UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

TUMMINO, Plaintiff,	**Docket#** 05-CV-355(erk)
- versus -	U.S. Courthouse Brooklyn, New York
ANDREW C. von ESCHENBACH, Defendant	December 22, 2005

TRANSCRIPT OF CIVIL CAUSE FOR MOTION HEARING
BEFORE THE HONORABLE EDWARD R. KORMAN
UNITED STATES MAGISTRATE JUDGE

A P P E A R A N C E S:

For the Plaintiff: **Andrea Costello, Esq.**
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Proceedings

THE CLERK: Tummino v. von Eschenbach.

Your appearances, counsel.

MR. HELLER: Simon Heller for plaintiffs.

MS. STRAUSS: Nan Strauss for plaintiffs.

MS. SMITH: Priscilla Smith for plaintiffs.

MR. COHEN: Sanford Cohen for plaintiffs.

THE CLERK: On conference for plaintiffs?

MS. COSTELLO: Andrea Costello for the plaintiff.

MS. DAY: Shelbi Day for the plaintiff.

MR. AMANAT: Your Honor, I am Franklin Amanat, assistant United States attorney here for the Commissioner Andrew C. von Eschenbach.

MS. SCHIFTER: Karen Schifter for FDA on behalf of the defendant.

MR. AMANAT: Good afternoon, your Honor.

Before the Court today is defendant's motion for judgment on the pleadings. I just want it to be clear that what's before the Court is only that motion, not any motion for summary judgment by the plaintiffs.

Therefore, the only question before the Court today is whether the allegations in the complaint standing alone are legally sufficient to establish this court's subject matter jurisdiction and to withstand a motion for judgment on the pleadings. As set forth in our briefs, we respectfully submit that they are not.

But if the Court disagrees with our position and believes that the complaint is legally sufficient, the most the Court can do today is to deny our motion in whole or in part and set the case down for submission of the administrative record or the relevant parts thereof, and for further briefing on cross motions for summary judgment.

THE COURT: I can allow discovery, too.

MR. AMANAT: Well, discovery is an issue that's currently before the magistrate judge --

THE COURT: No, no.

MR. AMANAT: -- in connection with our motion for protective order but that is, of course, an issue that would have to be resolved.

THE COURT: He stayed discovery.

MR. AMANAT: I beg your pardon?

THE COURT: He stayed discovery.

MR. AMANAT: He -- yes, he stayed discovery until this conference and reserved ruling on our motion for a protective order which we filed a couple of months ago.

In saying this, I just want to emphasize that nothing before the Court today would allow the Court to actually grant the plaintiffs any of the relief they were seeking by the Court.

THE COURT: I understand this. You don't have to tell me.

MR. AMANAT: Okay.

THE COURT: It's your motion.

MR. AMANAT: Right.

THE COURT: You want, in effect, summary judgment.

MR. AMANAT: Now, we have submitted a lot of paper to the Court and let me just take a few moments, if I may, to just try to encapsulate what I see as the main themes that I would like the Court to hear in connection with our motion.

First, in considering the legal sufficiency of the allegations of the complaint, the Court should keep in mind that the only administrative proceeding which the Court conceivably has subject matter jurisdiction to evaluate in this case is listed in petition. And the plaintiffs lack standing to contest any aspect of FDA's handling of Barr's supplemental new drug application.

THE COURT: That may or may not be so. I don't know -- if you want to argue it, you could argue it but it's not clear that they necessarily lack standing.

MR. AMANAT: Well, I --

THE COURT: Or third party standing. The question there is whether if they're going to -- to the extent they stand in Barr's shoes, to challenge what they allege to be a final decision of the FDA, then whether it should be in the court of appeals or not.

MR. AMANAT: Well, then that's an excellent

question, your Honor. Let me touch on that for a moment.

THE COURT: I mean, I don't necessarily accept that they don't have third party standing but that in itself may involve a question that has to be dealt with discovery. Part of it may depend on why it is that Barr has sort of acquiesced in what the FDA has done, and if, in fact, Barr acquiesced in what the FDA has done or has not sought to challenge what the FDA has done is because they don't want to -- this may not be a drug from which that will derive much economic advantage if it's because -- and, therefore, do not wish to launch a wholesale legal war over it or because they may be concerned about getting on the wrong side people at the FDA whom they may have to deal with in other instances where they're actually seeking approval of drugs. That might be an instance in where you could conceive of an argument, the kind of -- where the third party is "hindered" from asserting his own rights. And I think that in my view, they have -- they can show the kind of discrete injury to themselves that would be sufficient to justify third party standing.

MR. AMANAT: Well, we would respectfully disagree, your Honor. As we set forth in our supplemental brief which we've filed last week, the case law is very clear that a plaintiff seeking to challenge federal agency action cannot predicate Article 3 standing on the rights of a third party. And we believe that that case law applies here.

Simply stated, your Honor, the only entity that has standing to challenge FDA's handling of Barr's SNDA (phonetic), whether on a claim of unreasonable delay or on a claim that FDA's issuance of the May 2004 letter was arbitrary and capricious would be barred.

THE COURT: I know you harp on the May 2004 letter but it was no -- and it may have been the significant document at the time the complaint was filed, there is an even more significant document here which is the August letter --

MR. AMANAT: Right, but even if --

THE COURT: -- which to my mind constitutes -- I mean, you know the agency could put it in whatever form it wants but it's a clear rejection of over the counter authorization for the sale of plan B to persons under the age of 17.

MR. AMANAT: Well, I would disagree with that, your Honor, and I will address that in a moment.

THE COURT: You do?

MR. AMANAT: But --

THE COURT: Well, I mean, I -- you can disagree with it but it seems clear to me that it is and that they don't intend to do anything about that and their rule making is, in fact, designed to deal with how they address -- they claim that they don't have the competence to decide now how to deal with authorizing over the counter for women above the age of 17

while not authorizing it for women below the age of 17 and that's the purpose of the -- the stated purpose of their rule making which suggests that they have no intention, aside from the fact that they say there's no evidence that -- that there's insufficiency that it could be safely sold to what we'll roughly call minors. I don't know -- what do you need, some sort of a formal stamp to say denied?

MR. AMANAT: Well, I don't know if it needs to be a formal stamp, your Honor, but I think it is certainly --

THE COURT: Well, you know, this is an argument -- you know, you started off lecturing me about what this case is about. But what it's really about is throwing them out of court without any further adieu and whether there's a sufficient basis to do that.

MR. AMANAT: Well, I think certainly --

THE COURT: I mean, you can't tell me that it's so clear that this is not final with respect to people under the age of 17 that that claim -- that an administrative challenge to that order cannot be made.

MR. AMANAT: Actually, your Honor, you know, I believe --

THE COURT: I mean, may be if you got me an affidavit and you actually made a motion for summary judgment instead of asking me to give you summary judgment without affidavits you might, you know -- you might advance the

argument.

MR. AMANAT: Well, what --

THE COURT: You have an affidavit from anybody that says they have any intention of authorizing over the counter sales to people under the age of the 17?

MR. AMANAT: Well certainly what's before the Court at this time, your Honor, is of course the pleading filed by the plans and the other --

THE COURT: I understand the pleadings are not wonderfully drafted. The complaint should be amended again to include what's -- you know, the factual allegations that are in their memoranda but fundamentally for these purposes, for the purposes of not dismissing the not only the complaint but also the --

MR. AMANAT: The judicial notice of all materials that the --

THE COURT: Well, also what they allege in their memo of law, the factual allegations that they allege there because I could assume that they could easily put it in their complaint. I may not be able to consider it for the purpose of granting a motion to dismiss but for the purpose of sustaining the complaint, I can consider what else they've alleged. They haven't alleged a lot of things that I think ought to be alleged in the complaint.

MR. AMANAT: But even with regard to the August 26

action taken by the commissioner, the letter which your Honor has in front of you now, even that letter, even based on that letter, I believe that it is premature to conclude -- there is no basis to conclude -- that there is no possibility that FDA will at some point in the future approve --

THE COURT: Look, anything is possible but this is what they actually say in the letter. The Center for Drug Evaluation and Research, CDER, and they have come up with documents that suggest that it really wasn't the Center for Drug Evaluation and Research, has completed its review of this application as amended and has concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product but only for women who are 17 years of age and older.

MR. AMANAT: And it said that the verdict is out as to the user's below that age.

THE COURT: No, there's --

MR. AMANAT: What the commissioner stated, your Honor, in that letter was that regard to the younger age groups, the --

THE COURT: No, I --

MR. AMANAT: -- agency still did not have enough information to make a final determination and there are legal issues.

THE COURT: This is one of the problems here. Barr

withdrew that request, so they didn't offer any additional evidence. You have not told these plaintiffs that their request is in any way deficient. You have taken no action on the citizen complaint. And as far as, you know, you're trying to say that they don't have enough information, you know, basically Barr has thrown in the towel in an effort to accommodate the FDA and the concerns about the sales of these to minors. So, Barr says, all right, you're worried about sales to minors, we're just asking for over the counter authorization for adults. So, they're not going to do it, since Barr has effectively amended its own application.

They're not going to take any further action with -- on this issue with respect to Barr because Barr has submitted an amended application. Their application is still pending and you haven't told them anything about their application.

MR. AMANAT: Well, your Honor --

THE COURT: And basically what you're -- this has all the earmarks of an administrative agency filibuster.

MR. AMANAT: Well, your Honor, if I could break down a couple of the issues that your Honor raises there, first of all, with regard to the citizen's petition, the plaintiffs have not established that there has been a --

THE COURT: Before you get to this --

MR. AMANAT: Yes.

THE COURT: -- this is my roughly my view of the

third party standing issue.

MR. AMANAT: Yes.

THE COURT: I think whether they have third party standing, I can't determine on the basis of the record right now because it in part depends on why Barr has essentially acquiesced in the FDA's concerns and why it hasn't chosen to litigate the matter right now.

And number two, I think if they're going to proceed solely on a -- if you limit the action solely to their ability to stand in the shoes of Barr, it seems to me they have to go to the form where Barr would go to indicate its claim which is the court of appeals, at least to the extent that they're, in effect, seeking to put themselves in the shoes of Barr and exercise third party standing on behalf of Barr.

So, that's my view of that. I think that I'm inclined to disagree with most of the arguments that you raise as to why they couldn't but on the issue of standing alone, I think I can't resolve the third party standing issue on the current state of the -- without knowing why Barr isn't here.

MR. AMANAT: May I address that, your Honor?

THE COURT: Yes. And then we can go on to the other.

MR. AMANAT: Okay. Let me address a couple of aspects of what you said. First of all, even assuming that there would be standing, even Barr would not be able to raise a

challenge as your Honor yourself pointed out in this court. It would have to raise it in a petition for review to the third circuit or the DC circuit and even then --

THE COURT: Why the third circuit?

MR. AMANAT: Because its venue -- it's domiciled in Pennsylvania and the statute allows it to petition for either --

THE COURT: Well, I don't know that they couldn't go to the second circuit but that's neither here nor there. I think obviously what congress was looking for was an appellate court review.

MR. AMANAT: Right.

