

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF NEW YORK

-----X **Docket#**  
TUMMINO, et al. : 12-cv-763 (ERK) (VVP)  
Plaintiff, :  
 :  
- versus - : U.S. Courthouse  
 : Brooklyn, New York  
HAMBURG, et al,, :  
Defendant : May 7, 2013  
-----X

TRANSCRIPT OF CIVIL CAUSE FOR CONFERENCE  
BEFORE THE HONORABLE EDWARD R. KORMAN  
UNITED STATES SENIOR DISTRICT JUDGE

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1 THE CLERK: Tummino v. Hamburg. Your  
2 appearances, counsel.

3 MR. AMANAT: Good afternoon, your Honor.  
4 Frank Amanat, senior counsel, United States  
5 Attorney's Office, Eastern District of New York,  
6 appearing on behalf of the defendants, Dr. Margaret  
7 Hamburg, the Commissioner of Food and Drugs and Kathleen  
8 Sebelius, the Secretary of Health and Human Services.

9 THE COURT: Does she want the stay?

10 MR. AMANAT: I'm sorry?

11 THE COURT: Does Ms. Hamburg want the stay?

12 MR. AMANAT: I haven't heard anything to the  
13 contrary, your Honor.

14 THE COURT: Do you have anything affirmative?

15 MR. AMANAT: I don't know one way or the other.

16 THE COURT: It's no joke; I'm quite serious.

17 MR. AMANAT: I haven't heard about her plans  
18 one way or the other.

19 THE COURT: Because basically, what you're  
20 trying to stay is essentially the relief that she wanted  
21 to give and that was overruled by the Secretary. So now  
22 the Commissioner of the Food and Drug Administration  
23 wants a stay of an order that would give effect to what  
24 she thought was the appropriate relief in this case.

25 MR. AMANAT: That's correct, your Honor.

1 THE COURT: So now you're certain.

2 MR. AMANAT: Yes.

3 THE COURT: Okay. Before you didn't hear to  
4 the contrary.

5 MS. CREPPS: Your Honor, I'm Janet Crepps with  
6 The Center for Reproductive Rights. I'm joined by Andrea  
7 Costello on behalf of the plaintiffs.

8 THE CLERK: I will need you to keep your voice  
9 up, okay?

10 MR. CREPPS: Okay, thank you.

11 THE COURT: I'm sorry I had to make you work  
12 the weekend but I am going to California Friday. I sit  
13 on the Ninth Circuit next week and I wanted to get this  
14 resolved by Thursday. Otherwise, I would have given you  
15 all a little more time.

16 MS. CREPPS: It's no problem here.

17 THE COURT: Okay. It's your motion.

18 MR. AMANAT: I apologize, your Honor. I  
19 realize now that I misunderstood what you had asked me.  
20 I thought you said she wants to stay as in she's not  
21 planning on resigning. That's why I was --

22 THE COURT: Nor was anybody planning to fire  
23 her.

24 MR. AMANAT: -- uncertain about my answer. But  
25 yes, she and the Secretary are both jointly requesting --

1 THE COURT: And she asked the Solicitor General  
2 to authorize the appeal?

3 MR. AMANAT: And the Solicitor General has done  
4 so; yes.

5 THE COURT: No, no, but she asked him to?

6 MR. AMANAT: Yes.

7 THE COURT: Okay. You know that?

8 MR. AMANAT: Yes, I do.

9 THE COURT: Okay.

10 MR. AMANAT: So, your Honor --

11 THE COURT: Do you want to note your appearance,  
12 my amicus here, my friend?

13 MR. SHUMSKY: Good morning, your Honor.

14 Formerly proposed intervenor now amicus  
15 (indiscernible) by Mike Shumsky.

16 MR. AMANAT: Your Honor, thank you for the  
17 opportunity to appear before the Court on our motion.  
18 Let me begin with the substantial likelihood of success  
19 on appeal prong of our motion. Of course any party that  
20 makes a motion like we've made has a bit of a dilemma  
21 which is that we've already litigated the issues in this  
22 case in great detail. Your Honor has already reached his  
23 decision in a detailed opinion.

24 THE COURT: Right. And ninety-nine percent of  
25 which, as far as I could tell, you don't dispute.,

1 MR. AMANAT: Well for purposes of the stay, my  
2 job is not to relitigate the issues --

3 THE COURT: I understand.

4 MR. AMANAT: -- that the Court has already  
5 decided.

6 THE COURT: But you just said, you've got to  
7 show me that you have likelihood of success on the  
8 merits and as far as I could tell, the only thing that  
9 troubles you is my remedy.

10 MR. AMANAT: Well, let me get to that.  
11 Essentially what I am here to do is to try to persuade  
12 your Honor to accept the possibility that the Court of  
13 Appeals will conclude that your Honor's decision was  
14 wrong in some respects.

15 THE COURT: Anything is possible.

16 MR. AMANAT: Of course but you know --

17 THE COURT: You've got to do better than that.

18 MR. AMANAT: I know, it's --

19 THE COURT: And you even say that in your  
20 papers, you've got to do better than that.

21 MR. AMANAT: Well, we have to show less than a  
22 substantial likelihood --

23 THE COURT: Right.

24 MR. AMANAT: -- for the substantial  
25 possibility.

1 THE COURT: Right. That's right; yes.

2 MR. AMANAT: We don't have to persuade you that  
3 it's more likely than not that the Circuit will find that  
4 your Honor erred as long as the balance of harm tips in  
5 favor of the stay as it does here for reasons I'll  
6 explain. We only have to show a substantial possibility  
7 of success and I think we've done that.

8 In fact, I think we've shown for reasons I will  
9 elaborate, a substantial likelihood of success. Now I'm  
10 not going to try to relitigate issues as to which we  
11 don't think we stand a chance of convincing the Court.  
12 So instead we focused our argument with regard to  
13 substantial likelihood of success on two aspects of the  
14 Court's order as to which the order itself or else this  
15 Court's decision --

16 THE COURT: I don't understand what you're  
17 saying. The argument is that you think you have a  
18 substantial likelihood of success are two.

19 MR. AMANAT: Yes, right.

20 THE COURT: And --

21 MR. AMANAT: And we're focusing our argument on  
22 two aspects of the Court's decision that we think the  
23 decision itself or the Court's earlier decision, the 2009  
24 decision in Tummino I, support a likelihood of success on  
25 appeal.

