EXHIBIT B

TO THE THIRD DECLARATION OF JENNIFER A. SORENSON

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NATURAL RESOURCES DEFENSE COUNCIL, INC., CENTER FOR SCIENCE IN THE PUBLIC INTEREST, FOOD ANIMAL CONCERNS TRUST, PUBLIC CITIZEN, INC., UNION OF CONCERNED SCIENTISTS, INC.,

Plaintiffs,

v. 11 CV 3562 (THK)

UNITED STATES FOOD and DRUG ADMINISTRATION, MARGARET HAMBURG, CENTER FOR VETERINARY MEDICINE, BERNADETTE DUNHAM, UNITED STATES DEPARTMENT of HEALTH and HUMAN SERVICES, KATHLEEN SEBELIUS,

Defendants.

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New York, N.Y.
February 23, 2012
3:15 p.m.

Before:

HON. THEODORE H. KATZ,

Magistrate Judge

APPEARANCES

NATURAL RESOURCES DEFENSE COUNCIL
Attorneys for Plaintiffs
BY: JENNIFER SORENSON
MITCHELL S. BERNARD

UNITED STATES DEPARTMENT OF JUSTICE
Attorneys for Defendants
BY: AMY A. BARCELO

ALSO PRESENT
THOMAS COSGROVE - FDA Associate Chief Counsel

(In open court)
THE COURT: Do you want to state your names?
MS. BARCELO: Good afternoon, your Honor. Amy Barcelo for the defendants and Tom Cosgrove of the FDA.
THE COURT: Hello.
MS. SORENSON: I'm Jennifer Sorenson representing the plaintiffs.
THE COURT: Hi, Ms. Sorenson.
MR. BERNARD: Mitchell Bernard for the plaintiffs.
THE COURT: Hi. Have a seat, everybody.
You requested oral argument, Ms. Sorenson, are you going to be handling it?
MS. SORENSON: Yes.
THE COURT: Want to begin?
MS. SORENSON: Your Honor, FDA pulled the trigger when it made findings in 1977 that penicillin and tetracyclines in animal feed are not shown safe to be for human health. Those findings set in motion a statutorily mandated process for withdrawing approval of that drug uses.
The first step in that process was issuing notices of opportunity for hearing. Now, under the press of litigation, FDA has withdrawn the notices, but that doesn't change the fact that the trigger has been pulled.
FDA's position on the science has only gotten stronger, but FDA has veered away from the statutory process

because it would prefer to address this acknowledged danger to human health through voluntary measures. That's not what the Food and Drug Act commands.

Plaintiffs ask the Court to restore the statutory process by ordering the FDA complete withdrawal proceedings promptly for these drug uses.

THE COURT: I know this issue isn't before me on this motion, but are you saying that the FDA does not have discretion as to the remedy?

MS. SORENSON: No, your Honor, FDA does not. FDA has to conduct these withdrawal proceedings that are required by the statute because it has made these findings that penicillin and tetracyclines are not shown to be safe for human health.

Plaintiffs are not asking this Court to prejudge the outcome of the hearing that the FDA holds, if the agency holds a hearing, but the agency does have to complete the process, and that's what plaintiffs asking this Court to order.

THE COURT: These findings were made more than 30 years ago. Did the FDA have discretion to amend the findings?

MS. SORENSON: Yes, your Honor. FDA could change its view on the findings if it addressed the science and revised its view of the scientific evidence. The agency hasn't done that.

Instead, over the years it has continued to reinforce its position that these drug uses present a danger to human

health. It did that in 2010 when it issued its draft guidance. It spent ten pages summarizing 40 years' worth of science on this issue and concluding that these drug uses are not in the interest of protecting and promoting the public health. In the government's responses in this litigation, the government has continued to reinforce its conclusion that these drug uses are dangerous. It has never moved off of the findings nor would it have the scientific justification for doing so.

Your Honor, plaintiff's view of the statute, which is that it requires FDA to conduct these withdrawal proceedings, having made the findings that the drugs aren't shown to be safe, is the same understanding of the statute that FDA itself has adopted and put into a regulation that has force of law. That regulation is 21 CFR 514.115. It says the Commissioner "shall afford an opportunity for a hearing on a proposal to withdraw approval of an animal drug if he finds that new evidence shows that the drug is not shown to be safe."

That's precisely what happened here. The government's position now that only a finding after a hearing requires it to do anything is a new position that it is advancing for the first time in this litigation, and it is not deserving of this Court's deference.

THE COURT: They argue though that they have historically interpreted that differently than what it actually says.

MS. SORENSON: Your Honor should reject that argument for two reasons: First of all, the regulation is clear on its face, which the government acknowledged in its brief. It said on its face, this regulation appears to predicate the issuance of a notice of opportunity for hearing on a finding that a drug is not shown to be safe. And the Supreme Court has held that when a regulation is clear on its face, then the Court shouldn't defer to the government's contrary interpretation of the regulation.

Second of all, FDA's litigation position is contrary to its own historical practice. It has consistently initiated withdrawal proceedings on finding that a drug is not shown to be safe. That's clear in the adjudications that FDA cites in its briefs. So there is really no evidence that the agency has presented that it has any practice that's contrary to the position that its own regulation sets out.

THE COURT: The government tries to create a distinction between a preliminary finding and a final finding. Does the statute allow for that?

MS. SORENSON: No, your Honor. The statute doesn't make any distinction between a finding triggering the obligation to hold withdrawal proceedings and a final finding. FDA's only support for that argument is these administrative adjudications where the government mentions that its interpretation of the not-shown-to-be-safe standard is that

there are serious questions about the safety of the drug. FDA argues in its brief that these are two different standards, but the adjudication is made clear that they are the same standard. Once FDA finds that a drug is not shown to be safe, it is required to conduct withdrawal proceedings.

THE COURT: So, if it then proceeds with a hearing, presumably it could take evidence that might cause it to alter its conclusion, correct?

MS. SORENSON: Correct, but it has to hold a hearing, your Honor, because the structure of the statute is to require drug sponsors to carry the burden of showing that a drug is safe. So, once FDA has concluded that a drug is not shown to be safe, the drug sponsor then has an opportunity to come forward and show that the drug is safe. FDA could decide in a hearing that the drug sponsor had carried its burden, but it has to require the drug sponsor to show that the drug is not safe. It can't say a drug is not safe and then leave it on the market for decades without ever requiring the drug sponsor to come forward and prove safety.

Your Honor, the government argues for the first time in its reply brief that the action that plaintiffs seek is not a discrete agency action. The Supreme Court has made clear in Norton v. Southern Utah Wilderness Alliance that an agency adjudication is a discrete agency action and that the discrete action can involve multiple steps, and it can be an action with

an uncertain outcome, but that doesn't mean that it's not a discrete agency action.