THE COURT: And I think it said either in the District of Columbia which is where the agency is or in the --

MR. AMANAT: Or in the court of appeals where the --

THE COURT: -- where the plaintiff is --

MR. AMANAT: -- sponsor is venued.

THE COURT: Well, I don't know that they use sponsor but I think they use applicant. But I don't have to get involved in this. I think they could go to the second circuit but, go ahead.

MR. AMANAT: In any event, the petition for review could only be brought by Barr after FDA renders a final agency decision on its application and after Barr exhausts its administrative remedies.

THE COURT: Right.

MR. AMANAT: Barr hasn't raised such a challenge to FDA's actions.

THE COURT: Well, the issue is why they haven't and whether these people can have third party standing to do it.

MR. AMANAT: Well, I think why Barr has not done so is ultimately irrelevant.

THE COURT: It's not. A third party standing inquiry depends in part on the reason why the, shall we call it the first party -- I'm not sure who the second party is but -- shall we call it the first party, hasn't asserted its rights. You know, the classic case is the Batson cases where under the rationale of the supreme court decisions when a juror is struck because of race, the constitutional violations is of the prospective jurors right to the equal protection of the laws. It does not involve a violation of the right of the defendant who is asserting that there was an improper objection.

Nevertheless, one of the reasons for according third party standing was that there really isn't any realistic way that a challenged juror can assert that claim. They may not even know to begin with why it is that they've been kicked off the jury. But there are a number of practical reasons why that juror whose right has been violated is hindered in asserting it.

And so that the defendant in that case, whose rights

have not been violated, his equal protection rights have not been violated, is accorded third party standing. So, then the question -- it's relevant.

Now, there also has to be some sort of injury to the first party but if you take a look at Ohio v. Powers, that injury isn't very much. It could even be -- I mean, if you read Kennedy's opinion very carefully, it could almost be potential, it doesn't even have to be actual.

MR. AMANAT: But your Honor's reference to the Batson case in connection with third party standing we would submit is distinguishable because in this case, this is not a case where Barr is somehow prevented from asserting its own rights. It certainly can.

THE COURT: We don't know. It's not prevented in the sense that it's barred.

MR. AMANAT: Well --

THE COURT: Forgive the pun. But neither is the juror.

MR. AMANAT: Well, but --

THE COURT: It's not barred. There's no rule that says the juror can't raise his hand and say, Judge, why am I being thrown off? It's just realistically, it doesn't happen that way and the question then becomes why is it that Barr acquiesced first of all in withdrawing in response to the commission's concerns its application for over the counter

authorization for minors and why is it that they're not here. That's relevant. It's sort of like asking why the juror in the Batson case is unable to assert its right. It's part of one of the prongs that are relevant to the issue of third party standing and I can't find that they have that unless I know the reason for Barr's absence from this table.

MR. AMANAT: Well, but Barr has not intervened in this case.

THE COURT: I understand that.

MR. AMANAT: They haven't filed an amicus.

THE COURT: They haven't.

MR. AMANAT: They haven't given any indication that they support --

THE COURT: I know.

MR. AMANAT: -- what the plaintiffs are trying to accomplish here.

THE COURT: I understand that. So, why not?

MR. AMANAT: Well, whatever Barr's reason for protections, plaintiffs cannot presume to step in Barr's shoes and speak --

THE COURT: Well, but that can be determined. That's an issue of fact to be determined. That could be determined whether or not why Barr -- you know, we don't have to sit and speculate. That's an issue that could be resolved in discovery.

MR. AMANAT: Well --

THE COURT: You know, it may be that Barr says, you know, whatever they want to say. But I could conceive of reasons why they wouldn't -- I don't know but I could speculate that there's not a hell of a lot of money to be made in this. It's not like Lipitor and they may make a judgment that it's not worth expending the time, effort or money to litigate and/or alternatively, they could determine that they don't want to aggravate the FDA since there's some indication here that this is not being handled in the ordinary course and they have other fish to fry with the FDA that may be more important than this one.

MR. AMANAT: Well, let's assume that those are their rationale.

THE COURT: Well, then I think that --

MR. AMANAT: Let's assume that this --

THE COURT: -- they have satisfied that prong for third party standing. That's what I think.

MR. AMANAT: Then we would submit --

THE COURT: And I think their own injury is sufficient here to satisfy the prong of a discrete injury that gives them a sufficient interest in the case to litigate it in an effective way. In fact, you recognize -- the agency itself recognizes their interest in these proceedings by giving the right independently to file a claim. And there are two

interests here; one is their potential, the fact that some of the plaintiffs may in the future have some need for this plan B but there is yet another -- I know you've tried to make it appear that it's the whole population of the United States that's somehow effected by it when we're talking about even under your view is simply that portion of the population of child bearing years which is considerably less than the total population of the United States.

But the more pertinent ones is that they're also here essentially representing people who may need it and who may at the time that they actually need it, possibly to avoid an abortion at some future date, will not be in the position to go bring a legal action to obtain it.

So, in a sense there's a different kind -- there's a different third party now in the third party standing equation and I think that would be sufficient to satisfy the discrete injury aspect of the standing requirement. But again, I don't know -- if you want to press it, we could continue this argument. But go ahead.

MR. AMANAT: Well, I don't necessarily want to press it except to jury reiterate --

THE COURT: No, the only reason I ask is because until -- well, go ahead.

MR. AMANAT: Well again, the cases such as Simon v. Eastern Kentucky Welfare Services and the other cases that we

cite, the cases that we cited in our supplemental brief, make it clear that absent very limited circumstances which we respectfully submit do not apply here, a plaintiff challenging government agency action cannot predicate standing based on the rights of third parties who are perfectly capable of asserting of the argument.

THE COURT: There it is; perfectly capable. And perfectly capable is a question here. They may be capable theoretically, just as the juror that I posited in the Batson case, but the question is basically a more practical one and you're operating on a premise, it seems to me, that has yet to be established. And that premises is why it is that the first party here Barr, is essentially acquiesced in whatever the FDA has chosen to do here, whether it's to question the authorization for over the counter use by minors or to just endlessly delay a final resolution of their application.

MR. AMANAT: But even assuming that the third party could vest, because such third party standing would only take place in the court of appeals, we would submit that it would be inappropriate for this court --

THE COURT: No, I understand that.

MR. AMANAT: -- to order discovery --

THE COURT: That's true.

MR. AMANAT: -- or to authorize discovery because the answer that would come out of that discovery would at best

show that these plaintiffs might conceivably have standing to raise a petition for review in the DC circuit or the third circuit or the second circuit as your Honor posited and it would seem to us that the decision as to whether discovery would be necessary to determine whether they would be able to exercise such third party standing in the context of an appellate petition for review should be made by the court of appeals, not by this court.

There is no discovery which could take place which would result in the discovery of facts which would vest this court with Article 3 jurisdiction to review these plaintiff's challenges to any action which the FDA has taken or may have failed to take with regard to Barr and the FDA.

THE COURT: Now we're dealing with discovery, which we could get to at the end.

MR. AMANAT: Okay.

THE COURT: So --

MR. AMANAT: If I may then proceed, your Honor, with regard to the citizen petition, although these plaintiffs or at least one of them, arguably have standing to contest FDA's response of the citizen's petition through an HP (phonetic) action in this court, the Court lacks subject matter jurisdiction to review such a challenge for a different reason, namely the absence of a final agency action which is ripe for judicial review.

THE COURT: No, no.

MR. AMANAT: No?

THE COURT: First I want to deal with -- there's a separate issue there as to where that ought to be brought. I thought you were going to go -- I thought you were going to deal with -- well, go ahead. I don't want to --

MR. AMANAT: You thought I was going to deal with what?

THE COURT: I thought you were going to deal with the unreasonable delay.

MR. AMANAT: I will deal with the unreasonable delay in a moment but if I could just --

THE COURT: Look, I think there's clearly -- I mean, you know, except for form, I don't understand how you could sit here and tell me on behalf of the agency that there's any possibility except to the extent that anything's possible in this world that they are -- they have any plans or that there's any process --

MR. AMANAT: Right.

THE COURT: -- through which they are going to authorize over the counter dispensing of this Plan B, that children under the age of 17.

MR. AMANAT: I mean, I --

THE COURT: I don't know how much more final it can be --

MR. AMANAT: Well --

THE COURT: -- except for the fact that, you know, it's not in the form order.

MR. AMANAT: Well, let me address that, your Honor. As set forth in the commissioner's letter of August 26 and the ANPR, the advanced notice of proposed rule making which was issued on the same date, the reason the agency did not go ahead and approve the SNDA as of that date, notwithstanding its finding that the science supported over the counter status for drug for users over the age of 17 was because as indicated in the commissioner's letter and in the ANPR, there were several discrete legal questions involving the agency's authority.

THE COURT: Look, they could make up all sorts of discrete legal questions. There is a serious issue here as to whether they are acting in good faith. I mean, there's a very serious issue that certainly can be dealt with in discovery in terms of the cause of action relating to the unreasonable delay in ruling on their application.

I mean, there's just -- you could make up anything. I quite don't understand -- I mean, you have to understand, first of all, the nature of rule making, administrative rule making, which it takes forever.

MR. AMANAT: I can take a while.

THE COURT: It takes forever. First of all, they

didn't just promulgate a proposal and ask for comment; no. First they asked, we have this problem that we, for some reason are so difficult -- it's so difficult that we need advice from the whole world on how to deal with what seems to be a nothing with nothing issue. But we have this terrible problem. We don't know how to authorize the dispensation for over the counter Plan B to adults and not authorize it for minors. Not that we haven't done it before but in this case, you see, the dosage is exactly the same. So, this creates, oh, all sorts of problems for us which strikes me as being totally ridiculous but let's put that aside.

Because now that it's finished --

MR. AMANAT: Right.

THE COURT: -- they could take forever to promulgate a draft rule.

MR. AMANAT: Well --

THE COURT: Wait. That's not the end.

MR. AMANAT: Right.

THE COURT: Because after they promulgate the rule, then they have to ask for the opinions of everybody once more and then that could take God knows how long. And then there's no time limit under which they have to formulate the final rule after giving notice and an opportunity to be heard.

So you're talking about a process that could take years. You, yourself, cited a rule that they proposed in 2004

dealing with this 180 day period which they have yet to finalize. So you know, what you're talking about here is a fundamentally endless process at which in no way will deal with the issue of sales of this drug to minors.

MR. AMANAT: Well, I want to address of this --

THE COURT: Over the counter sales.

MR. AMANAT: I want to address the issue of unreasonable delay in a moment but I wanted to get back to your earlier question regarding what conceivable scenario might happen that would result or could result in the drug being made -- being approved for over the counter sale to minors.

THE COURT: Yes.

MR. AMANAT: And the answer is that at the end of this process that your Honor described, however long it takes, the agency might come to the conclusion, it's quite conceivable, that it may very well come to the conclusion that it does not have the authority to approve a split marketing approach.

THE COURT: That's ridiculous. They say they have the authority.

MR. AMANAT: Is it --

THE COURT: They say they've done it before.

MR. AMANAT: Well, it's still marketing as to age, I mean.