1 THE COURT: From which you didn't appeal.

2 MR. AMANAT: True, you know --

3 THE COURT: Right.

4 MR. AMANAT: -- but there are aspects of that  
5 decision which we believe support a substantial  
6 likelihood of success after -- I mean what better  
7 authority to try to persuade your Honor of the  
8 possibility that the Court of Appeals might reverse than  
9 your Honor. So, the both aspects of the decision that  
10 we've highlighted in the Court's order essentially relate  
11 to the remedy that the Court awarded after finding agency  
12 action to have been arbitrary and capricious.

13 So first, the Court exceeded its subject matter  
14 jurisdiction in ordering agency approval of Plan B One-  
15 Step for unrestricted OTC availability and more broadly,  
16 in reviewing the agency's denial of the SNDA.

17 THE COURT: I did not do that.

18 MR. AMANAT: Well let me explain why we think  
19 that your Honor did.

20 THE COURT: You know, I think my own view of  
21 what I did will prevail in the Court of Appeals.

22 MR. AMANAT: Fair enough. But let me lay out  
23 the government's position.

24 THE COURT: In fact you quote twice what I said  
25 which is exactly that I wasn't doing that.

1 MR. AMANAT: Well, exactly. So the Court  
2 recognized that it doesn't have --

3 THE COURT: Right.

4 MR. AMANAT: -- the jurisdiction to review the  
5 SNDA or to grant relief with regard to the SNDA.

6 THE COURT: Exactly.

7 MR. AMANAT: But in the government's view, the  
8 Court's decision really can't be read in any way other  
9 than as a direct review of the SNDA and the end result of  
10 which is a directive to FDA to reopen it and to grant  
11 Teva's SNDA and here's why.

12 THE COURT: Absolutely not.

13 MR. AMANAT: Well, the Court's decision --

14 THE COURT: Absolutely not. In fact, the last  
15 thing I would want to do is give Teva any relief.

16 MR. AMANAT: Well, but the problem with -- and  
17 I understand that, your Honor. But the problem is that  
18 the Court, first of all, undertook an extensive review of  
19 the SNDA --

20 THE COURT: Right.

21 MR. AMANAT: -- and devoted the great majority  
22 of its decision to discussing that proceeding.

23 THE COURT: Look, you're going over what I -- I  
24 said that I wasn't ordering any relief to Teva and I did  
25 not order any relief to Teva. I explained in my opinion

1 that the denial of Teva's SNDA by the Secretary of HHS,  
2 not the FDA -- but the Secretary of HHS, was inextricably  
3 intertwined with the Citizen's Petition. If the  
4 Secretary is correct, then I would have denied the  
5 Citizen's Petition. And if she was wrong, I would have  
6 to go and address the merits of the Citizen's Petition.

7           The fact that from my conclusion that the  
8 Secretary was wrong led me to address the Citizen's  
9 Petition does not mean that I was granting any relief to  
10 Teva.

11           MR. AMANAT: But let's look at the relief that  
12 your Honor granted if I may for a moment. What the Court  
13 ordered the FDA to do was to "make levonorgestrel-based  
14 emergency contraceptives available without a prescription  
15 and without point of sale or age restrictions."

16           THE COURT: Right.

17           MR. AMANAT: In the, not the sentence but the  
18 sentence after that, the Court went on to expressly  
19 preclude FDA from complying with this directive by means  
20 of a rule-making. But here's the problem --

21           THE COURT: I didn't preclude them. I mean,  
22 you have to -- first of all, you're jumping around. The  
23 FDA had about thirteen years to do rule-making. In fact,  
24 it did rule-making once as part of the administrative  
25 filibuster that it engaged in here.

1           Again, this is not -- there's no absolute right  
2 that I have to keep remanding and the FDA could take  
3 three years and come back and do the same thing and then  
4 the only remedy that I can invoke is to remand again.

5           MR. AMANAT: Well --

6           THE COURT: Why did it not order rule-making  
7 before?

8           MR. AMANAT: Well, the agency explained the  
9 reasons for that on the record and we understand that the  
10 Court disagrees with that.

11          THE COURT: What reasons?

12          MR. AMANAT: The reasons that the agency  
13 articulated were --

14          THE COURT: First time around, I found that the  
15 process had been corrupted by political influence and I  
16 said, "I recognize that a remand is the appropriate  
17 remedy."

18          MR. AMANAT: Right.

19          THE COURT: And I remanded then because new  
20 administration was coming into office which I thought  
21 would be different from the administration that left and  
22 it turns out that the same policies that President Bush  
23 followed were followed by President Obama.

24          MR. AMANAT: Well --

25          THE COURT: And so that here again after I

1 remanded once because of the corruption of the  
2 administration agency process by political influence, the  
3 administrative agency process is corrupted again by  
4 political influence and now you want me to remand it  
5 again to the same people.

6 MR. AMANAT: Well --

7 THE COURT: Is that what you're saying?

8 MR. AMANAT: We do want --

9 THE COURT: Yes or no?

10 MR. AMANAT: Yes, we are asking --

11 THE COURT: Yes.

12 MR. AMANAT: Yes.

13 THE COURT: Yes.

14 MR. AMANAT: And --

15 THE COURT: Okay.

16 MR. AMANAT: -- and part of the government's  
17 position is that regardless of the grounds on which the  
18 Court found the denial of the Citizen petition to have  
19 been arbitrary and capricious, it's proper course of  
20 action again brought to have been to remand back to the  
21 agency again.

22 THE COURT: What would happened? What would  
23 happen on a remand?

24 MR. AMANAT: I can explain that to you.

25 THE COURT: Has the Secretary changed her

1 position? No. If you read the so-called confidential  
2 documents which you gave me for which Teva -- which Teva  
3 submitted to the Secretary, they were trying to comply  
4 with the Secretary's directive. In fact, they said so in  
5 so many words.

6 MR. AMANAT: Well, but your Honor, the process  
7 -- I want to emphasize --

8 THE COURT: I want to know what you would do if  
9 there was a remand. Has the Secretary changed her  
10 position?

11 MR. AMANAT: With regard to the younger  
12 adolescents?

13 THE COURT: What is your definition, by the  
14 way, of younger adolescents?

15 MR. AMANAT: Well, the Secretary hasn't changed  
16 her --

17 THE COURT: She didn't even -- I don't know,  
18 did she use the word younger adolescents by the way. Did  
19 she?

20 MR. AMANAT: The --

21 THE COURT: It was "the youngest of," wasn't  
22 those her exact words? What's the definition of that?

23 MR. AMANAT: Look, your Honor, this court --

24 THE COURT: And the point of the matter is,  
25 look, if we're only dealing with eleven or twelve-year-

1 olds or thirteen-year-olds, if that was the only issue in  
2 the case, it wouldn't make a hill of beans in terms of  
3 difference as a practical effect. But by hanging onto  
4 them, you're placing an enormous burden on older women.