THE COURT: So what is the discrete action you are asking me to order them to conduct or to do?

MS. SORENSON: The discrete action is to conduct this adjudication that may result in an order withdrawing approval for these drug uses.

THE COURT: To do that, would I have to direct the FDA to reinstate the notices?

MS. SORENSON: FDA would have to issue new notices of opportunity for hearing now that it's withdrawn them, and because the science since 1977, as the agency has acknowledged, has grown even stronger in support of the agency's conclusion that these drug uses are not shown to be safe. So the agency has to give the drug sponsors notice that it will be relying on this new science in addition to the science as of 1977.

But that shouldn't be any significant burden for the agency because FDA has been continually reviewing the science on this issue. As recently as 2010, it devoted ten pages on a review of the science and its draft guidance, and it also in the early 2000s conducted a risk analysis on the use of these drugs and asked drug sponsors to give it more information. So updating the notices shouldn't be a significant burden.

THE COURT: So if they are merely directed to hold the hearings, theoretically they do also have discretion as to what

steps to take as a predicate to the hearings? I guess they'd have to have a notice.

MS. SORENSON: Right. FDA's own regulation says that if the agency finds that a drug is not shown to be safe, it has to issue a notice of opportunity for hearing on a proposal to withdraw approval of the drug, and then the hearing procedures are set out in FDA's regulations. There is a hearing officer who will have discretion over how to schedule and conduct the hearing but the broad outlines of the procedure are set out in regulation.

THE COURT: You're saying by simply withdrawing the notice, that doesn't mean they withdrew the conclusion that it was unsafe.

MS. SORENSON: Correct, your Honor. FDA didn't withdraw its scientific findings that triggered the notices. Those findings had a consequence under the statute, and FDA can't undo that consequence simply by pulling the notices away.

The agency has an enforceable duty under the statute to act on its scientific findings. And there are cases where courts ordered agencies to act on their scientific findings. We cited two of them in our opening brief: NRDC v. Train and American Public Health Association v. Veneman.

One wonders why anyone would have bothered if the agency could have mooted the whole business by just getting rid of its findings without changing its position on the science.

THE COURT: Theoretically, they are in the process of implementing these voluntary guidelines, I guess, or maybe they've been issued already, do you know?
MS. SORENSON: They're draft, your Honor. They haven't been finalized.
THE COURT: So, if they had issued these voluntary guidelines ten years ago and there was compliance with those guidelines, could that have affected the validity of the initial finding?
MS. SORENSON: Only if FDA had decided based on that compliance that the risk had changed and the agency no longer viewed these drug uses as not shown to be safe for human health. But as long as FDA hasn't moved off of those findings, then it has a statutory duty to conduct withdrawal proceedings, and the statute doesn't give it an alternative option of addressing that safety problem through voluntary measures.
THE COURT: I know this is couple of steps down the line, but you're saying once they hold that hearing, if they don't alter the conclusion that it hasn't been shown to be safe, the only option is to withdraw it, not to condition it -- they don't have the discretion to condition the use in certain ways?
MS. SORENSON: No, your Honor. The statute says that they must withdraw approval of an animal drug if they find after notice of opportunity --

THE COURT: So they really have no discretion as to remedy.
MS. SORENSON: No, they don't. This is the route that Congress has chosen to ensure that animal drugs are safe for human health. FDA could then potentially re-approve some drug uses with conditions, but at this point, once it's made a finding that drug uses are not shown to be safe, it has to withdraw its approval for them.
THE COURT: OK. Anything else you want to bring to my attention?
MS. SORENSON: Your Honor, as far as a deadline for taking this action, plaintiffs believe that a deadline is very important if your Honor grants plaintiff's motion for summary judgment because this is a serious danger to human health. We're talking about people getting sick and antibiotics not working, and the agency has delayed for over three decades in acting on this.
Plaintiffs would recommend that the Court order postjudgment briefing on the deadline and give both parties an opportunity to weigh in, and then your Honor could decide on updating deadlines for taking this action.
THE COURT: Thank you.
MS. SORENSON: Thank you.
THE COURT: Go ahead, Ms. Barcelo.
MS. BARCELO: Good afternoon. The decision by a

subsidiary bureau of FDA to propose the withdrawal of two classes of antibiotics 34 years ago cannot form the basis for this Court to order FDA to pursue such withdrawals today.

That is particularly the case because in December of 2011, FDA withdrew those 34-year-old proposals. Moreover, before their withdrawal, those 34-year-old proposals were so outdated and based on such a stale description of the science surrounding antimicrobial resistance and use of antibiotics in livestock that they could not possibly form the basis for FDA to move forward with the withdrawals it proposed 34 years ago.

THE COURT: But the notice got stale because of the agency's own inaction. Did the findings become less valid or did they get stronger?

MS. BARCELO: That issue is not before the Court right now. I'm not sure that I understand --

THE COURT: You're saying no matter what the finding about safety is, as long as they withdraw the notice, FDA has no obligation.

MS. BARCELO: That is the law. Under the regulation that plaintiffs rely on so heavily, the 514. --

THE COURT: Yes.

MS. BARCELO: 514.115(b) only requires that the commissioner afford an opportunity for a hearing on a proposal -- excuse me -- hold an opportunity for hearing on a withdrawal where that withdrawal is proposed. That there is no

longer an outstanding FDA withdrawal of a proposal --
THE COURT: So you mean because the commissioner failed to follow the procedures it's supposed to follow under the regs, it now doesn't have to do anything.
You said only if they have a hearing. They issued a notice; they didn't have a hearing. So they can defeat the purpose by just taking no action. Wouldn't that be a violation of their own reg?
MS. BARCELO: It wouldn't, your Honor, for the additional reason that there is no finding that triggers a statutory duty. In addition, that is the underlying --
THE COURT: Wait. In order to have the notice, they had to have been applied, isn't that correct?
MS. BARCELO: There had to be the BVM's decision to issue an NOH, which, yes, the regulation does use the word finding to describe it.
THE COURT: You're not saying the BVM was acting ultra vires, are you?
MS. BARCELO: Not at all, your Honor. BVM was certainly delegated the authority to issue the NOH. The very moment, however, that the drug companies and drug sponsors requested a hearing on that proposed notice, BVM was divested of its authority to move forward and no longer was delegated the authority to do anything, hold a hearing, do anything at all.