THE COURT: Well, how --

MR. AMANAT: And if they come to that conclusion --

THE COURT: I mean, it's ridiculous. So, let's assume that they come to that conclusion.

MR. AMANAT: If they come to that conclusion --

THE COURT: Yes, let's assume that.

MR. AMANAT: One scenario is that they could say okay, well, let's then just make it over the counter for everybody.

THE COURT: Well, I don't know. If they're only convinced that it's safe as to adults, how are they going to authorize it for people who are not adults.

MR. AMANAT: Well, the fact of the matter is as your Honor knows, and as the plaintiffs are key to point out, the --

THE COURT: This is what they've concluded that the available scientific data are sufficient to support the safe use of Plan B as an over the counter product but only for women who are 17 years of age and older. So, they have concluded that it's not safe for people under. I mean, I don't know -- I really am at loss to -- you've basically undermined your credibility here by making every foolish argument that comes into your head or that necessarily suits your client's interests.

MR. AMANAT: Well, your Honor --

THE COURT: Do you know why you're here instead of an FDA lawyer?

MR. AMANAT: I beg your pardon?

THE COURT: Do you know why you're here instead of an FDA lawyer?

MR. AMANAT: I have an FDA lawyer here.

THE COURT: No, no, but why the United States attorney represents the executive agency and not the executive agency itself?

MR. AMANAT: Yes, I do, your Honor.

THE COURT: It's because congress wanted an independent lawyer who could give sound advice to a client and who was not necessarily a mouthpiece for the agency.

MR. AMANAT: Well, your Honor --

THE COURT: Otherwise, they don't need you here.

MR. AMANAT: Well --

THE COURT: She could simply moth what the head of the agency tells her to say.

MR. AMANAT: Well, your Honor, with due respect, we have --

THE COURT: Really, I don't understand how you could possibly sit here and tell me that there's any kind of realistic possibility that they're going to authorize it for people under the age of 17.

MR. AMANAT: By virtue of the fact that there has been a very serious debate within the agency and high level officials within the agency have --

THE COURT: The political appointees within the agency as opposed to the professionals within the agency. But I don't have any problem with the political appointees having a say in this. The real question is putting these cases in a posture in which they're subject to some form of judicial review to which agency action should be subject and what's happening here is they're doing a dance that's designed to prevent judicial review of their own actions. And this dance, particularly as it effects children or called minors under the age of 17, you know, I just don't understand it. They're basically saying that there's no evidence to show that it's safe.

MR. AMANAT: Well, but --

THE COURT: And to the extent -- and Barr, of course, is not offering any and these people have not been told what's wrong with their application yet.

MR. AMANAT: Well, your Honor, they're not saying that there's no evidence. They're saying there's insufficient evidence.

THE COURT: Well, you know, it's the same thing for our purposes.

MR. AMANAT: And I think that if your Honor were to look at the administrative record it would become apparent that this is not a case where the agency has been trying to avoid a posture of having its decisions subject to judicial review.

THE COURT: Actually, I don't know, I may be looking at the wrong record but it's certainly what it looks to me like.

MR. AMANAT: Well, your Honor hasn't seen the full administrative record.

THE COURT: I mean, well, I don't know -- I haven't seen the full administrative record but I am sure you would have called this before me and I'm sure you would have called any relevant parts of it to my attention.

MR. AMANAT: Well --

THE COURT: What we have in the administrative records is the professionals in the agency who have the expertise to determine safety saying there's no problem.

MR. AMANAT: Well, some of the professionals --

THE COURT: Well, some of them.

MR. AMANAT: Some of them; yes.

THE COURT: Well --

MR. AMANAT: Some of them are saying to the contrary. But in any event, your Honor, we would submit that certainly a review of the administrative record would make it clear that the agency --

THE COURT: Well, why don't you let the administrative record be reviewed?

MR. AMANAT: Well, if that's the course of action which the Court --

THE COURT: Well, no, I mean, you know --

MR. AMANAT: -- prefers to proceed on, we can do that but --

THE COURT: No, I mean, you basically don't want that. You're saying it's not final. It can't be reviewed.

MR. AMANAT: Well, it --

THE COURT: Whether it could be reviewed by me, as opposed to the court of appeals if it was final is a separate question. But --

MR. AMANAT: It goes down to the question, your Honor, of subject matter jurisdiction, Article 3 jurisdiction.

THE COURT: We're going in a circle.

MR. AMANAT: Well --

THE COURT: We'll dealing with you conceded that they have standing for their own complaint.

MR. AMANAT: Well, at least one of the plaintiffs has standing --

THE COURT: One is enough.

MR. AMANAT: -- as to the citizen petition.

THE COURT: One is enough. It doesn't require more than one.

MR. AMANAT: Well, if I then may address the question of unreasonable delay that your Honor has posited. In addressing unreasonable delay, let me say again first of all

that what we're dealing with here is the pleadings and --

THE COURT: Right.

MR. AMANAT: -- the pleadings --

THE COURT: The pleadings. You have to keep remembering that because you're asking me to throw them out of court --

MR. AMANAT: Well --

THE COURT: -- in a case that wreaks of unreasonable delay.

MR. AMANAT: But the complaint itself, the allegations in the complaint, do not support a finding or conclusion of the agency's unreasonable delay.

THE COURT: I think that the complaint has to be redrafted but fundamentally, there's enough there to avoid a dismissal on the face of the pleading and certainly if you take into account the factual allegations in their memorandum.

MR. AMANAT: Well, let me address, if I may, a couple of aspects of the claim of unreasonable delay with regard to the citizen petition.

THE COURT: Right.

MR. AMANAT: First of all, they have made a claim in their papers with regard to unreasonable delay. They characterize in kind of arguing as to why there's been unreasonable delay, they keep urging the Court to look at the

period of time from when the citizen petition was first filed on February 14, 2001 until the present. We would submit that that is an erroneous characterization for the following reason.

The citizen petition, your Honor, I have it right here, the citizen petition consisted of three -- of four pages. That's it. Okay? When the citizen petition was filed, it was filed almost 26 months before the manufacturer of the drug asked the FDA to approve this drug for OTC.

Now, first of all, as a threshold matter I should say that never has FDA ever approved a switch of a drug to OTC status based solely on its citizen petition when the manufacturer itself has not asked for it.

THE COURT: Is there anything in their regulations that precludes that?

MR. AMANAT: Well, the regulation allows a citizen to ask for --

THE COURT: Right.

MR. AMANAT: -- an OTC switch to a citizen petition.

THE COURT: Right. And does it say that unless the manufacturer joins in it, that it won't be granted?

MR. AMANAT: No, well the statute --

THE COURT: If your argument is that this is -- this four pages simply didn't warrant any relief, why don't you just deny that?

MR. AMANAT: Well, the reason it didn't deny it is

because instead what it did was --

THE COURT: They waited 26 months for the manufacturer to file.

MR. AMANAT: No, that's not correct, your Honor. After this was filed --

THE COURT: Yes.

MR. AMANAT: -- FDA published the federal register notice.

THE COURT: Right.

MR. AMANAT: Says substantially, petitioner has asked the drug to be made --

THE COURT: Right.

MR. AMANAT: -- available over the counter.

THE COURT: Okay.

MR. AMANAT: They think it's a good idea for it to do so. What does everybody else think?

THE COURT: Right.

MR. AMANAT: People then began filing by the tens of thousands public comments.

THE COURT: I understand that.

MR. AMANAT: The agency got those comments, reviewed the comments.

THE COURT: The reality is is that there aren't tens of thousands of reasons. There are probably two or three reasons that tens of thousands of people have.

MR. AMANAT: No, it's --

THE COURT: But the reality is is that there aren't ten thousand different reasons. You know, there are fundamentally -- there are reasons why the people oppose this. There are reasons why they are in favor of it. And they come down to possibly two or three. They don't come down to ten thousand.

What you have going on here, as a practical matter, is a letter writing campaign because there are people who have strong feelings about it.

MR. AMANAT: Well --

THE COURT: But this is not some sort of, you know, there are ten thousand people who have expertise in pharmacology who are giving you ten thousand different views.

MR. AMANAT: Well, that's the point, your Honor, is that neither citizen's petition nor the public comments that were submitted in response to the citizen petition contain a science. They don't --

THE COURT: So --

MR. AMANAT: They didn't have the scientific --

THE COURT: Why didn't you write him a letter and say we can't act on it because it doesn't contain the science instead of --

MR. AMANAT: Well, that's basically what we did.

THE COURT: I thought you just wrote him a letter

saying we'll get back to you.

MR. AMANAT: Well, we sent him a letter, the letter of which is attached as Exhibit B to --

THE COURT: What does it say?

MR. AMANAT: It says, "FDA has not yet resolved the issues raised in the citizen petition because it raises significant issues required extensive review and analysis --"

THE COURT: Right.

MR. AMANAT: "-- by agency officials."

THE COURT: Right. Okay.

MR. AMANAT: But the fact that --

THE COURT: It doesn't say it's inadequate.

MR. AMANAT: Well --

THE COURT: It doesn't say that it's three pages and it's just a plain -- it's three pages of worthless paper and so we reject it.

MR. AMANAT: But the fact --

THE COURT: We will respond to your petition, as soon as we have reached a decision on your request.

MR. AMANAT: And the --

THE COURT: "September 6, 2001, we will respond to your petition as soon as we have reached a decision on your request. And here we are, December what, 22, 23, 2005, and they have yet to hear from you since this letter on September 6, 2001.

MR. AMANAT: Well, but your Honor, my point is that at the time the citizen petition was filed, okay, let's say -- the citizen petition, if the agency were to grant the citizen petition prior to the SNDA being filed, what it would be doing was it would not be saying -- oh, okay, Plan B is now available over the counter.

The action it would take upon the approval of the citizen petition would be commence a rule making proceeding. A rule making proceeding which your Honor yourself posited, could take a long time because it is only through the mechanism of a rule making proceeding that it could have equipped itself in the absence of an SNDA, that it could have equipped itself with the information necessary to make this determination.

THE COURT: I don't understand this because first of all, I don't know -- you have an advantage. I don't know that a rule making proceeding would be necessarily required to act on a citizen petition. I don't know why you need this --

MR. AMANAT: On this kind of a decision.

THE COURT: I don't know why but so, I accept your word for it. When did they undertake the rule making effort that would be necessary to resolve this petition.

MR. AMANAT: Well, what they did was they published federal --

THE COURT: They have yet to do that. Isn't that true?

MR. AMANAT: Well, your Honor, what they did was as soon as Barr filed its SNDA, FDA acted diligently with dispatch, moved quickly, it convened advisory committee hearings, it evaluated the science. It worked with Barr to get the science and the scientific studies which it needed. And ultimately --

THE COURT: And this is its decision.

MR. AMANAT: Well --

THE COURT: The drug may not be legally marketed over the counter. And you put in the words, "at this time," and that sort of somehow insulates this whole thing from review.

MR. AMANAT: Well, the fact of the matter is, your Honor, the review --

THE COURT: And you don't respond to them. You still have not responded in any way to their petition.

MR. AMANAT: Well, your Honor, there is no mandatory duty in the regulations or in the statute for the agency to have responded to the citizen petition in any way other than it did.