5 MR. AMANAT: But what is the burden, your  
6 Honor?

7 THE COURT: What is the burden?

8 MR. AMANAT: Yes.

9 THE COURT: A photographic ID. You know that  
10 twenty-five percent, according to the Brennan Center of  
11 African Americans of a voting age don't have a photo ID?  
12 That eighteen percent of those between eighteen and  
13 twenty-five do not have a photographic ID? That a  
14 significant number of low income -- I forget the figures  
15 -- of low income Americans of voting age do not have  
16 photo IDs.

17 Let me ask you, if this were a voting rights  
18 case, you would be here on behalf of the Department of  
19 Justice telling me that this was voter suppression.

20 MR. AMANAT: But, your Honor --

21 THE COURT: Wouldn't you?

22 MR. AMANAT: The Supreme Court --

23 THE COURT: Is it your view?

24 MR. AMANAT: The --

25 THE COURT: As a matter of policy -- don't tell

1 me about the Supreme Court, isn't it the position of the  
2 Department that photographic identifications constitute  
3 voter suppression?

4 MR. AMANAT: But this is not a voting rights  
5 case, your Honor.

6 THE COURT: Exactly. It's not a voting rights  
7 case.

8 MR. AMANAT: This is --

9 THE COURT: But the reason for the Department's  
10 position in voting rights cases is because it prevents  
11 people from voting. It constitutes an impediment to  
12 their being able to vote. And those are adults who have  
13 time and it's an emergency situation. And you come here  
14 today when the Attorney General, by the way, cited these  
15 same figures in a speech to the NAACP and says that this  
16 obstructs people from voting. You come here and tell me  
17 that an emergency contraceptive which according to the  
18 label that Teva puts on it should be taken as close as  
19 possible after unprotected sex, that that doesn't operate  
20 to prejudice and discourage people older than -- forget  
21 about the thirteen-year-olds; I mean, they're such a  
22 small percentage that would use this pill that it  
23 wouldn't make a difference. The problem is because you  
24 focus on that, you're depriving -- you're putting an  
25 impediment to older -- not the youngest but the older --

1           MR. AMANAT: Well, except for the fact, your  
2 Honor, both the Supreme Court and the Second Circuit had  
3 found that there's no legally protected interest in  
4 purchasing a -- there's no invasion of a legally  
5 protected interest in having to show identification to  
6 purchase a product, even a contraceptive product. Whalen  
7 v. Roe, your Honor; it's what the Supreme Court said. The  
8 Berry v. New York, Second Circuit --

9           THE COURT: Yes.

10          MR. AMANAT: -- the Immitiatu (ph.) case. So,  
11 the government's position is based on that and the fact  
12 that now any person over the age of fifteen will soon be  
13 able to walk into any retail -- any of the 60,000 retail  
14 establishments in the United States that has an onsite  
15 pharmacy and be able to purchase this drug without --

16          THE COURT: Without what?

17          MR. AMANAT: -- a prescription, without having  
18 to take any measures other than what one would have to  
19 take to purchase Sudafed or Robitussin or smoking  
20 cessation drugs or any number of other products.

21          THE COURT: Right. And those were established  
22 by an act of Congress and they involved different kind of  
23 drugs. They weren't established pursuant to FDA  
24 regulation.

25          MR. AMANAT: And the --

1           THE COURT: And they can't get it because they  
2 don't have photographic IDs. That's the problem. They  
3 can't get it.

4           MR. AMANAT: But, your Honor, none of the --

5           THE COURT: Don't tell me that --

6           MR. AMANAT: There's no evidence in this case  
7 that any of these plaintiffs who are in this case have --  
8 don't have IDs or have not experienced -- or have  
9 experienced concrete difficulties in getting access to  
10 this drug. None of them submitted an affidavit. None of  
11 them submitted any evidence.

12           THE COURT: As far as I know, I dealt with the  
13 issue of standing. You don't even allege that as a  
14 parameter, that you have a likelihood of success. So  
15 you're making false statements about what fifteen-year-  
16 olds can do and sixteen-year-olds can do in spite of the  
17 fact that we all know that the extraordinary difficulty  
18 of producing photographic identification is for all  
19 practical purposes is -- renders that irrelevant.

20           You know, what you have done is you've given  
21 Teva the right to have all of its stuff on the shelves,  
22 only Teva and created -- and we're going to get to this  
23 -- you know, you complain about the confusing process,  
24 what you propose to authorize now, but we'll get to that  
25 when you get to the argument about the prejudice to the

1 government.

2 MR. AMANAT: Well, I would like to first answer  
3 the Court's earlier question as to why the Court should  
4 have remanded and why the government believes the remand  
5 would have served a useful purpose in this case.

6 THE COURT: Well, I've ask you that. What  
7 would have happened on remand?

8 MR. AMANAT: I'm trying to answer that.

9 THE COURT: Has the Secretary --

10 MR. AMANAT: Let --

11 THE COURT: Could you answer me -- could you  
12 please answer yes or no; has the Secretary changed her  
13 views; yes or no?

14 MR. AMANAT: Has the Secretary changed her  
15 views about the adequacy of the evidence that was  
16 submitted with Teva's SNDA that was under review --

17 THE COURT: Yes.

18 MR. AMANAT: -- in December of 2011?

19 THE COURT: Yes.

20 MR. AMANAT: No.

21 THE COURT: So that means that if I sent this  
22 back, the FDA -- The Citizen's Petition back, the FDA  
23 would have to reach exactly the same decision that it  
24 made before?

25 MR. AMANAT: No, not necessarily, your Honor.

1 THE COURT: How could you say that?

2 MR. AMANAT: I will explain. There are a  
3 number of different ways that a remand could play out,  
4 depending on the FDA's conclusions on certain issues.

5 THE COURT: I mean the FDA has concluded that  
6 this should have been made available to all women  
7 regardless of age. That's the decision of the  
8 specialized agency to which Congress has delegated the  
9 authority and the Secretary has delegated the authority.  
10 That's the FDA's view. The FDA's denial of the Teva  
11 petition was based on an order from the Secretary and  
12 that's what we're dealing with here. And you're going to  
13 tell me what?

14 MR. AMANAT: That that's not what we're dealing  
15 with here because that order is not under review, as the  
16 Court has acknowledged.