THE COURT: No, but the agency had to hold a hearing, didn't it?
MS. BARCELO: The regulation contemplated holding a hearing, which was never held for a number of reasons, and now we are in the position where there is no more proposed withdrawal. While the regulation talks about a finding, that finding that formed the basis for BVM's decision to issue the NOH is different than the finding that the statute actually talks about because the statutes's finding could only happen after those procedural rights have been fulfilled. Obviously, something needed to start process.
THE COURT: Yes.
MS. BARCELO: The regulation uses the word finding to talk about that.
THE COURT: Yes.
MS. BARCELO: That finding, however, was no more than the equivalent to a complaint in a civil case. It was BVM saying that we believe we have the evidence to support this withdrawal. That is all that they had authority to do. They could no longer move forward as soon as the hearings were requested, and they -- they could have moved forward as soon as the hearings were requested. Here, the fact is --
THE COURT: What would happen normally once a hearing is requested after a notice?
MS. BARCELO: Normally a hearing would be held.

THE COURT: OK.
MS. BARCELO: In this case, hearings weren't held for a number of different reasons that are all historical and date back to the Seventies and the Eighties and the whole history of--
THE COURT: And none of the reasons was that the agency came to the conclusion that whether you call it preliminary, final, or whatever, that the use of these drugs was safe.
MS. BARCELO: The agency --
THE COURT: Never changed that conclusion. Didn't the agency reiterate it several times?
MS. BARCELO: The agency has continually expressed concern about this issue and has moved forward in a path to address this issue which is different than the path that 34 years ago it originally expected would be the path. It has since the early -- which is, I think, all the more reason that this antiquated 34-year-old -- nobody thought for the last 30 years or, so nobody thought this was the way it was going to be done, this withdrawal procedure because it has been so stale for so long. Throughout the Seventies, Eighties and Nineties, there was continual research that was done that continued to raise more uncertainty in this area.
THE COURT: Did it raise more uncertainty or did it strengthen the original conclusion?

MS. BARCELO: There was plenty of indirect evidence that there was cause for public health concern. All of these things -- there was concern, and FDA has moved forward and acted on those concerns in a way that is different than the way that they proposed in 1977. The real issue that is before the Court on this motion, there are additionally -- there will be further briefing on FDA's decision to deny the citizen petitions, and I think the Court's concerns will probably be more fully developed there because that's the real heart of -- that is what FDA is doing now to go forward.

The only issue here in this case is what the FDA said 34 years ago can compel them to move forward on withdrawal proceeding even though it has withdrawn those withdrawal proceedings, and BVM had no authority to move forward whatsoever with the withdrawal as soon as the drug sponsor requested.

THE COURT: So, when the FDA is made aware through scientific studies that it finds persuasive, at least initially, that there is a threat to public safety, you're saying under the statute they have no obligation at that point?

MS. BARCELO: Their regulations do contemplate moving forward, and I think another -- something that might help sort of clarify the difference between the claims that plaintiffs are making here and I think perhaps the type of claim that your Honor is discussing, I think it would have been different if

they had been making an unreasonable delay claim perhaps which would say you need to move forward and complete the proceedings, and there would be obviously lots of different legal issues there and arguments there, and we are not in that world. And that would be, I think, does the government have the obligation to move forward. But the only thing that they are asking for now -- now, I think today for the first time they have explicitly requested a hearing. They have been sort of couching what the relief is that they're requesting in different ways, I suspect, to get around the problems with the type of relief that they're asking for, but the only thing they're here for today is the specific request now to compel the government to hold hearings.

That is not relief that they're entitled to. First, because it's not required where the proposal has been withdrawn. And, second, because even that isn't actually what -- that isn't even the next step. The next step, as everyone acknowledges, would be the updates, would be, as the Court recognized, a requirement that we would have to issue an entirely new NOH and do updates of the last 34 years of scientific research to be able to do that. That would be the first step in the process.

Then, keeping in mind also that while we can talk generally about the penicillin and tetracycline classes of drugs, it is actually approximately 73 drug products that would

actually be at issue here. So it would require scientific updates for all 73 of those products, which would be a substantial undertaking, particularly to put the drug sponsors and drug companies on notice of the basis for a proposed withdrawal. It would then --

THE COURT: I'm not moving on to that. The original notices had to do with tetracycline and penicillin. Why is it now 70 others?

MS. BARCELO: Because my understanding is penicillin and tetracyclines are used in -- it's the animal drug products themselves; it's not just one type of drug product and another type of drug product. They are used in a variety of types of drug products, and there are classes of drugs. My scientific knowledge of all of this is a little limited, but that's my general -- we are talking about 73 different products.

THE COURT: Right.

MS. BARCELO: So it would be a variable process to update them and then publish --

THE COURT: When the FDA began considering -- I don't know whether they actually took action, voluntary action, but they did that on the basis of updated findings, didn't they?

MS. BARCELO: They have certainly stayed on top of this for the last 34 years, and they made a number of statements, and there is a lot out there on FDA's view on this, but the precise scientific -- for each one of these 73 classes

and their resources out there, that is no small undertaking because the drug sponsors and drug companies would be -- the point of it all would be to put them on notice of what --

THE COURT: So that goes more to how much time they should have to re-issue them.

MS. BARCELO: That goes to whether what plaintiffs are asking for is really discrete relief or not. This update, then publication, then notice of hearings, then holding the hearings is this really substantial programmatic attack and FDA's entire regulation of antibiotics and animal feed. And I also don't think it's fair to say that the first time the government made this programmatic attack argument was in our reply brief.

Plaintiffs, as I suggested earlier, have sort of continually been changing what the relief is that they're requesting because they aren't really entitled to what it is that they're requesting. They initially in their opening brief said that they were requesting withdrawals in a year, withdrawals of these drugs in a year. Once we in our opposition brief said you can't do that, you have to do hearings, there's a number of procedural rights that need to be protected.

THE COURT: Of which there's no dispute.

MS. BARCELO: There is no now dispute about that, which plaintiffs didn't originally acknowledge. Now we're in the world where they are admitting that they need these

scientific updates and publications of these hearings, and that is an extremely broad attack on FDA's entire regulation of antibiotics in animal feed, which is not the type of discrete action that their claim to compel agency action unlawfully withheld, but the only thing that would be allowed to would be discrete and required action.

THE COURT: Let's go back to the language of the actual basic statute. It does provide for some compulsory action by the FDA, doesn't it?

MS. BARCELO: It uses the word "shall."

THE COURT: Yes.

MS. BARCELO: Its use of the word shall is in connection with a finding by the secretary. It is plain from the language of the statute that that finding could only happen after the drug sponsors' procedural rights have been fulfilled because it doesn't have to happen after that. Not only does --

THE COURT: Well, I'm not show sure it's clear. Something has to happen after, but maybe the thing that happens after is the decision to withdraw or not to withdraw.

