. So they can't simply allege harm to the environment as standing. They have to allege --

THE COURT: No, that is the injury. You suffer because the animals that you like are suffering and you watch it. That is clear. But you keep going back to injury in fact. Go to the redress ability and causation.

MR. CUTINI: Well, in Luhan they, I believe in that case, the Court did not dispute that what they alleged as an injury was an injury. But they said this would not be redressed, I believe that's what the Court held by a ruling in your favor. That's what we have here. The only redress they alleged is that there might be better information out there that might be to --

THE COURT: You are not listening to me. You might get a class three. That's what they're alleging. Give me a classification. Do what you are under the law required to do. What happens if they get class three? They get more protections than they're getting now. Whether or not it would cure anybody's past injuries isn't the issue. Would it protect people like the people in the dental office who are part of the plaintiff class, et cetera? Why wouldn't it have redressed that? They might get a class three.

MR. CUTINI: That's all speculative whether it would be a class two or a class three, we don't know that. And it would not be removed from the market whether it was a class two or a class three. So --

THE COURT: No class threes ever get removed

from the market after the period of time?

MR. CUTINI: If the, the manufacturer either does not apply, what happens when something is classified as a class three is that the FDA issues a regulation calling for a pre-market approval applications or PMAs. It remains on the market while those are submitted. If it is not submitted, then that manufacturer can no longer sell the product. But if that manufacturer submits a PMA, the product remains on the market pending review of the PMA.

THE COURT: And if the PMA is not successful, then what happens?

MR. CUTINI: In that situation, it would be removed. But that is extremely speculative. And the only harm again from this is maybe insurance would pay or doctors would provide us --

THE COURT: Only harm for what?

MR. CUTINI: From classification of any sort. That's what they allege to be their redress is that we would get better treatment from doctors. Again, that injects a third party.

THE COURT: How about the people who say that my continued exposure to this causes health risk, enhanced, increased risk of exposure to an unsafe product. So if you keep it on there -- yes, I know

that we don't have any guarantees that you are going to take it off the market. But it is one of the possibilities from a class three classification.

It has been debated apparently within your agency for 20 years, whether or not it should be this or that. You have never ruled one way or another. One can say, in fairly good faith, that maybe people have the right to have you rule and not drag your feet for 32 years. But that is not where we are today. We're at a standing issue.

MR. CUTINI: Again, it is highly speculative what sort of reduction this would have.

THE COURT: But you are saying that, your argument, it's lone logic is that no one can sue you for failure to act. If these people can't, no one could.

MR. CUTINI: In this situation, this is a unique product. It is legally on the market, it is regulated as a class two. It has been proposed by the FDA to continue regulating it as a class two. There is just no injury that they have alleged that would be addressed by that or that would be caused by activity from the FDA The special controls that they talk about are highly discretionary with the FDA.

THE COURT: I know. But, okay.

MR. CUTINI: There is no special control that is required; no particular special control that they have alleged would be imposed on this. And part of the issue in this case is because of the uniqueness of the product where it stands right now.

THE COURT: What does that mean? The uniqueness of the product --

MR. CUTINI: Because it is already on the market legally on the market, regulated as a class two, that it, what has been proposed and if they win, it will be classified either as a class two or as a class three. Whichever way it is classified, it is not going to address their injuries. It's highly speculative whether it will.

THE COURT: You don't buy the analogy to the environmental field in other words? Massachusetts versus the EPA, Supreme Court. Have you read Bower versus Veneman, the Second Circuit?

MR. CUTINI: Not that I recall. But I do recall in Luhan simply alleging a procedural injury is not sufficient. I believe in that case, the court said –

THE COURT: Well, you need an injury in fact.

MR. CUTINI: And you need redress ability and causation. Those were the factors missing as I

recall.

THE COURT: Often because there is a third party involved. We don't have a third party here.

Okay. Thank you. I must find the government's -- you didn't, nobody argued the right standing analysis here, frankly. I find the position of the government just befalling on standing. I understand other things. I am absolutely lost. The law is absolutely clear where this is an injury in fact for standing purposes.

They have done it here. They have done it under D. C. Circuit law. It drives everything else in a way. One would refer to Bower versus Veneman, which is a much weaker case than the standing showing here at 352 F3d 625.