17 THE COURT: Don't tell me it's not under  
18 review. It exists and you want me to send this back even  
19 though if under the Secretary's view, the agency would  
20 have no -- the agency would have no alternative but to  
21 deny it again.

22 MR. AMANAT: No, there are a number of things  
23 that could happen on remand with regard to the  
24 Citizen's --

25 THE COURT: Tell me what they are.

1           MR. AMANAT: FDA, for example, can make some  
2 information public after an SNDA is approved. So it's  
3 possible that parts of the record from the newly approved  
4 SNDA could become available for consideration in the  
5 Citizen Petition, subject to Teva's rights to  
6 exclusivity.

7           THE COURT: That's Citizen's Petition -- the  
8 Teva's -- you're talking about Teva's most recent  
9 petition that you're going to release all this great  
10 confidential information.

11          MR. AMANAT: It's subject to Teva's rights that  
12 the --

13          THE COURT: There's nothing in there that's  
14 confidential. You're just covering up.

15          MR. AMANAT: It's not a coverup, Judge.

16          THE COURT: It is.

17          MR. AMANAT: In addition, if FDA undertakes a  
18 rule-making that would trigger a formal process of  
19 (indiscernible).

20          THE COURT: You tell me -- you said here that  
21 they don't -- first they decide whether the evidence is  
22 sufficient and then they undertake rule-making.

23          MR. AMANAT: But if the Court were to remand,  
24 the --

25          THE COURT: Tell me what would happen; yes.

1 What would happen if they were to remand? You would make  
2 public some of the -- which I basically intend to do  
3 unless you make a better showing on confidentiality than  
4 you've already made, you're going to release Teva's  
5 letters. There's nothing in them that would make a  
6 difference. They're saying that they're basically trying  
7 to satisfy the Secretary.

8 MR. AMANAT: On remand, there would be a new  
9 record on which the FDA would act. It would include, for  
10 example, the affidavits that the plaintiffs had submitted  
11 to this Court and that your Court considered relevant.

12 THE COURT: There was nothing in those  
13 affidavits that would satisfy the Secretary's views on  
14 this issue.

15 MR. AMANAT: But the eventual outcome -- it's  
16 not a foregone conclusion that a remand would lead to  
17 another denial of the Citizen Petition or --

18 THE COURT: How could you say that when -- how  
19 could you keep saying that when the Secretary has not  
20 changed her position? How could you keep saying that if  
21 you don't --

22 MR. AMANAT: Because, your Honor, the --

23 THE COURT: You have absolutely no credibility.

24 MR. AMANAT: -- Secretary --

25 THE COURT: Do you understand that?

1           MR. AMANAT: The Secretary's position was  
2 articulated in the context of an SNDA which requested a  
3 particular form of agency action. The only options the  
4 agency had were to either approve it or to reject it.  
5 The Secretary found that the data that had been submitted  
6 by the sponsor in support of that particular agency  
7 action were not sufficient. But that does not  
8 presuppose --

9           THE COURT: But the same thing is true of the  
10 Citizen's Petition.

11          MR. AMANAT: No, because the Citizen's --

12          THE COURT: Yes, it says in fact that the  
13 Citizen's Petition denial says that what you need to give  
14 us, which is all a lot of nonsense, you need to give us  
15 what Teva gave us with respect to the actual use study.

16          MR. AMANAT: The --

17          THE COURT: And then after the Secretary denied  
18 it. I mean, you're just playing games here.

19          MR. AMANAT: Honestly, your Honor, I'm not.  
20 I'm trying to explain what the agency would do on remand.

21          THE COURT: But none of it -- as long as the  
22 Secretary who has no scientific expertise, whose  
23 expertise is in political science, as long as she is  
24 making the decision and her decision stands, there's only  
25 one result that could be reached if I remand the Citizen

1 Petition and that's that it would be denied again for  
2 political reasons.

3 MR. AMANAT: Respectfully, your Honor, the  
4 government disagrees and the Secretary made one decision.  
5 She made one decision in the context of a single agency  
6 adjudication --

7 THE COURT: Give me an affidavit from Margaret  
8 Hamburg saying that if this were remanded, she would  
9 grant it.

10 MR. AMANAT: That she would grant the Citizen  
11 Petition?

12 THE COURT: Yes.

13 MR. AMANAT: Well understand, your Honor, the  
14 granting of a Citizen Petition does not necessarily mean  
15 that by granting the Citizen Petition, the agency would  
16 end up providing or agreeing to provide the full scope of  
17 the relief which was sought by the Citizen Petition. The  
18 granting of the Citizen Petition simply means that the  
19 agency would agree to move forward with a rule making  
20 proceeding which the public and all stakeholders would  
21 have an opportunity to participate and share their views  
22 including Teva, including plaintiffs, including the  
23 petitioners, including anybody else who has an interest  
24 in the issue would be able to submit their views.

25 THE COURT: Right.

1 MR. AMANAT: The Court --

2 THE COURT: And the bottom line is is that it's  
3 not possible to provide the data on eleven-year-olds and  
4 twelve-year-olds. That's the bottom line. And that's  
5 what the FDA found and if that's going to be the decision  
6 of the Secretary -- and by the way again, if it were  
7 possible to somehow separate it out, it wouldn't make a  
8 difference to me. The issue is you're using these eleven  
9 and twelve-year-olds to place undue burdens on the  
10 ability of older women to get this emergency  
11 contraceptive.

12 MR. AMANAT: Well, your Honor sees the  
13 obligation to show ID as an undue burden. The government  
14 disputes that.

15 THE COURT: That's basically -- no, the  
16 government agrees with it. When it comes to voting, the  
17 government agrees with it.

18 MR. AMANAT: In the context of --

19 THE COURT: But there's a --

20 MR. AMANAT: -- the purpose of this --

21 THE COURT: The analogy is clear, if it is an  
22 impediment to voting, it's an impediment to getting the  
23 drug. You know, when it suits the government's purpose,  
24 this becomes an impediment for voter suppression. Here  
25 you're suppressing the rights of women to get emergency

1 contraceptives and you come in here and make these  
2 ridiculous arguments. You cannot tell me that if I  
3 remand it, the result would be different. And if you  
4 were saying it, you were making an intellectually  
5 dishonest argument.

6 MR. AMANAT: Your Honor, the result is not  
7 necessarily going to be the result that the petitioner's  
8 asked for but that's not --

9 THE COURT: That's exactly it. That's what  
10 they want. They don't want fifteen and above. They  
11 don't want people to have to show IDs when it's not  
12 needed and when it constitutes an impediment to getting  
13 drugs. This is contrary to the policy of Congress to  
14 make drugs available without undue burden and expense.