MS. BARCELO: That decision --

THE COURT: Not a new finding. I mean, I guess if it's a decision not to withdraw, they'd have to make a new finding, but as long as they may come forward and made a preliminary showing that it hasn't shown to be safe, the burden then falls upon the companies to demonstrate otherwise. Even

the notices say if you don't come forward and show anything, we're going to withdraw it. So what's the choice here? Isn't it a compulsory act?
MS. BARCELO: There are sort of two questions tied up in that. First, BVM has not made that preliminary showing yet. All that they've done is issue a complaint, a document on paper saying we think -- 34 years ago we think that we had enough to do it. They have not -- because the hearing hasn't been held, they have not made that showing, and that would be -- they said that they think they have enough evidence. They haven't made the showing.
THE COURT: Are you saying they didn't make a sufficient showing to issue the notice?
MS. BARCELO: I'm not saying that at all. They unquestionably did have sufficient showing to make the notice. The question I am getting at is what was the effect of that notice, and what did that notice really do. It was BVM stating its position that --
THE COURT: Either that the drug is unsafe or it hasn't been shown to be safe. It had to make one of those findings or both in order to issue the notice.
MS. BARCELO: The regulation talks about it as a finding. On the face of the NOH, it talks about it as a proposal to withdraw.
THE COURT: OK.

MS. BARCELO: This is all, I think, sort of a game of word choice and what we really need to be focusing on is what is the effect of each of these things.
THE COURT: But the FDA couldn't propose to withdraw unless it made that finding, correct?
MS. BARCELO: BVM made the finding.
THE COURT: Are you making a distinction between BVM and the FDA?
MS. BARCELO: I'm not -- the reason I am so focused on the fact it was BVM is because BVM had such limited authority here.
THE COURT: But it was delegated that authority, right?
MS. BARCELO: It was delegated that authority and nothing more.
THE COURT: To make a determination and issue a notice, OK; and it did that.
MS. BARCELO: That's correct.
THE COURT: OK.
MS. BARCELO: Yes.
THE COURT: So, are you saying the determination has no weight?
MS. BARCELO: Now, well, I'm not -- I'm not saying that at all. It has -- it is what it is. It's equivalent, as we've explained it and as the hearing procedures -- FDA's

regulations that explain the hearing procedures, it is the beginning of a process that has now been completed with the withdrawal of that proposal.

THE COURT: Didn't the commissioner actually endorse the preliminary finding, whether you call it preliminary or final?

MS. BARCELO: In the sense that the commissioner denied the drug sponsor's request to withdraw those proposals earlier back, I believe it was in 1983, the commissioner, the only -- so, the commissioner, yes, did say -- did endorse it in the sense that they denied the drug sponsor's request to withdraw that. The commissioner did not endorse it in the statutory sense of having made a finding at the end of the required procedural hearings.

THE COURT: I guess this agreement is whether the only thing that the commissioner is left to do is either to withdraw or not withdraw versus make a second finding about safety.

MS. BARCELO: Again, I think this is just a question of word choice. Even the plaintiffs describe in their brief, they say that the secretary has to make a determination at the end of these hearings. Whether that determination is the same thing as a finding, we all agree that these procedural rights would have to be fulfilled, and then at the end of that so BVM has a burden -- if this hearing had been held, BVM would have had a burden, and the drug sponsors would have had a contrary

burden, and at end somebody would have needed to to protect the drug sponsor's rights, make a determination or a finding or whatever it is you want to call it. The statute uses the word finding. But that is what has to happen in the end to protect the procedural rights of those drug sponsors and to say that, yes, that we can in the beginning whatever our position is without having heard all of the evidence is enough to trigger withdrawal is -- I don't think --

THE COURT: At that point though once the determination to propose withdrawal is made, then the burden is upon the companies to demonstrate that it's safe; and if they don't do it, as the notices say, if they don't come forward and -- if you don't ask for a hearing, if you don't come forward and do this, it's going to be withdrawn, right?

MS. BARCELO: It's like a default judgment, that's right, yes. If we had been in the world where no one came forward and said "we'd like a hearing," this would be different.

THE COURT: But they did request it.

MS. BARCELO: And it was granted.

THE COURT: So why weren't the hearings held?

MS. BARCELO: For a variety of -- for a variety of different reasons. Going back historically, we explained some of it. Congress -- there is a completely new issue of science at the time back when these proposals were initially put out

there. Congress got involved and said, "Could you please do more research." FDA wanted to do some more research on its own and commissioned a number of studies and looked into this a lot more, and at some point along the way after decades of research, FDA made this sort of inform internal decision we're not going to move forward with these now-old NOHs; we are going to move forward with this different regulatory path that FDA is now on.

THE COURT: Maybe you can clarify this. When I was looking back at the old notices, I think particularly with the tetracycline one, it looked like even before that notice issued, there was a real preliminary finding where the drug companies were given a chance to come forward with information, and they didn't. Isn't that true?

MS. BARCELO: There was, if I have my history right, there were in the early Seventies, right -- at some point in the Fifties, these drugs were approved; in the Sixties FDA became concerned; in the Seventies, a task force, if I have my dates right, I believe a task force was pulled together and did give -- did ask for more input from the drug sponsors.

THE COURT: And their failure to come forward with anything then led to the issuance of this notice, right?

MS. BARCELO: I am not sure that I have my history right on that. That sounds right to me, but I don't think that anybody is arguing that that sort of initial request for more

information from the drug sponsors was a finding that could trigger any obligation on behalf of --

THE COURT: Because I'm looking at it and it says the director finds that the holders of approved NADA's for subtherapeutic tetracycline use have failed to show that widespread subtherapeutic tetracycline use in animal feed is safe.

So that was actually -- they did get to do something preliminarily, and then they still issued the second notice, which I guess is the more formal process.

MS. BARCELO: It is this notice that is the notice of opportunity for a hearing, which is what the regulation talks about and what the statute talks about. And that notice that instituted this process, whatever was done before then this preliminary concern --

THE COURT: You're saying at this stage it's still preliminary.

MS. BARCELO: That was still -- yes, the 1977 was still preliminary and could not form the basis for withdrawal at all in the world that we're in --

THE COURT: Yes.