It is also clear that standing requirements for causation and redress ability get relaxed, so to speak, when you have a case like this. This is not, you have exposure to an enhanced risk of disease that would qualify as an injury in fact from drug safety. That's the claim. I'm not litigating the merits of that. For standing purposes, there is a lot less to be shown especially at this stage.

You don't have to show, because if you had to show that for redress ability and causation, once

you've shown a real injury in fact, with a concrete, credible fear of harm from exposure to this product, you have debated apparently internally for many years whether that is right or wrong.

But the debate alone, I mean it's been banned in other countries, there is a lot of literature. The debate alone says they've got standing. They have credible fear of harm from exposure to this. So as a result to then say, well, by the way, that injury in fact can't be redressed because you cannot predict what the FDA will do. Nobody can because they have not done it.

But that isn't the law, you don't have to show ultimate success or what would happen. You don't even have to show that you would, you know, there is a 90 percent chance that this would be taken off the market. That's not what standing is all about. The procedural standing clearly shows you have, the question is whether or not your remedy, i.e., getting the FDA to act.

If they succeed in getting an order saying go ahead and do it now, act expeditiously, 32 years is too long, it's an unreasonable delay, the argument is that they would have an opportunity to try to convince you if you had to act to make a decision that would be

favorable to them.

Causation is, you don't the match, there are dozens of cases. I wish we had more time. It's a very interesting area. But they have sufficiently, once they made the conclusion, once they have shown that they have, face a reasonable fear of increased risk of injury or future injury sufficient for purposes of injury in fact, you go on.

You can't require, otherwise, you've turned the law on its head in a case like this. There would be no environmental law ever because you never know what the NEPA analysis would show. If you get what you want is a full, in a NEPA case, a full environmental impact statement. That's one of the kinds of remedies. You were unreasonable to say an EPA would be sufficient.

So, but nobody knows what the full environmental impact Statement would ever show. It does not tell you whether even you would get the highway removed. Or you would get no more bombing out in the ocean. It is that you are entitled to proceed with a chance that you may well prove.

But if you look at the Massachusetts EPA, that’s a Supreme Court case at 127 Supreme Court F.1453, when a litigant is vested with a procedural

right, and I view this as a procedural right, i.e., to have the process get going. That litigant has standing. If there is some possibility that the requested relief will prompt the injury causing party to reconsider the decision that allegedly harmed the litigant. That's Supreme Court precedent.

The D. C. Circuit goes on and says, "A litigant who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure, the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive results." The Sugar Cane Growers Coop of Florida versus Veneman, reported at 289 F. 3rd, 89, pages 94 and 95.

Similarly, the causation analysis is also quite different than the government is arguing here. It is not required that there be a match between the statutory objective behind the agency regulation, and the alleged injury can facilitate finding a causal link between the agency's conduct and the injury, Arent versus Shalala. This case is very much like the D. C. case of Cutler versus Kennedy. I found that very helpful.

In any case, the motion on standing grounds,

I regret to say I really feel the government has wasted a lot of time on the wrong issue.

I mean, what is reasonable delay, et cetera, et cetera may well be, but I find the standing question quite simple. Once they get to the injury in fact, they're in court. To keep the door closed is to say that nobody can ever come in and do anything under 706-1 because nobody ever knows when you act what you'll do. By definition, that's a loser.

They have a high showing here of injury in fact. So, that this motion to dismiss, I have jurisdiction under 706-1 and 1331. I probably don't under some of the FDA laws, I understand that. Plus, they have not acted. But you would tie up the world with your analysis. No one could ever challenge. You could sit on your duties. You have a duty to act under the law. Therefore, you are saying I have a duty but nobody can challenge me for not doing it.

Illogical and legally unacceptable and wrong under Supreme Court laws.

So I'm willing now to listen to the plaintiff on the P.I. But I think I've told the plaintiff what problem is here. So the motion to dismiss is denied.

The defendant better start thinking about how we're going to move this along. I can't decide the

ultimate issue of what is reasonable or unreasonable. But they're well on their way to convincing anybody that 32 years is a long time.

Okay.

You too, though.

How can I order the product taken off the market? You couldn't get that if you want.