15 MR. AMANAT: But, your Honor, FDA --

16 THE COURT: And by the way, tell me what the  
17 Secretary's competence is to make this decision?

18 MR. AMANAT: That's not part of the purview of  
19 this case, your Honor.

20 THE COURT: No, it's not.

21 MR. AMANAT: No. Again, your Honor --

22 THE COURT: It's not.

23 MR. AMANAT: -- because the Secretary's  
24 decision with regard to the SNDA is not within the  
25 Court's jurisdiction to review.

1           THE COURT: But it goes beyond that. It sets  
2 policy that affects this case and there's no way that the  
3 result would be any different if I remand it a third  
4 time.

5           MR. AMANAT: Second time.

6           THE COURT: Do you know what would happen?  
7 Well, it would be the third time they had it.

8           MR. AMANAT: You remanded it --

9           THE COURT: I remanded it once and it would be  
10 the second remand but for -- and what would happen?  
11 Nothing.

12          MR. AMANAT: That's --

13          THE COURT: For all I know you would sit on it  
14 for three years. You could wait until after the next  
15 election.

16          MR. AMANAT: No. No, that's not correct, your  
17 Honor.

18          THE COURT: That's not correct?

19          MR. AMANAT: The agency would act -- if the  
20 Court were to remand again, the agency would act on  
21 remand, consistent with the Court's directions.

22          THE COURT: What does that mean?

23          MR. AMANAT: It would take into account the  
24 findings that this Court -- the rationales that this  
25 Court articulated for finding its previously analyses

1 that the (indiscernible).

2 THE COURT: It can't -- you're basically lying.

3 MR. AMANAT: No, I am not, your Honor, with due  
4 respect.

5 THE COURT: They can't take it into account and  
6 grant any relief if they follow the Secretary's  
7 directive. That's the bottom line and if you could -- I  
8 can't believe that you could persuade the Court of  
9 Appeals --

10 MR. AMANAT: There's --

11 THE COURT: -- otherwise but you could go  
12 ahead.

13 MR. AMANAT: There is relief that could be  
14 relief on --

15 THE COURT: Tell me what it is.

16 MR. AMANAT: For example --

17 THE COURT: Why didn't you grant Teva? Teva  
18 would like to sell this over-the-counter to everyone  
19 without a prescription or without this rigmarole that's  
20 only going to make the cost of Plan B One-Step more  
21 expensive.

22 MR. AMANAT: For example.

23 THE COURT: They have to make this crab-colored  
24 package and they're going to have to put the device in  
25 the package, so that when it gets to the cashier, the

1 cashier will know to ask for ID. This whole thing is a  
2 charade. All they've done is change where you pay for --  
3 whether you pay a pharmacy or whether you pay at the  
4 counter of a large pharmacy.

5 MR. AMANAT: Your Honor, the agency's action  
6 last week pertained only to one product, Plan B One-Step.

7 THE COURT: That was purely coincidental by the  
8 way, that it happened -- you know, we have this little  
9 choreography here. First the President makes a speech to  
10 Planned Parenthood and throws them a kiss. The next day,  
11 in an application that was filed on March 9, 2012, the  
12 next day you grant their application to give it to people  
13 over fifteen. And the next day you file your notice of  
14 appeal and you say oh, this was entirely separate. No,  
15 it didn't have anything to do with it.

16 Why did it take from March 2012 to rule on  
17 their application till the day before you file your  
18 notice of appeal?

19 MR. AMANAT: Your Honor, FDA has a process --

20 THE COURT: Yeah, you want to keep those  
21 documents secret, don't you?

22 MR. AMANAT: Your Honor, FDA has a process by  
23 which drug approval applications are considered by a  
24 number of --

25 THE COURT: What was so difficult about what

1 they gave you in March -- you had all of the studies.  
2 You had them. They made this proposal on March 9, 2012  
3 and you act on it -- you file the act on it the day  
4 before you file a notice of appeal in this case, so you  
5 could try and sugarcoat the appeal? You could come in  
6 and tell me that that's an adequate remedy for fifteen-  
7 year-olds when it really isn't? You say fifteen-year-  
8 olds are not prejudiced anymore, Judge. You don't have  
9 to grant the stay. But they are prejudiced because they  
10 don't have the photo IDs.

11           And by the way, you know, birth certificates  
12 which you put out in your statement are not enough. You  
13 know as well as I do that a birth certificate will get  
14 you nothing. You need a photo ID and that's also in the  
15 materials that you want to file under seal.

16           MR. AMANAT: Or you need to have an older  
17 person, a sibling, a friend, a counselor, a teacher --

18           THE COURT: Oh, yes, that's what you told me.

19           MR. AMANAT: -- a parent who can --

20           THE COURT: You told me the last time that --  
21 Judge, don't worry about the prescription requirement  
22 because somebody else who is older could get a  
23 prescription and therefore, give it to someone who  
24 couldn't get a prescription which would violate the law.

25           MR. AMANAT: It wouldn't violate the law

1 anymore, now that it's a strictly over-the-counter drug.  
2 It's an over-the-counter drug.

3 THE COURT: It's an over-the-counter --

4 MR. AMANAT: An over-the-counter drug.

5 THE COURT: It's not entirely over-the-counter.

6 Look --

7 MR. AMANAT: Somebody who is fifteen who --

8 THE COURT: Yes, so you want --

9 MR. AMANAT: -- has the wherewithal to come up  
10 with \$60 to purchase the drug --

11 THE COURT: That's another problem.

12 MR. AMANAT: -- can most likely find --

13 THE COURT: Is that what it's going to be, \$60?

14 MR. AMANAT: That's the current price  
15 approximately.

16 THE COURT: Right.

17 MR. AMANAT: I have no way to predict whether  
18 the price will be the --

19 THE COURT: That's if these price-gougers  
20 here --

21 MR. AMANAT: The generic product is not that  
22 much less expensive.

23 THE COURT: I don't know. I understand the  
24 generic product is \$35.

25 MR. AMANAT: In any event, your Honor, the

1 government's position is that in this case --

2 THE COURT: You've made it even more expensive.

3 MR. AMANAT: Well, your Honor --

4 THE COURT: You've made it more expensive. So  
5 if somebody walks into -- a fifteen-year-old walks into  
6 let's say a supermarket that's open twenty-four hours,  
7 and the -- of course the pharmacy is closed, they have to  
8 pay -- they can't get the two-pill plan for \$35, so they  
9 have to pay Teva's \$60 and God knows what -- you know,  
10 you've given them so-called exclusivity, which means they  
11 could charge whatever they want.