MS. BARCELO: -- where the sponsors requested hearing and those hearing -- the second they requested those hearings, BVM's authority was divested completely. The fact that those hearings were granted and everybody recognizes --

THE COURT: OK. So BVM is out of the picture, but the FDA is still in the picture. What's their obligation?
MS. BARCELO: Their obligation at this point standing here today because they -- I mean, for a number of reasons, it's -- with respect to these 34-year-old NOHs, they can't hold a hearing. There is no basis to order them to hold a hearing.
THE COURT: Because they didn't do anything for 37 years, but they have not withdrawn the finding that led to the notice.
MS. BARCELO: They've withdrawn the proposal to withdraw, and that is --
THE COURT: But the safety issue remains.
MS. BARCELO: The safety issue --
THE COURT: The public safety is still at risk.
MS. BARCELO: The FDA has concerns regarding public safety and is addressing them on another route using a different route --
THE COURT: But not because it found that these are safe or that the companies demonstrated that they can be safe.
MS. BARCELO: Those hearings -- right. Hearings in which those determinations were made have not been held, but, I mean, I think that this concern that I am hearing is probably better for the next round of briefing where plaintiffs are focused more on what FDA -- plaintiffs claim is a challenge to what FDA has done, rather than --

THE COURT: Yes, go ahead.
MS. BARCELO: -- which is, again, I think the difference would be the different types of actions that you can bring under EPA.
THE COURT: In this proceeding they're not asking for specific remedy on this motion.
MS. BARCELO: That's right.
THE COURT: They're asking that the FDA complete the process.
MS. BARCELO: Right. While their next claim is a challenge to FDA action, which has all sorts of other legal problems and questions --
THE COURT: Let me ask you something: If the court were to agree them and say, let's say, after hearing from both parties that within 18 months a new notice will issue and hearings must be held, would that sort of moot the other part of it?
MS. BARCELO: That would be for plaintiffs, I think, to -- we would have to think about what our arguments would be. I had not --
THE COURT: OK. Maybe ms. Sorenson will address that. I am assuming if this Court gave an imprimatur to what they are proposing here, which is go ahead with the hearings and then, you know, you have to make a decision to withdraw or not to withdraw, I guess until that happened, the FDA is free to do

whatever they want experimentally in terms of voluntary conduct. I don't know there would be a ban on it, as long as they were following what -- if I say the regulations require to do this, you know.

MS. BARCELO: Right. And I think -- well, of course I think that the regulations do not -- the regulations do not require FDA to move forward with the hearing nor does the statute require FDA to move forward with the hearing.

THE COURT: And that's because you think there has been no determination made that these drugs are either not safe or have not been proven to be safe.

MS. BARCELO: Well, it's because FDA withdrew the proposals, and if FDA -- it's hard for me to answer that question because we're not in the world where the NOHs are still outstanding.

THE COURT: Would it be a lot different case or more difficult case if the FDA had never drawn any conclusions about these drugs, then, you know, what the Court -- I mean, I guess there would be a different form of relief being requested if they thought that there was all this scientific evidence. But the agency did draw some conclusions. It inevitably withdraw those conclusions. We're not talking about the ultimate withdrawal decision. And it just seems to itself cited all the updated scientific evidence that gave greater strength to the initial conclusion.

So, I would be surprised to hear if anybody in the FDA would argue that they came to the conclusion that the use of these drugs is safe or has been proven to be, you know, not to be unsafe.

MS. BARCELO: That conclusion has not been reached because these hearings haven't been held. I do think -- maybe there would also be another government that the government would have if these NOHs have not been withdrawn, which they, of course, have.

THE COURT: OK.

MS. BARCELO: That the government's decision with respect to how to move forward on the NOHs was not subject to judicial review because it was committed to agency discretion by law. We aren't I don't think in that world because the NOHs have been withdrawn, and there is no basis to move forward with the hearing, and the findings -- and, additionally, the findings that FDA made cannot compel withdrawal or compel the completion of it --

THE COURT: We are sort of talk technically, but isn't their basic mission under the statute to protect public safety?

MS. BARCELO: That is their basic mission --

THE COURT: When they make a determination that the use of certain drugs had not been shown to be safe for humans, don't they have to do something.

MS. BARCELO: If that's the Court's concern, FDA

certainly is doing something. The question here is --
THE COURT: For 37 years they have been.
MS. BARCELO: They have been doing something. They have been doing research for decades.
THE COURT: OK. And strengthened their original view.
MS. BARCELO: And determined that the most effective way to go about addressing this issue is to go on the path that they are going on now: Issuing these draft guidance, issuing veterinary oversight, trying to work -- rather than incur the cost of these 73 hearings and scientific updates and all these sort of massive undertakings the plaintiffs would prefer, FDA has in its expertise and discretion determined that the route it is on is a better one. And that these -- that the best way to get this done as quickly and efficiently and in the public interest that this is -- that's what we have FDA for is to answer these -- their expertise of working with the drug sponsors and working with all of the industry they work with to figure out --
THE COURT: And what if they weren't doing it because of public interest? What if they were doing it because of political pressure?
MS. BARCELO: Well, they are doing it here. That is what I think -- they are doing it, and they have left open the possibility, they explicitly said and an NOH withdrawal -- they have left open the possibility for pursuing more formal

withdrawal proceedings if necessary. That is certainly still out there.
THE COURT: Right. I get that you've changed your position somewhat in the briefs too because are you conceding that there was a determination made about -- that there was a potential -- that they had not been shown to be safe?
MS. BARCELO: No. What we, I think, are all on the same page about is that BVM had authority to issue these NOHs in 1977, and that what those NOHs are whatever it's -- what those NOHs are is equivalent to complaint that starts a proceeding and says we would be able to -- it's BVM's position that they would be able to meet a burden that they may eventually need to meet if hearings were held. And it is nothing more than --
THE COURT: I mean, as you have readily conceded if the drug companies didn't request a hearing or come forward with anything, then the only thing that could follow would be the withdrawal once BVM did that.
MS. BARCELO: If we were in that world, that would be right.
THE COURT: So it's not exactly just a complaint.
MS. BARCELO: Well, I mean, a complaint, you can get a default judgment. If a defendant doesn't show up to defend --
THE COURT: It has to on its face state a valid claim for relief, and here it's based upon the agency making a

determination that it hasn't shown to be safe.
MS. BARCELO: Which is BVM's statement. I mean, once we get in -- maybe it's helpful to go at it this way: Once we get into the hearings, BVM and the drug sponsors would be adversaries in that hearing, and the commissioner would be the adjudicator.
So it would be BVM -- it really is similar to civil proceedings with BVM stating its case and then an evidential -- BVM having not at this point put on any evidence whatsoever or met any burden whatsoever. As soon as the hearing started, there would be a wall between BVM and the commissioner with the commissioner making the conclusion first whether BVM met its burden, and, second, whether the drug sponsors met their burden in response.
THE COURT: All the plaintiffs are asking is, so let that happen. Let the commissioner make the final decision.
MS. BARCELO: There is no basis at that point to compel -- not only would it be much more complex than it sounds, if you phrase it that way, all the different steps that would be required, but there is no statutory or regulatory basis to require that to happen.
THE COURT: They would have never been able to issue this notice if it was just a complaint. They based it upon many years of scientific study, did they not?
MS. BARCELO: They did base it on -- yes.