MR. BROWN: You've convinced me, Your Honor. What we would like is an order requiring FDA to classify on a date certain like 30 days, or 60 days, because they can do it.

THE COURT: You just said, I won the lawsuit. They haven't had a chance to go the merits yet. You're in the door that's all you're in. How can you win the lawsuit before they have a chance to say it's unreasonable?

I hope in the future everybody will read the right law. Like start with the D. C. Circuit. It says: It is a fact intensive, "what is reasonable is a fact intensive analysis." That means that they're entitled to have a dispute, issues of fact or they can try to show why it is reasonable. You can't just say, well, today you win.

MR. BROWN: Well, we believe, we've met the prerequisites to a preliminary injunction. The

probability of harm is enormous. Today, the focus here does not really have to be moving this to a class three. The issue with the class two, and that's where they say they're going to end up in their brief is fine, is special controls. A class two has to have special controls.

Now, here is the brilliant and devious way that FDA has this product on the market now. They say the powder, the old way, the old pharmacist system is regulated, the powder doesn't have Mercury in it. So the special controls, it's a class two, has no mention of Mercury. The bottle of Mercury, amazingly is a class one, like a bed pan or a--

THE COURT: You are arguing to me what you argued to the FDA That's not the issue for me.

MR. BROWN: I'm explaining, Your Honor, that the FDA gives no disclosure whatsoever of the Mercury. They have done that for 32 years. That's the policy of the dentists at FDA. They know that if they get, put in the special controls, that it has Mercury, the ball game is over.

I know there are limits but they could put in contraindications for pregnant women alone, a disclosure to everybody, whatever they put in. If they don't put the Mercury in the special controls at

all, as they are trying to do from the 2002 rule, they know they lose that on appeal. So the lawyers know they're going to lose the way it is written. The dentists don't want to disclose the Mercury.

So the special controls will contain the Mercury. We have a probability of success on the merits. We have enormous irreparable harm. Every day the pregnant women who are injured by this and FDA's policy is never tell anybody about it. That is their policy today and it continues year after year.

They are now in their third public comment period. It's a total sham. They did the last one in 2006. They said they're still reading the materials. They want to send a sixth U. S. president out of town with it unfinished, two years to look at this record. Their position on Mercury changes every year. Now they have said, well it probably injures pregnant women but they're a sub-set. To me, the probability of harm --

THE COURT: Sir, it is not a probability of harm in that sense.

MR. BROWN: I mean probably success and irreparable harm, I'm sorry.

THE COURT: I understand that. But that is not the issue, again. The question here is not

whether people are going to be hurt or not hurt. For standing purposes, that's quite different.

The question is whether there has been unreasonable delay which is a fact inquiry whether there is a likelihood of success on the merits has to do with whether or not you'll get a better ruling than you got now. Maybe, maybe not. Those things, I can't find that sitting here today, you are entitled to the ultimate relief you've asked for. I couldn't possibly find that.

You are arguing based on the horrors of the product. That is not the issue. I wish, you would you like to think that a Court could just come in and say take it off the market, classify it as this, give it special controls. I don't have that power. All I can give you at the end of the day after a roaring success is tell them to do something quick. That's it.

MR. BROWN: That's what we're asking, Your Honor.

THE COURT: I can't do it today.

MR. BROWN: Well, we believe we have probability of success on the merits after 32 years. The courts would order, and under 98 percent probability will order FDA to classify. We believe

we've met the other prerequisites, the balance of equities, the irreparable harm.

THE COURT: You are the one who says in your papers, that there are many material issues of fact, on causation and redress ability.

MR. BROWN: Yes, we do.

THE COURT: On the irreparable harm issue alone, your own pleading says that there are issues of fact at issue. So that, even if the sort of aura, and I just can't emphasize enough that I'm not persuaded by the quote "horrors," it does not do it.

I am constrained by the law. Irreparable injury has to do with whether or not their failure to act is, again, if I order then to act, we'll redress the problem, and will be causative to make people's life better. That is somewhat speculative to say the least. And now, after 32 years, it is a little hard to say that if they act tomorrow versus three months from now or four months from now or whatever it is, that a P.I. is necessary.