12 MR. AMANAT: Your Honor, Congress has granted  
13 drug innovators the right to exclusivity and the right to  
14 a temporary monopoly on --

15 THE COURT: No, they say --

16 MR. AMANAT: -- on their product in order to  
17 promote innovation and research and development --

18 THE COURT: That's right.

19 MR. AMANAT: -- of new drugs.

20 THE COURT: But my decision that you want to  
21 appeal on the Citizen's Petition said that excluding this  
22 affidavit on this information, this one study on actual  
23 use, the plaintiff's were still entitled to win under the  
24 policies that the FDA has applied and which they violated  
25 one-by-one in this case. So that if I am right, they're

1 entitled to their relief and the study that Teva  
2 submitted the actual use study is not essential.

3           But I'm not ruling on that because I don't care  
4 what you do with Teva in terms of this case, although I  
5 think you ought to think -- not only is what you've put  
6 in place now a meaningless, in terms of these fifteen and  
7 sixteen-year-olds, it places a near impossible burden on  
8 most of them because of the requirement for photographic  
9 identification. It imposes burdens on adults -- twenty-  
10 five percent of African Americans who do not have  
11 photographic IDs, the eighteen percent who are between  
12 eighteen and twenty-five who don't have access to this.  
13 That's what you're doing here.

14           And on top of that, your exclusivity is going  
15 to let them price gouge; if that doesn't stop it enough,  
16 you're basically disadvantaging poor people, young people  
17 and African Americans. That's what you're doing. That's  
18 the policy of the Obama administration?

19           MR. AMANAT: I don't believe that's correct,  
20 your Honor.

21           THE COURT: No?

22           MR. AMANAT: The policy of the --

23           THE COURT: What have I said that just now is  
24 not factually accurate?

25           MR. AMANAT: The policy of the government is to

1 respect th exclusivity of drug innovators --

2 THE COURT: Good. I'm not stopping you.

3 MR. AMANAT: -- in order to promote research  
4 and development --

5 THE COURT: I understand that but we're talking  
6 about here -- I said that they were entitled to relief on  
7 the Citizen's Petition without the use of this report,  
8 this actual use report on which you've awarded  
9 exclusivity.

10 So what you propose to do is to continue that I  
11 remand it again where it will languish because there's  
12 nothing you can do, given the Secretary's decision and  
13 you've given them exclusivity which in my view, they're  
14 not entitled to.

15 MR. AMANAT: Again, your Honor, I am reticent  
16 to relitigate issues that we've litigated before. The  
17 reason we're here today is on the question --

18 THE COURT: The reason you're here today is  
19 because you want a stay and in telling me why I should  
20 give you a stay, you say you say don't worry about the  
21 prejudice to the fifteen-year-olds because look at what  
22 we've just done. We've given this wonderful gift.

23 MR. AMANAT: Right.

24 THE COURT: This wonderful gift which they  
25 can't -- the gift package most of them can't open. They

1 can't open because they don't have photographic IDs and  
2 because they're price gouging.

3 MR. AMANAT: The plaintiffs have suffered no  
4 harm.

5 THE COURT: I'm telling you -- you made a  
6 statement in your brief.

7 MR. AMANAT: Yes.

8 THE COURT: You say don't worry about the  
9 prejudice. There's no prejudice to anyone who is fifteen  
10 or over because look at this great relief that we've  
11 given them. You say that.

12 MR. AMANAT: They can now --

13 THE COURT: So I'm entitled to say that this is  
14 just a lot of nonsense, am I not?

15 MR. AMANAT: Your Honor, there's no principle  
16 of law which says that any consumer is entitled to buy  
17 whatever product they want from whatever establishment  
18 they want.

19 THE COURT: We're talking -- no, there isn't  
20 but we're talking about the Food and Drug Act and how the  
21 laws are administered with respect to whether drugs  
22 should be sold over-the-counter.

23 MR. AMANAT: That is correct.

24 THE COURT: That's right.

25 MR. AMANAT: And your Honor --

1           THE COURT: And you are telling me that in the  
2 prejudice prong, they suffered no prejudice because of  
3 the relief that you just gave Teva and I'm telling you  
4 that that's a lot of nonsense.

5           MR. AMANAT: Your Honor, if I may point out in  
6 the Court's decision, one of the ways in which the Court  
7 explained that the agency had gone astray -- and it does  
8 this four or five times in the opinion -- is the Court  
9 says that rather than approving these drugs in this  
10 little marketing regime that's partly RX, party OTC, it  
11 should have instead, approve the drug as an OTC drug with  
12 an age label, with an age-restricted label saying this  
13 drug is not for use by consumers below a certain  
14 pediatric age. The Court said that that was the  
15 preferred course of action that the agency should have  
16 taken.

17           THE COURT: No, you're mischaracterizing --

18           MR. AMANAT: The agency

19           THE COURT: -- what I said. I said that that's  
20 what the FDA normally does.

21           MR. AMANAT: And --

22           THE COURT: And if they follow -- if they want  
23 to deviate from their normal practice, they have to give  
24 reasons.

25           MR. AMANAT: And the agency has now done

1 precisely that. It has approved --

2 THE COURT: They've done that.

3 MR. AMANAT: -- as an OTC drug --

4 THE COURT: But that's --

5 MR. AMANAT: -- with a label saying it is not  
6 intended for consumers under the age of fifteen. And  
7 that is precisely consistent with how the Court  
8 characterized that the --

9 THE COURT: I know but there are no  
10 restrictions on -- for example, on the diet drug Alli.  
11 There's no restriction about -- you're putting an age  
12 restriction on it.

13 MR. AMANAT: The --

14 THE COURT: They want to sell it -- just look  
15 at this. What you're giving them, first of all, they're  
16 going to have exclusive rights to shelf space. The  
17 normal plan, the two pill, which I will call Plan B, only  
18 to -- it's a shorthand for the two-pill product, will not  
19 be on the same shelf as Teva. Somebody who wants Plan B  
20 2 and doesn't want to pay \$60 or more, because we don't  
21 know how much they're going to calculate -- they're going  
22 to have to invest money in this effort to change the  
23 place of where you pay for the drug. So they have to go  
24 to the counter -- to the pharmacy counter. And then if  
25 the pharmacy counter is closed, they have to buy Plan B

1 One at an exorbitant price.

2 MR. AMANAT: But, your Honor, there's no legal  
3 basis for the plaintiffs to assert that consumers should  
4 be able to buy the product they want at the price that  
5 they want.