THE COURT: Oh, so it's okay to never respond under your --

MR. AMANAT: That's not what I said, your Honor.

THE COURT: Well, I don't know what you said. You

said there's no obligation to respond. First of all, we'll deal with that statement. But I just want to know, there's a provision in the APA that requires that the agency not unreasonably delay --

MR. AMANAT: Right.

THE COURT: -- in acting upon matters that are before it. So, it doesn't mean that you can just take forever.

MR. AMANAT: I don't disagree with that.

THE COURT: Well --

MR. AMANAT: I'm not saying that the agency can take forever.

THE COURT: You just did.

MR. AMANAT: I don't think I did, your Honor.

THE COURT: Well, what you said was that they don't have to -- they could just delay as long as they want.

MR. AMANAT: No, that's not what I said, your Honor.

THE COURT: So, tell me again what you said so I could hear it -- so I could quote it.

MR. AMANAT: Because the question, as the Souther Utah decision from the supreme court said, "Unreasonable delay is -- the question of unreasonable delay is measured --

THE COURT: (inaudible.

MR. AMANAT: -- with regard to discrete agency action that an agency is required either by statute or by

regulation to take.

THE COURT: Well, first of all look, you got this case right when you described it the first time in your reply brief at page 18 in which you said that "That case stands for the proposition to the extent that the plaintiffs can seek to compel the agency to act and that at the same time to direct the content of that decision, the supreme court in SUA (phonetic) confirmed that such relief would be impermissible." You got it right.

This is different from SUA. First of all, there's a separate statute here in the APA which is cited in cases that you cite in your brief, which you cite erroneously.

MR. AMANAT: Section 555(b).

THE COURT: Yes, that you say are erroneously have been overruled. They haven't been overruled. Which explicitly mandate that the commission decide yes or no, not what the decision should be, but one way or another in a reasonable period of time.

MR. AMANAT: Well --

THE COURT: And that's the law. That's what the APA says.

MR. AMANAT: But, your Honor --

THE COURT: They're not asking you as was the case in the -- we'll call it the SUA case -- they're not asking you at the moment in this particular cause of action to decide it

in any particular way.

MR. AMANAT: Well, actually they are.

THE COURT: No, no. I'm talking about the unreasonable delay cause of action. They're simply asking you to decide.

MR. AMANAT: But the question as to what does it mean to decide. What the SUA case said was in determining what it means to decide whether for purposes of 555(b) of the APA or for persons of 7601.

THE COURT: They didn't say -- well, you put in there, "whether for the purpose of 555," they don't -- I mean, maybe I missed it but I didn't see that.

MR. AMANAT: Well --

THE COURT: In fact, what you're relying on is essentially what I would call dictum in a footnote in a distinguishable case.

MR. AMANAT: Well, what they say, your Honor, is --

THE COURT: This case that you're relying on did not involve a claim that the agency unreasonably delayed in making a discrete decision. And the discrete decision could be whatever the agency wants to decide. But that's not what that case involved. And I don't agree that it precludes this cause of action.

MR. AMANAT: Well, what it does provide, your Honor, is that when a party challenging agency action

seeks relief in the nature of mandamus, which is effectively what the plaintiffs are doing here, to compel the agency to do something that it's not doing --

THE COURT: Right.

MR. AMANAT: -- what the supreme court held in the SUA case was that such relief is not available unless the plaintiffs can point to a statute or regulation which requires the agency to take a discrete agency action.

THE COURT: 555(b). It says you have to decide one way or another.

MR. AMANAT: Well --

THE COURT: What they're trying to do in the SUA case was to get the agency to -- they say the agency did not consider X and they should have considered X. And it was an effort to use the statute to obtain review that was ont otherwise available. This is not that case.

MR. AMANAT: But, your Honor --

THE COURT: SUA did not involve an unreasonable delay case and there is a statute.

MR. AMANAT: But, your Honor, as was cited on page 23 of our supplemental brief, the case law provides in Section 555(b) does not independently impose a substantive duty on federal agency.

THE COURT: I don't know what substantive duty means. It implies a procedural obligation to make a decision.

Beyond that, I don't know what you're talking about.

MR. AMANAT: But the substantive content of --

THE COURT: They write - they're not asking -- the issue here is not the substantive content of the decision. It's simply saying make a decision.

MR. AMANAT: But that's what I am trying to say, your Honor. What cases like Lohan v. National Wildlife Federation (phonetic) and the Center for Biological Diversity v. Benhaman (phonetic) say is that in looking at 555(b) in terms of deciding what kind of decision the agency is supposed to make within a reasonable time, you have to find another statute which defines the kind of decision, the kind of action.

Here, in this case, your Honor, the regulation which describes the kind of action which the agency is required to take in response to a citizen petition is 21 CFR 10.30(e) and 21 CFR 10.30(h). And we identified on pages 20 and 21 of our brief, what those specific actions are.

So, to the extent that SUA or 555(b) or 7061 imposed on the agency an obligation to take a discrete agency action within a reasonable period of time after a citizen petition is filed, the definition of what action is for purposes of such an obligation is defined exclusively by the regulation. And the agency has complied with that regulation. It took action in accordance with the regulation in response to the citizen petition.

THE COURT: It basically wrote them a letter saying we'll get in touch with you.

MR. AMANAT: But --

THE COURT: And I mean, that's all they had to do. They're not obligated at some point to decide it.

MR. AMANAT: But, your Honor, let me point out the whole process of the citizen petition process --

THE COURT: Right.

MR. AMANAT: -- is not a statutory process.

THE COURT: So --

MR. AMANAT: It is a regulatory process --

THE COURT: So, it's a regulatory process.

MR. AMANAT: -- which is --

THE COURT: It still sets up a mechanism for people to seek relief from an agency which you're perfectly free to grant or deny and they presumably are free to then challenge in a court.

MR. AMANAT: True. But the regulatory process which the FDA developed to invite citizen petitions is governed by its own regulations as to what it's required to do in response to such citizen petitions and it did that.

THE COURT: So, it's not required by the regulations to decide. So, it could take forever.

MR. AMANAT: Well, it is required but it says -- the obligation to decide it comes from 21 CFR 10.30 (e)(1) which

says, "The commissioner shall in accordance with paragraph (e)(2), rule upon each petition."

THE COURT: Okay.

MR. AMANAT: That's where the obligation comes from.

THE COURT: So?

MR. AMANAT: But --

THE COURT: Where's the ruling?

MR. AMANAT: You have to read that in accordance with (e)(2) and with the subpoints, 1, 2 and 3, under (e)(1).

THE COURT: And so he never has to issue a decision.

MR. AMANAT: No, that's not what I said, your Honor.

THE COURT: He could delay interminably.

MR. AMANAT: No, that's not what I said, your Honor.

THE COURT: He could delay unreasonably.

MR. AMANAT: He cannot delay unreasonably.

THE COURT: Okay. So, we've established that. So, I don't know what you're arguing about.

MR. AMANAT: But the point is --

THE COURT: He cannot delay unreasonably but they have no remedy if he does. Is that your argument?

MR. AMANAT: That's not what I said either, your Honor.

THE COURT: Well, I don't know. I can't --

MR. AMANAT: What I said was that in terms of determining what is reasonable, reasonable has to be determined in taking into consideration what the agency is required to do in response to a citizen petition. What it's required to do.

THE COURT: But you ultimately read to me is to decide it at some point, not to delay it endlessly either because they don't want to put up with the political flack that comes from a decision one way or another.

MR. AMANAT: No, your Honor, the bottom line is --

THE COURT: Or for any other impermissible reason.

MR. AMANAT: The bottom line in our view is that what 555(b) and 7061 provide in this context is if an agency can be shown to actually have, as the plaintiffs phrased it in their papers, can sign to oblivion an application or an administrative action, put in our shelf to gather dust for years without ever taking any action that might very well engender a valid action on the appeals of unreasonable delay.

THE COURT: And what about moving it around like pieces in a shell game?

MR. AMANAT: No but here, your Honor, a review of the administrative record would show that the agency has from the very beginning taken very seriously the citizen petition and the SNDA. It has accumulated an administrative record on the citizen petition which to date spans well over 100,000

pages. The administrative record on the SNDA spans --

THE COURT: Why doesn't it decide it then?

MR. AMANAT: Because -- well, let me say first of all it's a complex issue. The agency has never before ever approved any hormonal contraceptive for over the counter marketing to any segment of the population. This is the first time the agency is even considering doing that.

Secondly, the agency has never before approved as Barr is asking to now --

THE COURT: It basically agrees, the agency, that it could be sold over the counter safely to adult women.

MR. AMANAT: That is correct. But --

THE COURT: Basically, it agrees with that.

MR. AMANAT: That is correct.

THE COURT: So, the business about this being the first time, it's made a judgment already it's made a judgment that this could be safely sold.

MR. AMANAT: It made a judgment that it took several years to reach.

THE COURT: I understand that.

MR. AMANAT: Which is how long it took to consider all of the policy aspects of it.

THE COURT: Right.

MR. AMANAT: Your Honor, keep in mind that the FDA is constantly under pressure because it is approving drugs too

quickly. You know --

THE COURT: Please. They're under pressure because they're approving it too slowly and they're under pressure because they're approving it too quickly.

MR. AMANAT: That's exactly correct.

THE COURT: But, you know, fundamentally here, there's a difference between -- look, I am not an expert in this but this is a -- there's a fundamental difference between approving a new drug for use by humans and simply deciding whether or not a drug that's been safely used by X numbers of hundreds of thousands of people and which their own experts tell them can be safely used, can be sold over the counter.

MR. AMANAT: Well --

THE COURT: There's a big difference.

MR. AMANAT: And it's a very different type of analysis.

THE COURT: Right. And it does not necessarily have to be -- you know, you don't have to do experiments on rats and you don't have to do a lot of other things that you have to necessarily do before you decide whether you want to authorize the approval of a drug for use by humans.

It strikes me that it's a much less difficult and complex issue. But in any event, that is an issue of fact as to why they haven't decided it and whether the delay was reasonable and whether or not they're improperly stalling a

decision here.

MR. AMANAT: Well on that question, your Honor, let me just make, in concluding if I may, a couple of observations. We don't believe the allegations in the complaint support a claim for unreasonable delay. Even if your Honor believes that the plaintiffs new cause of action under 7601 does survive a motion for judgment on the pleadings, we would ask that your Honor allow the next step to be the submission to the Court of the administrative record or the subset of the administrative record that the parties agree is relevant to that issue.

THE COURT: Who stops you? I told you to do that months ago.

MR. AMANAT: And to have that issue briefed on cross motions for summary judgment.

THE COURT: I am --

MR. AMANAT: We do not believe that there's --

THE COURT: First of all, you could do whatever you want but I am not dealing discovery. I don't require people to get my permission to make motions for summary judgment but that's what you should have done to begin with. But except, you know, I think you're engaged in continuing this administrative agency filibuster with a filibuster of your own.

MR. AMANAT: Well, I disagree, your Honor.

THE COURT: No, you did. You insisted. You asked me to delay the filing of this motion because of a

representation that this issue was ultimately going to be decided. It wasn't decided, notwithstanding, you know, admittedly weaslely (sic) worded letter to Senator Clinton, but that's ont he basis of which you delay this proceeding for three months.