You are actually asking for the ultimate relief in the case. And you are not entitled to it at this stage. So the preliminary injunction will be denied. It is absolutely clear. First, to ask me to take the product off the market. As I say, I don't

have the power. And this isn't, that's a mandatory injunction that goes way beyond my jurisdictional grant here. The only thing you can get at the end of the day is an order to act. Not an order to act as follows.

So if you could keep that in mind, I will please ask both sides to read the relevant law. But the Mashby case says, "Resolution of a claim of unreasonable delay is ordinarily a complicated and nuanced task requiring consideration of the particular facts and circumstances before the Court." You assume because it is awful and harmful that it therefore translates into unreasonable delay.

That is not the law at all. That does not motivate anybody including the Court.

I would like to say it would. If I were a personal or private citizen, it might. But I have to consider the debate out there, whether or not what they have in place does much or it doesn't do anything. Whether or not there are reasons for their side. So you can't control just because you have people on your side that say X, there is a debate and there is a debate about whether changing it to three will make a difference here or there, and whether the action of having them act sooner than later is, that

would constitute irreparable harm in the interest of the public interest. And it cannot by driven even if you would like it to be, solely by your point of you as to the science. It's not possible. So, the P.I. is denied.

We're moving this on an expedited basis, though. I don't see any reason not to.

Do you have an administrative record you want to file here? This is on a record. We're not here to decide the ultimate --

MR. BROWN: Oh, this goes on record, Your Honor. This is all record, no discovery then. No depositions.

THE COURT: I don't see why there would be. I don't know why there would be. You have not done anything for 32 years. In some way or another you have to be able to say based on the record that exists why that is reasonable.

The other suggestion that I've for you folks is to come up with a timetable, agree to it and get going. I mean, why litigate what timetable the Court is going to impose at the end of the day, if I find in favor of the plaintiffs.

Don't send me anything ever again, that does not go to the other side. I will give it to them. It

totally violates every ethical rule in the book. Something came to me by fax to say that settlement had fallen apart. That violates every conceivable, it was written by Mr. Brown.

MR. BROWN: Your Honor, right on the front page, under your name is CC'ed to your clerk, to Mr. Cutini and to Ms. Vicente, not on the fax page but by e-mail. You will see right there your name, and right under it, to Mr. Cutini.

THE COURT: I don't accept letters, period.

MR. BROWN: You would suggest that the government ought to want to settle this before the hearing, I thought you suggested that. So I wanted you to know we had tried. But I absolutely did not communicate to you without them. They have that letter by e-mail.

THE COURT: They don't know you communicated it to me. Don't ever do that. Ever. It violates every rule in the book.

Also, I don't want to get anything.

MR. BROWN: Just to make sure on record, Your Honor, they did receive a copy by e-mail, I'm sure they did because it is right there.

THE COURT: Is that –

MR. CUTINI: Yes, we did receive a copy of

the letter by e-mail but we do object that they said they submitted settlement discussions.

THE COURT: I agree. I don’t want settlement discussions to me. There is nothing that can come to me. First of all, I only accept pleadings. If you want me to do something, you file a motion. The law is very clear that I'm not here to settle. I cannot get intimately involved in a settlement. I can send you to somebody.

But to in some fashion, give me information about settlement by fax is to me is rather extraordinary, if not verging on unethical. I can't file that on ECF. I don't want to receive anything that can't go into ECF other than letters written on behalf of defendants at sentencing. That's the only kind of information that I would ever accept that I -- and I don't feel it is proper to put settlement stuff in the public record. So you can't avoid the public record by sending me little faxes without even telling them.

If they agreed to send me that for some reason, but that's not helpful. I have to decide this case. To in some fashion, perhaps color my view or give me background information that is not subject to their dispute, please, that's totally unacceptable and

not ethical, in my view.

MR. BROWN: I apologize, Your Honor.

THE COURT: Is there some schedule that you can arrive at between now and Tuesday to move this along or to go to settlement? I'll send you to a magistrate judge or a mediator immediately. But we're looking for a schedule. You can give me an administrative record to justify 32 years.

But I guarantee you that I will move quickly if need be. You'll have to break your back coming up with the administrative record it seems to me. How are you ever going to put together 32 years of delay to justify it. You may actually, I understand it is a very highly disputed issue. But you could say the time has come.