6 THE COURT: No.

7 MR. AMANAT: That's not the way the --

8 THE COURT: You're basically -- you're here  
9 asking for equitable relief.

10 MR. AMANAT: Right.

11 THE COURT: One of the things that you've put  
12 in your papers asking for equitable relief is you're  
13 saying that they were not prejudiced and I'm saying that  
14 they were.

15 MR. AMANAT: Certainly these plaintiffs --

16 THE COURT: Don't tell me about what rights are  
17 independent. I'm just addressing myself to an argument  
18 that you made that somehow this procedure that you put in  
19 place a day before you filed a notice of appeal on an  
20 application that was pending for over a year before, does  
21 not help them.

22 MR. AMANAT: It does help them, your Honor,  
23 because the twenty -- the eighteen individual plaintiffs  
24 in this case, none of them has made a factual showing --

25 THE COURT: Don't tell me --

1 MR. AMANAT: -- that they --

2 THE COURT: No, no, that wasn't your argument  
3 in your application.

4 MR. AMANAT: It was actually.

5 THE COURT: Give me -- no, no, no. Get me your  
6 brief on this motion.

7 MR. AMANAT: A stay --

8 THE COURT: You know, I don't believe that they  
9 have to show that they became pregnant because they can't  
10 get the pill in order to make this argument. That's my  
11 first view. And I felt --

12 MR. AMANAT: That wasn't the government's  
13 argument.

14 THE COURT: Well --

15 MR. AMANAT: The government's argument is that  
16 because --

17 THE COURT: Let's turn to the page in your  
18 brief where you talk about you're not prejudiced.

19 MR. AMANAT: This is page 11 of the brief --

20 THE COURT: Right.

21 MR. AMANAT: -- where we say "The plaintiffs  
22 including the most recently added plaintiff were all over  
23 age fifteen and therefore will soon be able to obtain at  
24 least one emergency contraceptive containing  
25 Levonorgestrel, that is Plan B One-Step, without a

1 prescription at retail establishments that have a  
2 pharmacy counter.

3 THE COURT: Provided they have an ID. Provided  
4 they have a photo ID which is very difficult to obtain,  
5 which most of these people -- most people that age do not  
6 have. And they will be able to obtain it at a -- if they  
7 could afford it, at a rate which is exorbitant.

8 MR. AMANAT: And we addressed that point in  
9 footnote 7 where we cite -- unfortunately there's a typo  
10 there but where we cite case law, Supreme Court case law,  
11 Second Circuit case law, for the proposition of the  
12 requirement to show ID does not constitute a harm from a  
13 legal point of view.

14 THE COURT: You keep saying that but first of  
15 all, that's a debatable proposition. It all depends on  
16 the context. The context here is whether in -- you're  
17 telling me that this gives them an adequate relief and  
18 therefore, they're not prejudiced. It's not a question  
19 of whether -- and the other half of it is we're dealing  
20 with a statutory scheme for the dispensation of drugs.

21 Even what you've done here is inconsistent with  
22 the policy that you followed and I have to thank you  
23 because in the thoughtless way that you make arguments,  
24 you call that to my attention; Alli, the whole practice  
25 of the FDA -- I mean, ultimately I would have found it

1 out when I read the document that was submitted to the --

2 MR. AMANAT: The difference is, your Honor --

3 THE COURT: -- Secretary but you don't follow  
4 that policy elsewhere. There are drugs in the pharmacy  
5 section of any drug store that could cause great harm to  
6 children and you sell them. You let them be sold and you  
7 let them be sold with something on the label that says  
8 not for use by children or not for use by people under a  
9 certain age.

10 MR. AMANAT: And the --

11 THE COURT: But somebody could go in and buy  
12 it, even though they're not of that age. And the FDA --  
13 and it's because the FDA is satisfied in every other case  
14 with doing it that way. And what I told you before --  
15 what I said in my opinion is if you want to change  
16 policy, you've got to give good reason.

17 MR. AMANAT: Yes.

18 THE COURT: And there was no good reason given  
19 by the Secretary. She didn't even say that the youngest  
20 of women of or girls of reproductive age would be harmed  
21 if they took this pill. Your colleague from the FDA when  
22 I said to him, "Tell me what is the reason problem here.  
23 After all, if they take the pill once and the most  
24 important thing is to take it" -- quoting from Teva's  
25 label is -- "'as early as possible,' what's going to

1 happen? Nothing." So he says to me, "Well, it's the  
2 second pill and they may might not take the second pill  
3 and they could become pregnant."

4 Of course, if you don't have access to the pill  
5 to begin with, that's what's likely to happen and it's  
6 also absurd and contrary to common sense to believe that  
7 someone is going to go in and pay \$35 or \$60 for one or  
8 two pills not take them when they're supposed to.

9 MR. AMANAT: Your Honor, with regard to the age  
10 verification, for example, and --

11 THE COURT: Let's get to it.

12 MR. AMANAT: -- your Honor mentioned policy --

13 THE COURT: Let's get to it.

14 MR. AMANAT: The --

15 THE COURT: The suppression of the ability of  
16 women --

17 MR. AMANAT: Your Honor?

18 THE COURT: -- to get emergency contraceptives.

19 MR. AMANAT: I would point out that the system  
20 for age verification that FDA approved with the recent  
21 Plan B One-Step SNDA was proposed by Teva --

22 THE COURT: It was proposed by Teva because  
23 they couldn't get what they wanted.

24 MR. AMANAT: These were --

25 THE COURT: They say in their papers that you

1 want to suppress, that you want me to file under seal  
2 that they think that it should be sold over-the-counter  
3 without any restrictions.

4 MR. AMANAT: Your Honor, FDA --

5 THE COURT: And so when you told them they  
6 couldn't do that, they came back with this proposal and  
7 then you sat on it for a year and did nothing until you  
8 decide -- until it became clear. You see a lot of all of  
9 this activity I told you at the end of February or early  
10 March that I intended to decide this case by the end of  
11 March. And then suddenly, there's all of this activity  
12 that takes place.

13 Don't you -- just as you forced them or Teva's  
14 predecessor, I don't remember whether it was Barr at the  
15 time, when you wouldn't approve the original application  
16 you invited them, I think, to submit one that might be  
17 approved.

18 MR. AMANAT: And --

19 THE COURT: So this is not voluntary.

20 MR. AMANAT: Your Honor?

21 THE COURT: Just take --

22 MR. AMANAT: Let --

23 THE COURT: You know, I am telling you now that  
24 I am not accepting the premise that Teva has any  
25 expectation of privacy in the documents that it

1 submitted. It understood that when it submitted it, that  
2 it had the relief that it wanted, the FDA could make it  
3 public.