THE COURT: So it wasn't like, OK, here's the opening round of discovery. They said there have been these studies, we've reviewed these studies, we've accepted some, we don't accept others, but the ultimate conclusion is that it hasn't been shown to be safe. Now you show us otherwise.

MS. BARCELO: Well, we need to put on our burden to actually carry that. It could be -- I mean, you could hold a hearing and the commissioner could say, BVM, you've not -- you wrote it all down on paper, but when it was time to show your evidence, you've got nothing.

Another thing, I think --

THE COURT: Who is the hearing officer of these?

MS. BARCELO: The commissioner. It may be delegated from -- the commissioner may delegate the running hearings, but that's my understanding is that the commissioner is overseeing the hearings.

Another thing I think that -- one thing that might be an assumption that the Court is taking in our discussion and I just want to make sure I am clear on. This finding that the regulation talks about, the regulation using the word finding that is the decision to issue the NOH is different than the finding that the statute is talking about. They both use the word finds, but it is not the same finding, and that may be the fundamental thing that we haven't been talking about but that's very important to recognize

THE COURT: You're saying it's a lower standard.
MS. BARCELO: It's the preliminary finding that starts the process. The only finding that triggers any mandatory duty by FDA on the face of the statute is a finding that can only happen at the end of this hearing process after the drug sponsors have had their procedural rights fulfilled. And that is something that is consistent -- to the extent that the Court finds any ambiguity whatsoever in the language of the statute, that position -- this is how the process works. The BVM only has authority to issue the NOH, but not to withdraw approval where someone has requested hearings. All this sort of the procedure -- the effect of the NOH and the procedure that it sets in motion and the fact that it is not a final finding that requires any mandatory obligation on behalf of FDA is consistent throughout all of FDA's regulations, throughout the delegation of authority to BVM, throughout the hearing procedures, and to --
THE COURT: The only thing that is inconsistent is whether it's a different or lower standard. I mean, yes, there has to be a subsequent finding after a hearing, but, I mean, the plaintiff's position is the only finding to be made at that point is whether to withdraw approval.
MS. BARCELO: Which can only be based on a determination of the evidence.
THE COURT: OK. So let's assume that's the case, but

doesn't that process have to go forward? I mean, we are not talking about the ultimate outcome, but doesn't the commissioner have an obligation once it's noticed to make that determination?

MS. BARCELO: There is no statutory or regulatory basis to find that obligation, particularly where the statute on which plaintiffs rely so heavily only requires a hearing where there is a proposal for withdrawal, and there is no longer a proposal for withdrawal.

And FDA explained in its proposal for withdrawal the basis for its decision to withdraw, in part because the science was so old and stale, we all, I think, agree what was said 34 years ago couldn't actually be the basis to move forward with anything.

FDA has also stated its discretion -- its position that it has discretion to determine -- if it decided to reinstitute these proceedings, it would have discretion to determine which drugs to move forward with, which drugs not to move forward with.

Were the Court now to now today say 34 years later, you need to go forward with all 73 of them, that would, I think, be a problem in light of FDA's authority and discretion to determine what it's going to pursue and whatnot.

Then the third reason was that FDA, as we have been talking about, has pursued this different regulatory path to

accomplish what its regulatory goals are now which it has determined will be the most effective method for the time being and for the present to address this issue.

THE COURT: Again, are you able to say whether the substantive position of the FDA at this point has changed in terms of whether it has found that there is no question -- either that the use of these drugs is safe or it hasn't been shown to be safe?

MS. BARCELO: I think the only real question before this Court -- that, I think, is too general of a question for me to answer. What I can answer for you is whether there's been a finding within the purpose of the meaning of this statute that would require FDA to go forward, and that definitely FDA has not --

THE COURT: Because they withdraw that finding.

MS. BARCELO: Because BVM finding back in 1977 wasn't the finding that the statute talks about, and because they withdrew the NOH, so they are -- not only would it have been within FDA's discretion to determine whether to move forward with these NOHs or take some ultimate path which it has chosen, but also because FDA withdrew the NOHs, there's no statutory regulatory, nothing; no basis to compel FDA to move forward with this will initial step -- with any of the steps let alone this initial step of the massive scientific undertaking.

THE COURT: I'm a little confused about the

commissioner's role here. I know it came out of BVM, but didn't the commissioner put his imprimatur on that finding?
MS. BARCELO: In the informal sense of the decision not to withdraw the NOHs, that was not a decision that was made within the statutory are sense here of a finding after a hearing. So the commissioner at that point said we would rather have -- it was I think in 1983, five years after the NOHs were issued the commissioner said that -- the commissioner denied the drug sponsor's request to withdraw them in light of the fact that there was going to be additional scientific research out there.
That was the point back in the Seventies and Eighties after the NOHs were published, Congress requested additional research. FDA itself wanted to do additional research. The drug sponsor said if there is going to be additional research, withdraw the 1977 NOHs, and the commissioner said we would like to have these still outstanding. That was also not the finding within the meaning of the statute which could only happen after the drug sponsor's procedural rights were satisfied.
THE COURT: OK. Anything else you want to bring to my attention?
MS. BARCELO: I think that's it. Thank you, your Honor.
THE COURT: Thank you.
Ms. Sorenson.

MS. SORENSON: May I have one moment, your Honor to confer with counsel?
THE COURT: Sure.
(Pause)
MS. SORENSON: Your Honor, I'd like to start by clarifying the issue with the 73 drug products that the agency has been talking about. This action may involve 73 drug products, but it only involve three drugs, and all of those products contain those drugs. The issue is whether the drugs are not shown to be safe, not the drug products. The initial notices of opportunity for hearing covered three dozen drug products that contain those drugs, and the agency proposed to dispose of the determination on whether those drugs are shown to be safe in a single hearing because the safety -- the dangers to human health presented by all the drugs was the same. So, the government's contention that suddenly this is not a discrete action because it involves multiple drug products is simply false.
Second, your Honor is correct that in the Seventies, the commissioner was concerned about the safety of these drug uses and asked drug sponsors to come forward and give evidence to the agency that these drug uses were shown to be safe for human health. The drug sponsors did come forward with what they considered to be that evidence, and BVM examined and rejected that evidence and came to the conclusion that these

drugs were not shown to be safe.

The agency has no evidence for its distinction that it's a drawing between preliminary findings and final findings, and even if the agency were correct that the word finding in the statute and regulation is somehow different, FDA still has an obligation under its own regulation to conduct these proceedings in light of the findings that the agency has already made.

THE COURT: But you accept that post hearing some further determination has to be made?