Now you make a frivolous, in my view, motion at least with respect to the unreasonable delay, and then you want to say well, now that I failed on this, I am going to make a motion for summary judgment based on the administrative record.

Do whatever you want but I am not going to stop you from making a motion but I am not going to delay discovery.

MR. AMANAT: Well, your Honor, with regard to the question of discovery --

THE COURT: And they could also make a cross motion for summary judgment.

MR. AMANAT: With regard to the question of discovery, I would again advise your Honor that we extensively briefed before Judge Pohorelsky a motion for a protective order in which we laid out in some detail all of the reasons why there should be no discovery and why this case should be decided only on the basis of the administrative record.

THE COURT: I don't believe that the unreasonable delay portion can be decided on the basis of the administrative record.

MR. AMANAT: Well, your Honor, but that's what the

cases say. The plaintiffs will --

THE COURT: No, but you're making an argument to me and you've made it before, this is because the agency has to balance priorities. How do I know that that's the reason?

MR. AMANAT: Well, but, your Honor, the case is -- the plaintiffs were unable to cite in opposition to the motion for protective order --

THE COURT: I --

MR. AMANAT: -- a single case in which any court has said that on a cause of action under 7061 alleging unreasonable delay, that discovery beyond the administrative record was permitted. We cited numerous cases which says it's categorically not permitted. And we haven't submitted those cases to your Honor because that matter is before Judge Pohorelsky.

THE COURT: Why is it not permitted on an unreasonable delay claim?

MR. AMANAT: That's what the cases say.

THE COURT: I am asking --

MR. AMANAT: I could cite the cases for your Honor.

THE COURT: You know, why is the reason I am asking for those cases. I assume I am not bound by any of them.

MR. AMANAT: I beg your pardon?

THE COURT: I assume I am not bound by any of those

cases.

MR. AMANAT: Well, they're appellate cases, your Honor.

THE COURT: Well, I don't know.

MR. AMANAT: I don't know that the issue has been decided in the second circuit but --

THE COURT: Well, what is the reasoning?

MR. AMANAT: Well, the reasoning is that in other forms of claims under the APA, APA claims are decided on the basis of the administrative record.

THE COURT: Well, I mean, that's true as a general matter. Obviously, if you had reached a final decision, it would have to be decided on the basis of the administrative record. But it seems to me that where there's a claim of unreasonable delay --

MR. AMANAT: Well --

THE COURT: -- factors that go to the issue of reasonableness, particularly where you have -- where there are indications that this has not been handled in the ordinary course, in the ordinary way that these applications are handled, should be explored in discovery. I mean, you've got to give me a reason.

MR. AMANAT: Well, I don't have these cases with me but I will read you --

THE COURT: Well --

MR. AMANAT: -- if I may, the footnote, that we submitted to Judge --

THE COURT: Give me the strongest case.

MR. AMANAT: The strongest case is called San Francisco Bay Keeper v. Whitman (phonetic). It's a ninth circuit case from 2002.

THE COURT: What's the cite?

MR. AMANAT: It's 297 F.3rd 877 which said, "The judicial review is on the administrative record even in a case based on agency inaction." Another case --

THE COURT: I'm going to read the case. I need to know the reasoning behind it.

MR. AMANAT: Yes.

THE COURT: I can't deal with decisions that are based on -- where all you're giving me is the whole --

MR. AMANAT: Another ninth circuit case is Friends of the Clearwater v. Dombeck (phonetic), 222 F.3rd 552, ninth circuit 2000 case which specifically reviewed the agency's failure to act on an open ended administrative record.

I also cited cases from the District of Columbia, from the Eastern District of Pennsylvania.

THE COURT: Well, the question was whether in those cases -- I mean, again, I can't deal with giving me citations for a holding, whether in those cases there was evidence that would suggest that -- evidence outside the administrative

record that would shed light on the reasonableness of the delay.

I mean, there's some reason here to believe that there are factors that play here in the failure to decide their application that would not be necessarily completely reflected in the administrative record.

MR. AMANAT: Well, but, your Honor, again my point is that on the discovery issue, before your Honor --

THE COURT: Why are you afraid of discovery, by the way?

MR. AMANAT: Why am I afraid of discovery? Well, I will give you a perfect example of why I am afraid of discovery. Because the plaintiffs initiated discovery.

THE COURT: Right.

MR. AMANAT: They initiated discovery by undertaking a fishing expedition in which they asked us essentially to compile the administrative record for all 66 applications in which various drug manufacturers over the last ten years approved or sought the approval of OTC status for prescription only drugs.

It's not so much that I am afraid of discovery as I am -- I am not at all afraid of discovery, your Honor. It's the fact that they're not entitled to discovery.

THE COURT: I know, but if the FDA didn't object there certainly could be discovery and I wouldn't --

MR. AMANAT: But the FDA does object --

THE COURT: But what I am asking --

MR. AMANAT: -- very strenuously.

THE COURT: I know. But all I was asking was why?

MR. AMANAT: Well, precisely because -- I mean, first of all, there's the principle matter that APA cases are decided on the administrative record, that --

THE COURT: Where is the language?

MR. AMANAT: It's on page --

THE COURT: I mean, I agree that normally they are but --

MR. AMANAT: -- 886.

THE COURT: -- it's normally decided on administrative record --

MR. AMANAT: Right.

THE COURT: -- where you're basically reviewing the decision to either grant or deny relief.

MR. AMANAT: All I wanted to say, your Honor, is that before your Honor assumes that there will be discovery in this case or orders that there should be discovery --

THE COURT: I don't know that they need all of that at the moment because they have a GAO report that says this wasn't done in the ordinary course, in addition to, I believe,

possibly statements of FDA employees.

MR. AMANAT: But we would ask, your Honor, that before your Honor makes any ruling on discovery, that your Honor allow Judge Pohorelsky to make such a ruling because the matter is fully briefed before him. And if the plaintiffs then have a problem or if either side has a problem with what Judge Pohorelsky decides in response to our motion, then they would have their rights under the rules to appeal to your Honor and your Honor could then make the decision at that time.

THE COURT: I don't really want to go through, you know, this endless delay that you have contemplated here.

MR. AMANAT: But we would submit, your Honor, that the --

THE COURT: Could you stop for a minute?

MR. AMANAT: Yes.

THE COURT: Where in this ninth circuit case --

MR. AMANAT: Page 886, your Honor.

THE COURT: It seems to say the opposite but I am -- it says Bay Keeper is correct. I'm reading from 886. "Bay Keeper is correct that generally judicial review of agency action is based on as said, administrative record."

MR. AMANAT: Right.

THE COURT: "However, when a court considers a claim that an agency has failed to act in violation of a legal obligation, review is not limited to the record as it existed

in any single point in time because there is no final agency action to demarcate the limits of the record."

I mean, this suggests that you're not bound by the administrative record.

MR. AMANAT: No, what it suggests is you're bound by the administrative record but the administrative record is an open ended universe of documents that continues to --

THE COURT: Well --

MR. AMANAT: -- be developed as the administrative -- as the underlying administrative proceedings have developed.

THE COURT: I don't know. I don't find these -- is that the strongest case you have?

MR. AMANAT: Well, there's also, as I mentioned, Friends of the Clearwater v. Dombeck.

THE COURT: I'll read it.

MR. AMANAT: 222 F.3rd 552 560.

THE COURT: I will read it.

MR. AMANAT: In any event, your Honor, we would ask that for the reasons that we set forth at some length in our briefs, that the Court grant our motion to dismiss this case and that in the alternative, that if the Court is not prepared to do so at this juncture, that the next step would be for the parties to submit cross motions for summary judgment on the administrative record. And that there be no discovery.

THE COURT: I'm not one of these judges who has to grant anybody -- needs to grant anybody permission to make a motion for summary judgment.

MR. AMANAT: I understand.

THE COURT: But what I am not going to do is delay the case from going forward.

MR. AMANAT: But, your Honor, allowing them to take discovery would delay the case from going forward.

THE COURT: Well --

MR. AMANAT: It would because we would have to complete discovery before the parties could --

THE COURT: To the extent that anybody wished to take discovery, you would have to complete it. But at least the issue of the motion for summary judgment gets decided on a complete record.

MR. AMANAT: Well, we believe that the Court has the complete record that it needs --

THE COURT: I'm sure you do.

MR. AMANAT: -- for purposes of deciding this --

THE COURT: I'm sure you do.

MR. AMANAT: -- based on the --

THE COURT: I'm sure you do but I am not sure -- I mean, look, do you want to accept the GAO report?

MR. AMANAT: I don't believe that the GAO report

reaches any conclusions that have any bearing on the --

THE COURT: Well, it --

MR. AMANAT: -- claims that the plaintiffs raise here.

THE COURT: It does have a bearing on the issue of the good faith of the agency and the reasonableness of the delay.

MR. AMANAT: I disagree with your Honor.

THE COURT: I know you're going to disagree with it.

MR. AMANAT: Would your Honor like to hear why?

THE COURT: Whatever I say that's inconsistent with your position, you're going to disagree with.

MR. AMANAT: Would your Honor like to hear why?

THE COURT: Yes.

MR. AMANAT: Well, for one thing, with regard to unreasonable delay, the GAO report only examines the course of administrative proceedings --

THE COURT: Right.

MR. AMANAT: -- through May of 2004.

THE COURT: Right.

MR. AMANAT: It doesn't even purport to address anything that happened after May of 2004.

THE COURT: I understand that but the conclusions that it reaches through 2004 shed some light on this.

MR. AMANAT: Well --

THE COURT: I am not going to assume as a matter of law that the agency has acted in good faith here. I told you that in the preliminary order that you entered. I said, you know, I am not going to decide that issue as a matter of law based on everything that's before me.

MR. AMANAT: But the GAO report didn't say that the agency acted in bad faith. They said that the agency's process was unusual.

THE COURT: Well, I understand that.

MR. AMANAT: Unusual doesn't state a claim under the APA.

THE COURT: Well, listen to me.

MR. AMANAT: Unusual is not arbitrary and capricious. Unusual is not in violation of the Constitution. Unusual simply means that the course of proceedings in this case was --

THE COURT: Not in accord with how the agency normally conducts business.

MR. AMANAT: But this --

THE COURT: That's what it means.

MR. AMANAT: But this drug is sui generis as the plaintiffs have themselves said in the papers.

THE COURT: Oh, come on.

MR. AMANAT: You know, and the controversy generated

by this drug is sui generis.

THE COURT: Well, I don't know --

MR. AMANAT: So, it's not surprising that the process is unusual.

THE COURT: I don't know what to degree the controversy generated by the drug is relevant to the agency's determination. Controversies are not necessarily related to the safety of the drug.

MR. AMANAT: Well, it's relevant that only in the sense, your Honor, that one of the core findings of the GAO report and concluding that the process was unusual and one of the core findings that the plaintiff's continue to harp on is the fact that the decision in this case was made by high level agency officials. It seems logical and reasonable and it's an every day occurrence.

THE COURT: It's not an every day occurrence, otherwise it would not be unusual.