MR. CUTINI: We can discuss a schedule with Mr. Brown and submit it to the Court.

THE COURT: You'll have to understand the schedule. The schedule for what?

MR. CUTINI: I'm not sure, I guess submitting the administrative record.

THE COURT: I would like you to get together with some kind of mediator type and come up with a schedule for the FDA to do something. You have a duty to act. It is only a question of when. I don't much

see the purpose in litigating whether or not you do it in four months or five, seven or -- you can come up with an agreement and a consent decree and do it. And you won't have to file an administrative record and have somebody rule that it will take five months to rule, say you are going to have pleadings. The law is clear on what is unreasonable delay, these factors. You'll have all these pleadings. Then, you could land up with an order to act at the end of it.

I think that when the public safety is at issue that you shouldn't be taking this position. Your client should rethink it. They should do what the law requires. Nobody says how they're supposed to act or what they're supposed to do. They're supposed to just do it. At that point, they can challenge what decision under proper procedures.

So there are one or two things. Yes, we'll have a schedule. You'll get this administrative record in, in your pleadings real quick, because we're on an expedited schedule. Or alternatively, you'll come up with the very thing that they're trying to do is have some kind of timetable for your client to meet its obligations to the public. Their obligations may be to continue the classification as two. I'm never going to rule on that, until some classification,

somebody may have to rule on that later on. But that's not the issue. I think that the client, who is the FDA lawyer?

MR. SENGER: Jeff Senger for the FDA, Your Honor.

THE COURT: I don't understand your client. They have had a lot of time to mull this issue over. Maybe the science is getting better. But they could issue a ruling. Do they have to propose a rule or they have one out there now?

MR. SENGER: The proposed rule that was issued and we just reopened comment on it several weeks ago.

THE COURT: When is that comment period over?

MR. SENGER: I believe it is 60 days or 90 days.

THE COURT: When is that over?

MS. SENGER: July 28.

THE COURT: Then how long would it take you to issue your, make a final rule? The final rule then goes out, what is the usual law, procedure?

MR. SENGER: It is a complicated thing. The last time we did this, Your Honor.

THE COURT: But we're not going to be guided about what you did last time. That's the point here.

That's the whole point, here. You don't have that leisure.

MR. SENGER: Yes, Your Honor. Very well. We are committed to moving this forward as quickly as we can, consistent with the public health issues and the enormous amount of public scrutiny and the practical consequences that are involved.

The last time we went forward on this was 2006. Two years ago, we received about 2,500 comments which is indicative of the complexity of the issue, the enormous public interests, the public policy issues and scientific issues involved. We've had multiple advisory committees on it. We need to get it right. We need to be careful. We need to consider all of the comments we received.

It is difficult to predict with certainty what we will hear in response to our latest reopening, which asked a number of questions on the costs of different options, the alternative if it is not dental Mercury amalgams is it composite amalgams, other types of substance. What are the practical consequences of that? Are those safe? Are those less safe, are they more safe? Do they cost more? What are the effects on people in different incomes?

THE COURT: Let's be frank, sir, on a blank

slate here. You've been grappling with the problem for years. So you are going to get comments, and you may get another 2,500. I suggest that a lot of them will be similar to the ones you've said before. You have not the slightest clue and are unwilling to get your agency to say we're going wrap this up. Is that what I hear?

MR. SENGER: No, absolutely not, Your Honor. We're moving forward as quickly as possible. We appreciate the significance of the issues. We appreciate Your Honor's comments about this has been quite a bit of time, and there have been a number of reasons that are responsible for that. And believe me, Your Honor, we have raised this to the highest levels within the Executive Branch.

THE COURT: Who is the highest level within the agency on this particular issue?

MR. SENGER: I don't know that there is a specific person. The process requires clearance by the Department of Health and Human Services, and then, by the Office of Management and Budget. For the government to issue something like this requires clearance from among all the agencies. Everyone gets an opportunity to weigh in on a situation such as this. We're moving as quickly as we can. I

appreciate the Court's comments.

THE COURT: You have two choices here. You can litigate it. If you loose, you are going to have to do it overnight, this is silly. Or you come up with a schedule. This is government at its worst. Really, sir, yes, you have to consider all the things. But you can't keep saying that for 30 years or since the ’80s.