MS. SORENSON: Of course, your Honor. That's the outcome of an agency adjudication. But unless the agency finds that the drug sponsors have carried their burden, it is required by the statute to withdraw approval for the drug uses.

Your Honor asked how a decision in favor of plaintiffs would affect the further briefing on plaintiff's third claim for relief.

If this Court were to order the agency to proceed with the penicillin and tetracycline withdrawal proceedings, then that would moot out that part of the third claim for relief, but the third claim for relief also covers other forms of antibiotics that are also used in livestock feed, so that part of the claim would still have to be briefed.

Finally, the government repeatedly says that it is on a -- it is pursuing a different path to addressing this danger

to human health, but the path the agency has to follow is set out by the statute. What plaintiffs are asking is for the Court to play its traditional role in returning the agency to the statutory path.

THE COURT: What were the plaintiffs doing for the last 37 years after these notices came out? Why was there never any prior proceeding to compel action?

MS. SORENSON: Your Honor, plaintiffs have advocated on this issue with FDA for years. They submitted citizen petitions 12 and six years ago to try to get the agency to act on these drugs. The agency ignored the petitions for all this time until plaintiffs brought a lawsuit. FDA continued to do research over the years that reinforced its findings that these drug uses are not shown to be safe. But then instead of taking action, it came out in 2010 with this draft guidance that promotes voluntary reform, and that lack of action on this critical issue is what compelled plaintiffs finally to bring a suit here.

THE COURT: So, do you agree though that the 1977 notice is outdated?

MS. SORENSON: Your Honor, I would like to point out that the only person who has ever used the word outdated is the agency's litigation counsel. In withdrawing the notices of opportunity for hearing in December, the agency didn't actually say the notices were out dated. What it said was that the body

of scientific evidence examining the effects of these drugs -- these drug uses on human health has expanded considerably over the years, and were the agency to withdraw approval now, we would have to supplement the notices to give the drug sponsors notice that the agency would be relying on the more recent science as well. But the agency never stepped off of its 1977 findings, and the agency itself, as opposed to litigation counsel, has never said those findings are in any way sale.

Plaintiffs agree that the notices would need to be updated to take account of the developing science which is now virtually a consensus throughout public health and governmental authorities that these drugs uses present a danger to human health, but that doesn't mean that the 1977 findings don't still have validity; they do.

THE COURT: Is it conceivable that in the 30-some-odd years, practices could have changed which that made the use of it less -- made it safer?

MS. SORENSON: Not given the facts of what's happening. The use of antibiotics in livestock has increased exponentially even since the Seventies and now constitutes 80 percent of the antibiotics used in the United States.

In that scenario -- public health authorities have come out stronger and stronger against that misuse and overuse of in livestock. The danger certainly hasn't lessened. HHS -- the director of Health and Human Services, FDA's parent agency,

has said that the weight of the evidence shows that this drug use has consequences for human health, and that there is little evidence to the contrary.

THE COURT: Again, I think your position was that the Court was inclined to entertain -- to accept your position, there should be further consideration of time frame?

MS. SORENSON: That's entirely within your Honor's discretion, but if your Honor seeks guidance on how long it should take the agency to conduct these withdrawal proceedings, then postjudgment briefing would be appropriate.

Thank you.

THE COURT: Anything else?

MS. BARCELO: If I may, just a few quick points.

I just want to be clear about one thing that I may have misspoken about earlier, which is, just to be clear, the regulation that we're talking about that everyone is focused on does not require FDA to necessarily move forward with the hearings once it's issued an NOH.

This is a classic example -- the decision -- as this has played out, it's a classic example of FDA's enforcement discretion, discretion to decide to move forward with NOHs as opposed to -- or to do what it has done, which is move forward with an alternate regulatory path of trying to see, first, if voluntary compliance will work, to save the expense -- the massive undertaking and the expense of the process that it

initially began in 1977. And this issue of whether FDA had the discretion to determine to take the alternate path instead of the path that it originally thought it was going to take, that discretion issue is what's going to be at issue in the next round of briefing.

So that the regulation here to be -- if I did say earlier, which I may have, that the regulation required us to move forward with those hearings, that was an incorrect statement by me; that FDA had the discretion to move forward or not to move forward. It exercised its discretion by not moving forward, but regardless of that, now that the proposals to withdraw have been withdrawn themselves, that's all the more reason that there's no basis for FDA to be compelled to move forward.

THE COURT: So you're saying that the regulation which talks about the commissioner shall notify in writing the holder, if he finds that experience or scientific data show that the drug is unsafe, you're saying he didn't -- the commissioner doesn't have to do that if he finds that --

MS. BARCELO: The NOH was -- I do think the NOH is what is contemplated by subpart B in 514.115, but whether or not after issuing that NOH, the commissioner needed to -- was there by compelled to move forward with the process is something that was within FDA's discretion, enforcement discretion not to do, and instead do what they did do, which is

take this alternate path and try voluntary compliance rather than requiring this issue again with the 73 products versus the three products, there would be 73 drug sponsors at issue here, each of whom would be required to have a hearing, so it could be that it would be fewer than 73 but more than three.

THE COURT: Would they be separate hearings?

MS. BARCELO: That is all something that would --

THE COURT: It's up to the commissioner to decide.

MS. BARCELO: Yes, that's something yet to be determined.

THE COURT: I mean, even if the commissioner uses this voluntary approach, ultimately is it going to have to go through that same complex process? How will it evaluate?

MS. BARCELO: That, again, is -- we are not in that world, and that is yet to be determined, and FDA has explicitly said that if this voluntary compliance doesn't work to save us ten years of -- however, I don't want to put a time frame out there, but however long these hearings would take and however millions of dollars of resources it would take up, FDA is trying its other voluntary compliance method first, and it's within its enforcement discretion to make that decision, and specifically the issue of whether it is in its enforcement discretion is what we're about to brief, so that those issues will be before the Court.

THE COURT: Well, I think though on this motion, the

plaintiff's position is, is once there was a finding, preliminary or otherwise that it wasn't shown to be safe, it didn't have discretion; it had to act.

MS. BARCELO: And there is no statutory or regulatory basis for that. There is no regulation or statute that says you can't, you know -- that says what they would like it to say; that you need to keep updating these -- you know, you need to hold the hearing immediately or you need to update your NOHs as science evolves and you need, you know, there's just -- there is nothing that --

THE COURT: So, under this statutory scheme if there is something that is found to be a clear threat to human health, and the commissioner just decides not to do anything about it, that's his discretion.

MS. BARCELO: If there -- I'm not sure what your Honor means by the word find. I mean, I think that's what this whole case is about. It's hard for me to --

THE COURT: But I think the record suggests that the commissioner has never withdrawn or stepped away from finding that these drugs have not been shown to be safe.