MR. AMANAT: No, no. What I am saying is it's an every day occurrence that when an agency is confronting an issue which is not routine which engenders a great deal of public interest, which engenders a great deal of interest from many quarters within society, that the decision making process is going to be kicked up to the next level of the chain of command. That's something which is to be expected rather than allowing those controversial decisions so-to-speak to be made

by the lower level officials who may act on the more routine aspects.

THE COURT: The scientific evidence -- who may act under scientific evidence.

MR. AMANAT: No. You know, in this case, the decision makers did act on the scientific evidence but they also brought to bear perhaps a different perspective on the conclusions that could be drawn or should be drawn from that scientific evidence.

THE COURT: All right. You have made your points.

MR. HELLER: Your Honor, I will try to be brief. I wanted to begin by briefly addressing standing. I think to some degree the plaintiffs in this case may stand in the shoes of Barr. Frankly, I don't know and I think it's a factual issue as the Court indicated, what Barr's -- where Barr's interest lies here. Does their interest lie in accommodating the FDA so that their other drugs get approved fairly? Does their interest lie in avoiding some political controversy if they were to file a lawsuit seeking over the counter status?

I don't know where the interest lies. It's clear that for some reason, they made a decision to pursue a more limited over the counter status.

So, our interest, the interest of these plaintiffs which is an unrestricted over the counter status may to some degree overlap with Barr's and may to some degree stand in

their shoes so-to-speak. And to that degree, we may be pursuing something that Barr -- a result that Barr would be happy with. We don't know.

THE COURT: It's possible. There's a real issue as to why they're essentially acquiescing in what the FDA wants.

MR. HELLER: Exactly. At this point, unfortunately due to the -- I think the stay on discovery, we couldn't even take the deposition of a Barr official and ask them why did they accommodate the FDA, so we can find out.

THE COURT: Yes, well I am going to lift that stay.

MR. HELLER: The second sort of standing we have here is as the Court indicated, one of our -- one of the plaintiff's, one of my client's, is one of the citizen's petitioner's.

THE COURT: Right.

MR. HELLER: And they have remained now for --

THE COURT: There's no question. There's no question you have standing on your own claim. You have standing.

MR. HELLER: And I think the their type of standing which the Court also eluded to is the second kind of third party standing which has been rather routinely accepted by the federal courts which is the standing of people who stand in sufficiently close relationship to user's contraceptives specifically, such as Eisenstat v. Bayer. We had some --

THE COURT: Also beer.

MR. HELLER: What's that?

THE COURT: Also alcohol.

MR. HELLER: Or alcohol, exactly. Commercial sellers who want to sell something to the consumer --

THE COURT: I understand.

MR. HELLER: -- they have in general been granted third party saying to represent the interest of those consumers.

THE COURT: I understand that but it's all reconcilable. It's all consistent with the doctrine of third party standing.

MR. HELLER: The beer seller or the contraceptive seller has an interest of his own in selling the product and therefore satisfies the injury as to himself and the people who are the potential purchasers. It's not practical for them really to bring actions in their own name.

So, you basically satisfy -- those are clear examples of the third party standing. In fact, in the Batson case which is Powers v. Ohio, Justice Kennedy cited those cases and said, you know, these are examples of instances and the actual -- Powers is interesting because the actual injury to the defendant in a Batson case, the supreme court has articulated what Batson is about, is very, very -- it's almost in the air.

MR. HELLER: Etherial.

THE COURT: Etherial. It's potential, at most. I mean, if you read Kennedy's opinion, he was pulling things out of the air to essentially justify it.

MR. HELLER: I think in our case, certainly for example, we have individual plaintiffs --

THE COURT: I agree with you about that.

MR. HELLER: -- who obtain prescriptions. All right.

THE COURT: I don't know what --

MR. HELLER: I won't belabor it.

THE COURT: I mean, I agree that we have these two separate claims or three actually. First, is the extent at which you assert third party standing to argue on behalf of Barr, I think that that depends on discovery as to why Barr is not here but assuming you can show why Barr is not here and that it would otherwise satisfy the test, the question is why this case doesn't belong in the court of appeals.

MR. HELLER: And let me just briefly address that. I think there's very, very, limited case law on the applicability of I think it's 355(h), title 21, which makes this provision for an applicant --

THE COURT: Right.

MR. HELLER: -- who has been an applicant for drug approval --

THE COURT: Right.

MR. HELLER: -- whose application has been denied, to bring --

THE COURT: Which you are, by the way, in both capacities; whichever, third, first.

MR. HELLER: In one of the parties -- to bring a case directly to the --

THE COURT: Right.

MR. HELLER: -- appeal directly to the court of appeals.

THE COURT: Right.

MR. HELLER: But a couple of courts have addressed this and I will acknowledge that it's largely in dicta but what they've said is, for example, the first circuit -- I believe it's the first circuit in Bradley v. Weinberger (phonetic), which is 483 F.2nd 410 in footnote 1, the Court says, "The right to petition the court of appeals for review under 21 USC 355(h) is available only to a drug marketing applicant after an order refusing or withdrawing approval of a drug application."

THE COURT: Well --

MR. HELLER: I read that statement to mean --

THE COURT: I understand you could read it to support the view that it's not available to you and, therefore, you should be able to come here but did that case involved, you know, a circumstance of the kind that we have here, where a

third party essentially was saying put me in the shoes of Barr?

MR. HELLER: Well, this was a case involving suit by physicians and a patient to enjoin the FDA from complying with proposal for relabeling certain drugs. It's quite clear that you have on the one hand, a manufacturer who sort of puts forth the labeling, gets approval for the labeling and on the other hand, you have these physicians and patients who have a different -- perhaps a different interest.

THE COURT: Well, that's --

MR. HELLER: And the Court said --

THE COURT: But they're arguing against, in effect, what the manufacturer wanted. It just -- you know, I have to say that intuitively, it doesn't make sense to me that to the extent that you stand in the shoes of Barr, that you shouldn't go to the forum where Barr would have to go.

Now, there's nothing to preclude you from doing that while we're doing business in this case. The one possible thing is there is a statute of limitations but at least with respect to the August letter, I think that I can treat your -- the filing that you filed within 60 days of the August letter as, in effect, seeking review of that August decision. But I think that in this context, it seems to me the place for that is the -- it seems to me what would make sense as a practical matter and aside from the fact that you think I'm sympathetic now to your position, it's quicker to go directly to the court

of appeals than it is to go through here and then whatever I do, there is going to be an appeal to the court of appeals.

And I assume perhaps one of the reasons for providing for direct review is to eliminate -- at least that's normally why congress does that, they've just done it in immigration cases, is because they want a process that moves faster.

MR. HELLER: I just want to give the Court just one additional citation.

THE COURT: I will look at them.

MR. HELLER: This is a case from the Western District of Wisconsin, Barnes v. Shalayla, 865 F. Sup. 550. And there the Court again was -- this was a case against HHS and the FDA, and the Court -- it was suggested by the secretary of HHS that the case belonged in the case of appeals under 355(h). The Court said as a general rule if the statute does not specify the appropriate forum for judicial review of an administrative action, the presumption is the review is available in a federal district court under 28 USC 1331, federal question statute.

And the Court said, "Therefore, as in non-applicants," because the plaintiffs there were not drug manufacturers applying for drug approval, "as non-applicants, plaintiffs are making a different challenge from the kind congress contemplated when it enacted 355(h)."

So, while I agree with the Court that going directly to the court of appeals might sort of skip a step in terms of expedition of the case, moving the case forward, I think that at least under these limited -- and again it sets a precedence that sort of -- that are largely dicta because I haven't been able to find a case that sort of says, "This federal district court is trying to win a case at the court of appeals because it can't -- doesn't have jurisdiction."

THE COURT: Well, the question is is there a case -- I mean, it doesn't strike me, I mean to the extent I -- maybe I didn't hear it correctly, that what you were dealing with was someone who basically wanted an applicant wanted and what the applicant didn't get and, therefore, was going to the court of appeals to seek review in a sense, in the shoes of the applicant of an adverse administrative agency determination.

MR. HELLER: I know of no such case. But I will say that again, we go back to the issue of what does Barr want? Is what Barr want what we want or is there a major difference which is --

THE COURT: Well, there is.

MR. HELLER: -- want unrestricted access.

THE COURT: There is. But to that extent, you have your own standing. I mean, this is where there is obviously a difference but that gets to the issue of how we handle your own, as opposed to the issue of Barr's application.

MR. HELLER: I agree. I think it would not be unreasonable if we were solely standing in Barr's shoes to say well, then you are the applicant. You are supposed to go under 355(h). I think that because we are alleging things -- we are both seeking relief that Barr may not want, in fact.

THE COURT: I don't know that it doesn't want but let's put it this way, it's acquiesced in the concerns of the FDA.

MR. HELLER: Well, also --

THE COURT: They originally wanted it.

MR. HELLER: We are also, perhaps, making arguments that Barr would not make. I have no idea whether Barr would make an argument that constitutional rights are violated by the FDA's action, where as we are.

THE COURT: Well, I --

MR. HELLER: So, I think it's a hard and novel issue about where jurisdiction --

THE COURT: Well, if they were really serious, they would make the argument.

MR. HELLER: Well, that may be true. So, I just wanted to say that about the standing jurisdictional questions and then I wanted to say a couple of words about discovery. We did propound discovery to the FDA that at the time we propounded it, we had no idea whether what we were asking for was, you know, three cases of over the counter approvals or

500.

We were unable to, I think, effectively negotiate in any way to limit the scope of discovery because the FDA's position was you get no discovery. I am more than happy to try to limit the scope of discovery, so that we can really determine sort of was this process genuinely different, as much of the administrative records suggest. Was it really very different from what had been done before?

Every drug is sui generis. I don't think we've claimed this is sui generis in terms of its scientific or medical safety --

THE COURT: No, I think your argument though is in terms of other forms of birth control and that it was unusual in that respect.

MR. HELLER: In that respect. But it's not unusual in terms of the type of evidence you would need to show that it's safe or effective for over the counter use. In fact, with the citizen's position, the three or four page document, the FDA also received in support of that, affidavits from experts testifying that it was safe and effective for over the counter use. So, it wasn't quite just four pages.

But in any event -- so one area of discovery was sort of was this process abnormal? Another area was what were the reasons for the decisions the FDA made? We know that the scientists -- there was an overwhelming consensus among the

scientists who reviewed the scientific data that this was safe and effective for over the counter use.

In fact, even after Barr acquiesced and said we only want it for 16 and over, the scientists persisted. They said that should not be approved. The FDA should approve it with no age restrictions because the scientific evidence doesn't support any difference based on age.

On the other hand, what we know about the use of --

THE COURT: Well, I don't want to interrupt your train of thought --

MR. HELLER: Yes, sir.

THE COURT: -- but I think we have to keep -- the question is what the discovery is designed to which cause of action?

MR. HELLER: Yes.

THE COURT: Is it to the unreasonable delay or is it to the claim that there is a fact of final decision and I should review that final decision on "your own standing."

MR. HELLER: I think that --

THE COURT: Or is it with respect to the issue of the unreasonableness of the delay?

MR. HELLER: I --

THE COURT: And then I don't want to -- go ahead.