You inadvertently did not classify it in the first instance. So, you are already on quicksand. That was in the ’80. I am suggesting to you that you cannot continue to say what you are saying consistent with the rule of 706-1. It is just not, it is government jargon. I know you are trying to help the public interest. I know you have to consider all these things. But you can't just keep saying it.

At some point, the people who are in this agency have to step up and make a decision. You get the sense that they can't do it for whatever number of reasons they have their theories. But I'm not going to engage in that.

I want you to come back here next week. I want a schedule. I want the FDA to figure this out. If not, I am going to decide it on the pleadings before Labor Day. So, either way, you can do it on

your own terms in consultation with the plaintiff.

I've had dozens of EPA cases, that's failure to act, and clean air, other environmental harms where the agency has stepped up to do what they're supposed to.

Sometimes we had to give a little on the schedule that they agreed to because there was one component that had to be by law heard from. I understand that. But if you can't get your agency to do what they're legally required to do, and nobody is telling them what the answer is, we're just saying, get off it now.

There is a potential public safety issue to be resolved. If you feel, after all your consideration of 40 million comments, that you are unable to do it, then you'll say, we're going to keep it where it is. We don't have the smarts to figure it out. Nobody can. That's our decision. You'll put it in better language than that.

It will come by way of an arbitrating capricious claim at that point or whatever. You can’t do what you’re doing. You can’t keep saying it needs to be studied more and more and more. And we the agency are unable, unwilling or cannot, we’re not capable of it or we have too many conflicting points

of view represented because we're beholding to this agency or this constituency. I don't' know what your problem is.

But it isn't to say well, we need more comments, more time, more agency input, more constituency input. You went through it 2002. You've reopened it now, 90 days. So we know the comment period closes. So, your schedule kicks off then.

So we'll be back here. If you can't settle it yourselves, with a schedule agreed to, I will impose a litigation schedule that the government, if they can't get the administrative record together on time, according to whatever schedule I put together, too bad, you won't be able to rely on it. You are entitled to have the Court consider whether your delay is unreasonable. But it's hard to see at the end of the day, how 32 years, it has sort of a presumptive ring to it. Don't you think?

Maybe you'll be right, maybe the product is not unsafe. But why can't you decide it. Doesn't the public have the right to a decision by the experts who have the information?

So, we will be back. I suggest you think reasonably. He has the comment period. It is already there. You can't stop that.

So, I'm ordering you to, if you need a mediator or help on this, let me know, but we're coming back. I'd like you to stand up and say that you've come up with the following schedule, your agency will live with it and we'll do it, and make a decision. Like they're required by law to do. If you can't do that and you want to stand up and say what you just said again, I will do what I have to do to move the case along.

The motion to dismiss is denied. The motion for P.I. is denied. We'll go on an expedited basis.

By Wednesday 21, you will have had enough time to talk to plaintiff's counsel and come up with a proposed schedule that the FDA will live with. It is not going to do you any good to make sure that they don't do it right, because the dentists will come in here and say well, they didn't do it right.

MR. CUTINI: That's right.

THE COURT: So, don't cut off your nose to spite yourself. Because it is a procedural issue, don't forget. It's not whether you have the better merits case on harm. I want you to focus on the right issue, please, sir. They can lose here and the dentists could win say if that's who your opponents are. I don't know who your opponents are.

Assuming that they don't come up with a reason carefully considered opinion, whether you like the bottom line or not, you don't want it to be subject to attack for procedural inadequacies. So what you want is a timetable here that is going to produce their best analysis. Whatever it is. And that at least procedurally, it will be not subject to attack. Substantively, it could well be as arbitrary and capricious. That is something else. Okay.

MR. BROWN: Your Honor, I am out of the country next week on my schedule. I don’t know if we could do this the week after.

THE COURT: No, not very well. Let’s see. Don't talk to me about delay then. The 29th we could do it or the 30th. I would prefer the 29th I'm not here Tuesday and Wednesday. But if you are out of the country next week, who is going to talk to them? That's what I wonder. Can you communicate with them, the other side?

MR. BROWN: Yes, absolutely.

THE COURT: Even though you are not here?

Is it, Sanger. S. A. N.?