MS. BARCELO: It's never withdrawn or stepped away from its expression of concern on this issue, and it has also addressed its concern on that issue by doing something that's different than what 34 years ago it originally thought was the right path. It's changed -- as science has evolved and as the

word has evolved, and facts have evolved, the FDA has been working with drug sponsors and is very keyed into this issue, and what's happening over time has determined in its expertise that the way to pursue this is first through this voluntary compliance.

THE COURT: Theoretically, it could hold the hearings, and if the evidence didn't come forward to rebut the finding; say we are going to withdraw the approval except in conditions where the drugs are prescribed by a veterinarian. They could accommodate -- they have flexibility there, right?

MS. BARCELO: That would be a massive undertaking.

THE COURT: Why?

MS. BARCELO: The holding that the enrofloxacin withdrawal, which I think happened in 2005 and was just one drug, took five years and I cannot remember how many millions of dollars, but I think millions and millions. I think about five million dollars. And this was a much less -- I don't know much about enrofloxacin withdrawal, but this is an extremely substantial process that we're talking about here.

THE COURT: Are there any regs that specifically deal with what happens at a hearing?

MS. BARCELO: There are. They are at 21 CFR 12.80 is the beginning of a hearing procedure regulation. It sets forth the filing of submissions, the oral and written testimony and burdens of proof. These hearings are extensive --

THE COURT: Does the commission have the discretion to set time frames for submissions?
MS. BARCELO: I don't know off the top of my head, but I would assume so.
THE COURT: All right.
MS. BARCELO: Even after this massive undertaking of updating the last 34 years of science.
THE COURT: Well, doesn't the commissioner have to do that anyway? I mean, is the commissioner not going to update the science where it has concern about public safety?
MS. BARCELO: These are all, I think --
THE COURT: I mean, this is something they have been doing all along, haven't they? Haven't they been updating the science?
MS. BARCELO: They have been on top of this issue as a general matter. In terms of the update that would be required to hold a hearing and pursue a trial on the matter and the burdens and the resources that that would take are very, very substantial. It is within FDA's enforcement discretion to decide to forego that enormous burden and try to do it this other way.
THE COURT: Right. Let me ask you something. I don't know or I don't remember if anybody cited any precedent one way or the other in terms of are there any other cases where findings have been made that have sparked the notice of hearing

where the agency then chose to just go a different route?
MS. BARCELO: The closest case to that -- there was the case I think of it as the Veneman case, which is a case in which -- it was not animal drugs, but it was an FDA drug case in which -- it was a different process. It was this process where after the law changed, FDA needed to determine whether drugs were effective in addition to being safe, and they set up this whole regulatory scheme of deadlines. There was this whole process. And the Court told FDA that they needed to operate within that structured process.
Here there is no structured process. There is no structured regulatory framework in this case. In addition to that, that case I think was a 1972 decision.
THE COURT: And it's not been updated?
MS. BARCELO: Not that I'm aware. It wasn't just that it's old, which is not helpful, but in addition to that, since then there has been a lot of additional case law. Heckler v. Chaney by the Supreme Court, which very much clarified the presumption of unreviewable discretion when we're talking about matters of enforcement, which is what this is. So a district court case from 1972 with a different regulatory and legislative framework.
THE COURT: So there isn't a lot of experience with issuing these notices of hearing?
MS. BARCELO: I don't know how many. I know the

enrofloxacin, which was in 2005. I don't think it's a regular--

THE COURT: So this is a pretty unusual process?

MS. BARCELO: That's my understanding.

And, finally, on the issue of the scientific update that would be required, it really would, I think, require FDA to make new findings based on all of this evidence, and there really is no regulatory or statutory basis to require FDA to conduct that scientific update and then make new findings. The statute and the regulation talk about the findings that are already made. Anything that the regulation calls a finding in this preliminary sense of beginning the process is the 34 year old document which has no current validity in terms of what the world is like today.

THE COURT: Thank you.

MS. BARCELO: Thank you.

THE COURT: Want to add anything?

MS. SORENSON: A couple of quick things, your Honor. You asked about FDA hearings regulations. 21 CFR 12.7E gives FDA's hearing officer a lot of discretion over the process. It says: The presiding officer has all powers necessary to conduct a fair, expeditious and orderly hearing, and it sets forth those powers. That is a matter that will be within the hearing officer's power to determine.

This is the first time that FDA has invoked Heckler v.

Chaney and called this a discretionary and unreviewable enforcement action. This is not an enforcement action. There is a section of the Food and Drug Act that sets out enforcement actions for violations of the statute. This is FDA having to exercise its own authority to withdraw its previous approvals of an animal drug that is not shown to be safe.

The agency has been citing enrofloxacin withdrawal proceeding which took five years. In that adjudication, the agency's own hearing officer chided the agency for proposing a schedule that provides for "an unduly prolonged process that would extend this proceeding." The hearing officer has the discretion to shorten the time frame and to cut short the agency's time of delay.

THE COURT: So after the taking of all the evidence, does a hearing officer issue a recommendation to the secretary, is that how it works?

MS. SORENSON: The hearing officer makes an initial determination, and then only if that determination is appealed does the question go to the commissioner. The initial hearing officer is someone different from the commissioner, who is appointed to that position, and an appeal goes to the commissioner who makes a final decision.

THE COURT: So it's an adversary proceeding where there is the agency and the --

MS. SORENSON: It is, your Honor.

I would like to briefly address the APHA v. Veneman case that the government mentioned. This is a case where the District of D.C. ordered the agency to conduct withdrawal proceedings for human drugs that were not shown to be effective.

The agency is right that it was a different process that led to the agency's findings that the drugs were not shown to be effective, but once the agency made those findings, it was confronted with almost identical statutory language that we have here, which said that the agency must after noticing an opportunity for hearing withdraw approval for drugs if he finds that the drugs -- there's not substantial evidence that the drugs are effective.

FDA had made those findings and published them in the Federal Register, but instead of conducting withdrawal proceedings, the agency had asked drug sponsors to come forward with more evidence, and the agency was sued.

Just like it does here, the agency argued that the findings that it published in the Federal Register weren't findings that triggered action under the statute, and the Court said, no, the statute is perfectly clear that once the agency makes these findings, it must proceed immediately with withdrawal proceedings for these drugs. That is what Congress has ordered because the agency's duty is to protect public health.

THE COURT: Is that a D.C. Circuit or District Court?
MS. SORENSON: That was the District of D.C.
THE COURT: No appeal?
MS. SORENSON: No appeal. That case is still good law, your Honor. Thank you.
THE COURT: Thanks folks. Very interesting question. See you.
(Adjourned)