MR. HELLER: I think it's on each of those, to some degree. What we know about the reasons for sort of steps that

were taken in the process, whether you view the end result as a final one as we do or as a --

THE COURT: Well, but that's important and, you know --

MR. HELLER: Well, we view --

THE COURT: I mean, you might win if it were -- you know, if they were certain they could win by turning it down, they would decide it.

MR. HELLER: Yes, I think that whether an agency's action is final, I think as the Court has indicated, is not determined by whether the agency issues some formal document stamped final decision.

THE COURT: Right.

MR. HELLER: It's determined by whether they've actually -- they're actually still actively considering something.

THE COURT: Right.

MR. HELLER: And it's clear not only from the public August letter but from the prior documents that scientists within the agency and I think we've put this in the letter sent to the Court yesterday, there were scientists who were essentially saying something like if this doesn't prove that this is safe for younger women, we have no idea what we could come up with that would ever satisfy the commissioner.

THE COURT: Oh, I understand that.

MR. HELLER: And so, the question is sort of is there some -- because it's not apparent from the administrative record, I think, is there some knowledge that these upper level people have about this drug being dangerous or requiring pharmacists or physicians other than what they've said, for example, you know, speculation about sex cults would form among teenagers if this drug were available over the counter. Is that the sort of scientific reasoning that --

THE COURT: But that information you have from the -- they can't rely on anything -- they can't rely on to sustain it if you were sitting to review a final agency action. They could only rely on what they've got in the record. They can't rely on something that's hidden.

MR. HELLER: Exactly. But in order to decide -- so, let's say first in order to look at whether the delay was reasonable, there are a number of things to look at. What are reasonable and appropriate for these higher level people to say this evidence isn't satisfactory?

THE COURT: Well, because that -- you know, the unreasonable delay part assumes that they haven't decided it.

MR. HELLER: Right.

THE COURT: So, you know, we're operating with two --

MR. HELLER: Two.

THE COURT: -- which you're perfectly permitted to

do as we have been through that --

MR. HELLER: Yes.

THE COURT: -- you're perfect permitted to argue that they've actually resolved it or if they haven't resolved it, there was unreasonable delay. So, the unreasonable delay proceeds on the premise that accepts his argument that there is no decision and then the question is well, why hasn't there been any decision and there, it seems to me, there might be some reason to examine further the issue of why there has been delay and why they have not finally resolved the issue.

MR. HELLER: I do think that the same limited discovery that might disclose why there has been delay is likely to also have been upon the merits --

THE COURT: So, okay.

MR. HELLER: -- of whether the decision was on --

THE COURT: It won't be fruit of the poison tree.

MR. HELLER: No.

THE COURT: I mean, if it serves two functions, it serves two functions.

MR. HELLER: I do want to just briefly note one example of why I think discovery would be fruitful in general in shedding light on some of these issues which is one small piece of the administrative record that we received was some e-mail correspondence between someone named Galson (phonetic), who was one of the key officials involved in this, shortly

before May of 2004, in which he seeks some documentation for a point he wanted to make in his final decision to issue a non-approval letter.

What struck me is not so much the content of this e-mail, which is I think the GAO report refers to this exchange, as well, but that this is the only e-mail correspondence that's in the administrative record. Where are -- I mean, I find it really hard to believe that this is it. That there's no other e-mail correspondence in the FDA about this entire process other than the two pages that they've included in the administrative record. And that's an additional reason to allow that. It's a -- THE COURT: I mean, they don't necessarily -- I don't know that you need all of that now. But I mean, this is not something that -- these are public documents that are available and you can just look at the public records if that's the road you want to go down.

MR. HELLER: I think that there's -- I think I have said enough about discovery.

MR. AMANAT: May I briefly say something in response, your Honor?

THE COURT: Go ahead.

MR. AMANAT: Mr. Heller's discussion of discovery suggests that they are intending to use discovery to really probe the decision making process and the thought process of the decision makers here including, for example, by taking

depositions of high ranking government officials.

We would strenuously object to that. I think all of the information that Mr. Heller indicated would be relevant or probative to the causes of action which the plaintiffs have asserted here is in the administrative record.

And to the extent that he indicated, for example, that the needs to know what was the basis for the agency's decision making process, you know, for the decisions it made. For example, the decision that was made in August to proceed with the advanced notice of proposed rule making, that's in the administrative record, the rationale behind that.

In terms of why did Barr amend its supplemental new drug application and replace it with this new dual marketing proposal that's in the administrative record, Barr submitted a very extensive discussion as to why it was doing that, I don't believe discovery would add anything to any of those questions.

I think the question of unreasonable delay, the question of any substantive review of the merits of any decision which the Court finds the agency has finally made, can be reviewed and need to be reviewed based on the administrative record. We would --

THE COURT: That's on the decision that have made of which you claim there isn't any.

MR. AMANAT: I beg your pardon?

THE COURT: There's no decision that they've made.

MR. AMANAT: Well, we don't believe that the agency has made any findings.

THE COURT: No, I understand that.

MR. AMANAT: But if your Honor --

THE COURT: So, then we're left with the delay part.

MR. AMANAT: Well, as to the unreasonable delay, the reasons why the agency has made its various decisions along the way, decisions not to decide are all documented in the administrative record.

The question whether those -- ultimately, the question of whether there's been unreasonable delay turns on whether the various steps of the administrative process the agency's decision not to decide was a supportable decision.

THE COURT: But suppose it was in bad faith. Suppose the real reason was not a justifiable one. That's not relevant to the issue of whether the delay was reasonable or not?

MR. AMANAT: Well, but they have made no showing of bad faith, your Honor.

THE COURT: That's what you say.

MR. AMANAT: Well, your Honor, we would submit that we haven't briefed that to your Honor. We briefed that to Judge Pohorelsky.

THE COURT: What you'll tell me is the same thing.

MR. AMANAT: Well, if you --

THE COURT: But, you know, fundamentally there's been to my mind, an extraordinary delay here.

MR. AMANAT: Well --

THE COURT: And certainly in dealing with their petition, you've basically not decided it.

MR. AMANAT: Your Honor, I understand your Honor's --

THE COURT: And even on the issue of whether, you know, you stand here and say oh, that's not final about over the counter to people under the age of 17, it's clearly still being considered.

Why shouldn't the head of the agency be asked to say that under oath?

MR. AMANAT: Well, he's explained the reasons for that.

THE COURT: Under oath? Why shouldn't he be questioned about that?

MR. AMANAT: Well, because the case law --

THE COURT: I'm not what has he explained. You're telling me that they're still considering -- they're still actively considering the possibility of authorizing if the people under the age of 17 --

MR. AMANAT: Would your Honor like us to supplement the administrative record, the affidavit from --

THE COURT: I don't --

MR. AMANAT: -- the head of the agency?

THE COURT: I'm not sure that they're necessarily bound by the affidavit but it would be nice since you're saying all of these things.

MR. AMANAT: If your Honor would like us to supplement the administrative record with such a statement, we could do that.

THE COURT: I don't know what supplementing the administrative record means. There's a record here of which the administrative record is a part.

MR. AMANAT: My point, your Honor, is I know that your Honor is anxious to move this case along and we're anxious to move this case along. But my point is that before your Honor orders or authorizes any discovery n this case, at the very least we would ask your Honor to review the briefs which the parties -- the extensive briefs, which the parties submitted on the motion for a protective order.

THE COURT: Well, I don't know how operative they are at this point. I don't know precisely -- is it clear what you're asking for at this point?

MR. AMANAT: They're asking --

THE COURT: You?

MR. HELLER: Well, we're just asking -- do you mean in terms of discovery?

THE COURT: Right.

MR. HELLER: We're just asking for discovery to proceed in the normal way that it would, that we -- or they propound discovery, we make objections and they're ruled upon as they go and to have absolute bar on discovery lifted.

THE COURT: Well, that I am going to do.

MR. AMANAT: But, your Honor, the basis for our motion for protective order, we made a motion before Judge Pohorelsky asking him to preclude any discovery in this case and we offered the reasons and rationale for doing so.

THE COURT: I'm not precluding discovery on the issue of whether there's been unreasonable delay.

MR. AMANAT: Can we at least submit the briefs on the issue, your Honor?

THE COURT: I'm not -- you could submit it to me but I am not -- my feeling now is I will reconsider it after I read your briefs.

MR. AMANAT: Well, what would --

THE COURT: But my basic feeling -- look, you could solve this problem in part. You could acknowledge that there's a final decision here and then we don't have to deal with the unreasonable delay. Instead, you don't want to acknowledge that there's a final decision even though it's quite clear to me that there has been one and essentially, you want to argue that -- notwithstanding the fact that there is no final decision, there's been no unreasonable delay.

And you could solve a lot of these problems by simply being honest and say they've decided it and then we don't have to get into the issue of unreasonable delay and I can focus on where this case belongs.

But fundamentally, your positions -- they could have inconsistent positions as the plaintiff but I am not sure that you can have inconsistent positions as a defendant. But it's your choice. If you can have it, you can have it.

But fundamentally, you could just be honest and say yes, it's been decided. We have -- the drug may not be legally marketed over the counter at this time and when it might be, you can't say, can you?

MR. AMANAT: No.

THE COURT: No. It could be five years from now. It could be ten years from now. It could be never.

MR. AMANAT: Well, if your Honor -- your Honor seems inclined to --

THE COURT: I mean, if you want to consult with your client and tell me a time, that might be helpful. But you know, this is an endless process and quite frankly, in my own view of the justifications for this rule making is that it's absurd. But that's a separate issue.

You have either decided it, in which event you could have your decision on the administrative record. The only question is where or you could take the position you haven't

decided it, to which event I am not going to stop them from taking discovery on the issue of whether there's been unreasonable delay. And if you have specific objections, you could deal with it --

MR. AMANAT: Well, what --

THE COURT: -- you could take it up with the magistrate.

MR. AMANAT: What would the scope of that discovery look like?

THE COURT: Well, I don't know what they're asking for yet. I'm just -- all I am doing is lifting an absolute ban on discovery. And when they make a particular discovery request that you're unhappy with, you could make a motion.

So, I'm going to deny the motion to dismiss the cause of action based on reasonable delay. I'm going to deny for the moment, the cause of action until I decide where it should properly be brought, the cause of action that the plaintiff's bring on their own based on the citizen's application. And to the extent that they're standing in the shoes of Barr, it seems to me they have to stand in the court of appeals on that one, that this isn't the place to stand in Barr's shoes isn't Barr's forum.

I would suggest, although I don't think it's -- that you amend this complaint one more time to deal with some of the things that I have suggested that I think ought to be in the

complaint that are particularly dealing with this letter of --

MR. HELLER: Well, I think there is both information from that letter and from the administrative agency record which are included in the allegations of the complaint.

MR. AMANAT: Is your Honor prepared to make a ruling on their claims of constitutional violation and our motion to dismiss those claims?

THE COURT: Well, I don't know that I have to. I mean, it seems to me that -- I mean, I have sort of a pragmatic rule of thumb that basically says that, you know, where a number of causes of actions arises, common nucleus effects and I sustained one. I don't necessarily have to rule on all of the others in the interim.