MR. SENGER: That’s with an A., Your Honor, S. E. N. G. E. R.

We are, the Court has suggested mediation.

THE COURT: No, no, I want to see whether you can't step forward and do what the government is supposed to do, come up with an agreement with the other side. I will then, if you can't, I'll put you on a parallel track of both mediation and litigation.

MR. SENGER: I suspect mediation could be helpful here, Your Honor.

THE COURT: Call Facciola, if he is not physically here that's a problem.

Why can't the government come up with something without help?

MR. SENGER: Your Honor, respectfully, we are willing to accept the Court's earlier suggestion of the possibility of mediation and to consult with plaintiff's counsel on that and proceed. It may be helpful in the remedy the Court is seeking.

THE COURT: I could do this in 10 minutes. I have to tell you, I'm disappointed that the government doesn't see the public interest at issue.

MR. BROWN: Your Honor, could I ask, does that mean the government will not give us a schedule? Even now, they aren't even going to go back and ask the commissioner for a schedule. Is that what they're saying here?

THE COURT: I don't know. But that's all

right. I can take care of that.

(There was a pause in the proceedings.)

THE COURT: Okay. Counsel, your going out of the country makes things very difficult. But the magistrate judge is available. I will refer it to Magistrate Judge Facciola to see if he can't help you come up with a schedule. Remarkably disappointing that people can't work things like this out.

I suggest you try to do it yourselves. Otherwise, you can go the 23rd at 2:00, the 27th at 2:00. I want a schedule. If you can't reach one, you only have until either the 29th, 30th or 2nd.

At that point in time, I will impose my litigation schedule. So it is up to you.

Are you, when are you able to sit down with a mediator?

MR. BROWN: I can sit down on the 27th.

THE COURT: 2:00.

MR. BROWN: That's fine, Your Honor.

THE COURT: Defense counsel?

MR. CUTINI: Yes.

THE COURT: All right. I want you to go down to the Magistrate Judge forthwith from here. I will do the referral for settlement.

Tell them that you will take the 27th at 2:00.

Before that though, I would think that you would, the government would come up with a proposal. You are in the situation which you have a better sense than they do, that you can both live with and we call it expedited. Not your usual 32-year schedule. We're now on a short fuse. If you can't prove your case then you get the fuse any way. So why don't you use this opportunity to exercise some discretion regarding your own schedule.

Then, we will be back here on the 9th. I'm giving the Magistrate Judge until the 9th to figure out whether, no, the 2nd, the 2nd, is fine. June 2 in the afternoon. At that point in time either you have come up with a stipulation basically settling this matter because you have agreed to a schedule for when they're going to act. That is the end of the lawsuit. That's all there is to it. That's what settles the lawsuit. If you don't, we'll have a very quick schedule with the paper. And I'll decide whether your delay in acting --

On the 2nd, if you are having any trouble Mr. Senger,

MR. SENGER: Yes, Your Honor.

THE COURT: The highest level ought to come here with you because I'll talk to them. If you need

somebody to, for the Court to convince, I will be happy to convince somebody to buy into a reasonable schedule that you and the plaintiffs have worked out. I don't know who the person I, who is the decision-maker here. Who is the head of the FDA now?

MR. CUTINI: Andrew von Eschenbach.

THE COURT: If you think it is necessary, I can always invite him to attend.

Okay. We will be back either having settled the matter by 2:30 on the 2nd of June, or we will get going in litigation. Okay. The motion for P.I. is denied.

The parties are required to go down now to Magistrate Judge Facciola to confirm that appointment. Settlement discussions are going to start now.

No more letters or faxes to the Court.

MR. BROWN: Okay, Your Honor. I apologize for doing that.

THE COURT: I feel as though anything like that, I have to report. Okay.

Thank you. Have a good day. We'll be back at 2: 30 on the 2nd. Hopefully, you will have solved this case. Be reasonable. It’s not going to do you any good to cut off your nose here. Thank you.

MR. BROWN: Thank you, Your Honor.

MR. CUTINI: Thank you, Your Honor.

(Whereupon, at 11:22 A.M., the hearing concluded.)

CERTIFICATE OF REPORTER

I, Lisa Walker Griffith, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

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Lisa Walker Griffith, RPR Date