They certainly, to the extent that they have a viable claim, that if there has been a final decision and it's reviewable judicially, the statute itself gives them the right to allege any violations of a constitution that may have taken place as a result of the final agency decision. So, I don't see why I have to -- I don't know why I have to rule on that independently right now.

MR. AMANAT: The reason I raise it, your Honor, is that in the course of our discussions before Magistrate Judge Pohorelsky on the subject of the scope of discovery --

THE COURT: Right.

MR. AMANAT: -- the plaintiffs repeatedly insisted that their entitlement to seek discovery and their justification for the scope of the specific discovery that we're seeking, lies in the fact that they had raised these constitutional claims.

THE COURT: Well, they have a right to raise the constitutional claims. To the extent that there's a final order and, you know, I really think it's final clearly as to the people under the age of 17, they have a right to say that one of the things that's wrong with this order is that it's unconstitutional and that it violates their constitutional rights. The statute, I believe, it's right in the statute that provides for judicial review.

MR. AMANAT: Right.

THE COURT: So, they have a right to say that to the extent that the order is a final order that it violates their constitutional rights. so, I don't --

MR. AMANAT: But that wasn't our argument, your Honor. Our argument was that the allegations which they raised failed to state an actionable claim under either the right to privacy or (inaudible).

THE COURT: Well, why do I have to decide that now?

MR. AMANAT: Because if your Honor -- I understand your Honor's usual practice as set forth in your previous decision --

THE COURT: This applies more so here since they have this -- they can raise this claim in a -- as part of the review of such -- as part of the review, to the extent that there may be a final decision here.

MR. AMANAT: So, my understanding, your Honor, that your Honor understands their constitutional claims as relating only to a potential claim under 7062.

THE COURT: That's my current feeling.

MR. AMANAT: So that if, for example, since your Honor is authorizing discovery --

THE COURT: For the moment, that's all I have to decide. Let me put it that way.

MR. AMANAT: Okay. And so if your Honor is authorizing discovery as to their claim under 7061 for the unreasonable delay claim --

THE COURT: Right.

MR. AMANAT: -- the fact that they have asserted constitutional claims in their complaint would not be germane then to the scope of any discovery --

THE COURT: Well, I am not sure.

MR. AMANAT: -- that would be permitted under 761.

THE COURT: I don't know what we're talking about. It seems to me that if there is a serious constitutional issue here that could go to the reasonableness of the delay, I mean, you know, if you accept the allegations of the complaint as

true, that what this delay is doing assuming that it's doing it, whatever the decision of the FDA because they would at least be able to obtain a review, and I assume for the purposes of this that it's true that this order is arbitrary and capricious, is essentially there are people, women, who may not be able to get access to this drug within 72 hours either because you have to call a doctor, you have to maybe get an appointment, unless he's prepared to write a prescription over the telephone, which I am sure you wouldn't be too happy about, you have to make sure that he's available.

And so the delay could result in someone becoming pregnant and having to have an abortion at some point. And I think that however you want to characterize it is a significant -- should be a very significant concern of the FDA in terms of how they go about processing this application, that you know, they're undertaking a course of action that could actually result in abortions that might not otherwise be necessary.

MR. AMANAT: The agency certainly has taken that consideration into account --

THE COURT: Sure.

MR. AMANAT: -- among the many other considerations its taken into account.

THE COURT: I don't know what discovery -- separate discovery you're looking at.

MR. HELLER: I mean, if I may just indulge a brief,

hypothetical example, it's pretty clear to me from the limited administrative record that I have time to review that one of the former commissioners of the FDA, Mr. McClellan (phonetic), had a significant role in thinking about and deciding what would happen with this drug.

Frankly, I myself don't find anything he said to be either scientific or reasonable based on evidence but my opinion doesn't count. If it turns out --

THE COURT: But he said what he said.

MR. HELLER: He said --

THE COURT: You know what he said.

MR. HELLER: Yes, we know what he said. But if it turns out that this is a pretext and I think there's significant indication of things happening in an unusual way with this drug, if it turns out that the commissioner of the FDA was told by someone who is his supervisor, you can't approve this drug period, this cannot be approved, not while we're in office, because it's a contraceptive drug who some people believe is an abortivefasion drug. We don't want it approved.

That would certainly be relevant to our constitutional claim. It's not going to be the administrative record.

THE COURT: But it would be --

MR. HELLER: It's our position --

THE COURT: Your constitutional claims would be -- are litigable in the administrative action.

MR. HELLER: They are. But it's also our position that we are entitled to, with respect to constitutional claims because constitutional issues --

THE COURT: I don't know why we have to get into the -- that goes to the -- what you're doing is saying is it simply goes to the reasonableness of the delay. But you're basically in effect --

MR. HELLER: Well, he's --

THE COURT: The conversation that you have -- the hypothetical that you give is that he is told by someone outside of the agency that they are not to decide this. And that goes to the reasonableness of the delay.

MR. HELLER: Yes.

THE COURT: I don't think you have to get involved in any issue about --

MR. HELLER: No, no, no. I'm just suggesting again that --

THE COURT: I don't see that this goes to what separate cause of action this is.

MR. HELLER: No, I am not suggesting that. I'm just suggesting that again, discovery may bear upon causes of action other than unreasonable delay.

THE COURT: Well, look --

MR. HELLER: Even though it's --

THE COURT: It's not a crime if you take relevant discovery to a particular cause of action if it also has a bearing on the other cause of action, you know, so it has -- it's simply has that bearing. It doesn't mean that there's something wrong with doing that. I think it's best not to get --

MR. HELLER: I agree.

THE COURT: -- caught up in confusion here. I don't have to rule on the constitutional claims and I may never have to.

MR. AMANAT: Is your Honor anticipating issuing a memorandum? I say that simply because there may be discussions or debates in front of Judge Pohorelsky as to the scope of discovery and he may, well obviously have the transcript of this proceeding, but it --

THE COURT: Well, why don't you do this? Why don't you -- I don't like to get involved in discovery just because I always hated it when I was a lawyer, but why don't you -- first of all, you should try and reach some agreement in good faith, so that you don't have to -- it may not be necessary to litigate every single discovery request.

But you could let me know first what it is and then I will tell you whether I could go to Pohorelsky or not. I think he told me his law clerk was going to be here and there

is also a transcript. His law clerk is here. There's also a transcript available of the proceedings but I don't want to delay things to write an opinion. I may write something but, you know, I am reasonably clear.

I don't know what you want to do with the Barr claim. If you want, I could transfer it to the second circuit. I don't know whether this is the second circuit or the third circuit, I don't know.

MR. AMANAT: Would there be a basis for concluding that Barr's an indispensable party to this action that needs to be added pursuant to Rule 19?

THE COURT: Tell me what it says.

MR. AMANAT: I'm sorry?

THE COURT: What does Rule 19 say, the indispensable part?

MR. AMANAT: Well, it talks about joinder, indispensable parties and it talks about -- I mean, your Honor's comments earlier suggest that your Honor felt it was difficult, if not impossible to --

THE COURT: Well, to my --

MR. AMANAT: -- adjudicate some of the --

THE COURT: Am I going to have compulsory interpleader of them as a plaintiff? I mean, I don't quite --

MR. AMANAT: Involuntary plaintiff, I assume that's what they would be.

THE COURT: I don't know.

MR. AMANAT: I am just raising the question, your Honor. If they're present in their explanation for their behavior is of such critical moment to adjudication to the plaintiff's claims --

THE COURT: Well, I don't know enough about interpleader actions to tell you the truth. I pull down books when I have to find out specifically what to do. I don't know as I sit here precisely whether I -- it's up to you to insist whether there's some sort of necessary party or for them to bring on a compulsory interpleader. It's not up to me. But I think you should tell me what you want to do with the cause of -- you don't have to do it right now, I mean, you could think about it.

MR. HELLER: With what, your Honor?

THE COURT: The cause of action relating to Barr.

MR. HELLER: Well, I think in order to decide whether we want to be viewed as standing in Barr's shoes, we would have to do, I am afraid, some very limited discovery of Barr to find out what their interest is and why they acquiesced the FDA's decision. I understand there may be some indication of that in the record but given -- I mean, for example --

THE COURT: Well, you know, you can't always assume that what people say in the record is accurate.

MR. HELLER: Right, it's --

THE COURT: They're not going to --

MR. HELLER: As far as I know, it's not under oath.

THE COURT: Aside from that, you know --

MR. AMANAT: It's a submission from their counsel, I believe.

MR. HELLER: Right.

THE COURT: I know.

MR. HELLER: Not from them.

THE COURT: If you assume hypothetically the reasons we've been speculating about it, it's pure speculation, they might not want to say that.

MR. HELLER: But we may need to do that but I mean, my own view is that indeed it is likely that Barr's interests in this drug's being approved or not for over the counter use are primarily commercial and that our interest, the interest of my clients are non-commercial and that's a significant difference.

THE COURT: No, I understand that.

MR. HELLER: Yes.

THE COURT: But that's the first part of giving you third party standing is that you have your own -- injury to your own interests and you want to, in addition to that, allege the interest of the third party. And I think -- we can go around on the circle on this. You have standing on your own complaints. The question is -- on your own -- on the citizen's

petition. The question is what you want to do about -- this whole issue of third party has been argued and the question is what do I do with that cause of action. I mean, I don't have to do anything now. I mean, you could take that limited discovery of Barr and then you could let me know. It may be that you can't satisfy the "hinderance" prong of this third party standing and then that would take care of that and then you would just be left with what I call sort of a clean case of your own without having to get involved in the --

MR. HELLER: I think we would probably want to do that limited discovery and then expeditiously inform the Court of our view of whether we can make such a sandbar issue or not, depending on the result of that.

THE COURT: Okay. So, for the moment I will reserve on that. I am denying the motion to dismiss across the board. What I do with that case, whether I, for the moment it's without prejudice to renewal, if you don't come up with anything that justifies third party standing and if you do, I think it's got to go to the circuit. And I deny the motions to dismiss the other causes of action.

As I said, I think the -- it seems to me that you could argue it either way, that they've decided it for the purpose of this -- you know, you have to keep reminding yourself that I'm not granting any relief here. For the purpose of this proceeding, it's whether I throw them out of

court.

MR. HELLER: Right.

THE COURT: And for the purpose of throwing them out of court, I think there's a strong enough basis to conclude that there has been a final agency decision on both and that if there hasn't been, it's one that's been unreasonably delayed. I think there's a sufficient basis, so that they can avoid dismissal of the complaint. Thank you.

MR. HELLER: Thank you for your time, your Honor.

(Matter concluded)

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C E R T I F I C A T E

I, ROSALIE LOMBARDI, hereby certify that the foregoing transcript of the said proceedings is a true and accurate transcript from the electronic sound-recording of the proceedings reduced to typewriting in the above-entitled matter.

I FURTHER CERTIFY that I am not a relative or employee or attorney or counsel of any of the parties, nor a relative or employee of such attorney or counsel, or financially interested directly or indirectly in this action.

IN WITNESS WHEREOF, I hereunto set my hand this **26th** day of **December** , 2005.

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Rosalie Lombardi
Transcription Plus II