4 MR. AMANAT: Your Honor, if --

5 THE COURT: And you write me a letter saying  
6 after they sat on it for a year, that they didn't have a  
7 chance to look at -- to study it which could take you  
8 fifteen minutes, to decide whether or not they want to  
9 release something or another.

10 MR. AMANAT: There's a couple of things in  
11 there which I would like to respond to if I may,  
12 your Honor. First of all, with regard to the notion that  
13 Teva's proposal of the age verification process was not a  
14 voluntary act --

15 THE COURT: Right.

16 MR. AMANAT: -- we would beg to differ, your  
17 Honor, and let me explain why.

18 THE COURT: Why don't you just --

19 MR. AMANAT: When --

20 THE COURT: People could read the documents and  
21 they could decide whether it was voluntary or not. You  
22 know, you told --

23 MR. AMANAT: When --

24 THE COURT: -- what they wanted -- what Teva  
25 wanted was to have it -- to be able to sell Plan B One to

1 everybody --

2 MR. AMANAT: And --

3 THE COURT: -- without a prescription.

4 MR. AMANAT: In broad strokes; yes. That's  
5 what they --

6 THE COURT: And that's what they wanted and the  
7 Secretary said no.

8 MR. AMANAT: And --

9 THE COURT: So then they came back in their --  
10 and said well, we'll try this and see -- and we think  
11 this would satisfy the secretary. So that's voluntary by  
12 you?

13 MR. AMANAT: Yes, it is, your Honor, because  
14 when the --

15 THE COURT: Go onto your next argument.

16 MR. AMANAT: When FDA gave the complete  
17 response letter, they had the right to go to the Third  
18 Circuit or the D.C. Circuit on a petition for review and  
19 ask to review it.

20 THE COURT: I know. And I don't know why they  
21 didn't. They would have won.

22 MR. AMANAT: Because they exercised their  
23 commercial interests --

24 THE COURT: I understand.

25 MR. AMANAT: -- to decide instead of pursuing

1 that course of action --

2 THE COURT: I don't know what interests they  
3 exercised.

4 MR. AMANAT: -- to --

5 THE COURT: I don't want to speculate on what  
6 their state of mind was. The basic fact was they asked  
7 initially to have it made available without prescription  
8 to persons of all ages. The FDA, the agency, has  
9 specialized knowledge, said yes, you could have it. The  
10 Secretary of Health and Human Services who has no  
11 specialized knowledge, said no. And so they came back  
12 shortly thereafter, with their proposal.

13 You could tell me it's voluntary and you could  
14 go and tell the Court of Appeals that it's voluntary and  
15 if people want to believe that's voluntary, that's all  
16 right. If I say to you, you money or your life and you  
17 give me your money, is that voluntary?

18 MR. AMANAT: There certainly is no evidence on  
19 the record before the Court that Teva's decision to  
20 propose to FDA an amended drug application which  
21 implicated an age verification process different from  
22 Alli, the drug that your Honor mentioned, or other drugs  
23 which are labeled not for use below a certain pediatric  
24 age.

25 THE COURT: Aspirins, which you could die from

1 and which children can die from.

2 MR. AMANAT: The sponsors of those drugs did  
3 not submit SNDAs to FDA asking to have an age  
4 verification approved as part of the drug application.  
5 Teva did in the course of shifting gears and trying to  
6 get its product approved.

7 THE COURT: I know but you're just jumping  
8 around. That's what I said. They did it -- you tell me  
9 they did it voluntarily and --

10 MR. AMANAT: And FDA approved it.

11 THE COURT: -- I'm telling you they didn't do  
12 it voluntarily and they did it only because their  
13 original application was denied.

14 MR. AMANAT: Let me get back if I may to the  
15 question of whether a remand at this juncture would have  
16 served the purpose. Again, I want to emphasize that if  
17 the Court had remanded, the outcome of the remand is not  
18 a foregone conclusion. The agency would have prepared a  
19 new record and you know, the -- I know the Court has been  
20 frustrated by the length of time that the Court -- that  
21 FDA has taken with regard to this drug but I would beg to  
22 point out, your Honor, that during that time it's not as  
23 if the process has been static.

24 FDA has invested tens of thousands of hours  
25 reviewing multiple iterations of drug applications by

1 Teva and its predecessor, by generic competitors.

2 THE COURT: In bad faith.

3 MR. AMANAT: It is --

4 THE COURT: The reason for the delays are bad  
5 faith.

6 MR. AMANAT: But, your Honor, it has --

7 THE COURT: And that's my finding and you  
8 haven't even disputed it in your papers. And you haven't  
9 even given me an affidavit from the Secretary. Her  
10 reasoning is totally, totally -- even the President had  
11 to embellish it by saying that she said that it would  
12 harm eleven-year-olds when she never said that it would  
13 harm eleven-year-olds.

14 I mean, the bottom line is the Secretary is  
15 calling the shots here and the reason for all this delay  
16 and there will be more delay until the next election  
17 maybe and that's what one could expect. There's no way  
18 that this could be approved unless the Secretary gets out  
19 of the way.

20 MR. AMANAT: What is the -- when your Honor  
21 says this, may I ask what the this is?

22 THE COURT: The Citizen's Petition; there will  
23 not be even -- there won't even be a request for rule-  
24 making, which you've already had by the way. What you  
25 think you're going to get beyond the 47,000 responses the

1 first time is beyond me. You've already gone through  
2 this process as part of your --

3 MR. AMANAT: Your Honor, that was an issue --

4 THE COURT: That was a different way of  
5 delaying.

6 MR. AMANAT: -- no, with due respect --

7 THE COURT: That was an issue where you didn't  
8 whether you needed rule-making in order --

9 MR. AMANAT: FDA --

10 THE COURT: -- to decide whether you could have  
11 a process that was -- you know, that was partially over-  
12 the-counter and not partially not.

13 MR. AMANAT: FDA didn't --

14 THE COURT: And so you needed to ask the whole  
15 population of the United States for their views on what  
16 the -- and then you come in here and say you know the FDA  
17 is entitled to deference.

18 MR. AMANAT: Public participation and the  
19 agency decision making process is a very important and  
20 vital part of FDA's process.

21 THE COURT: Right. You didn't ask the public  
22 about Teva.

23 MR. AMANAT: Because it's -- that's an agency  
24 adjudication. There's an entirely different --

25 THE COURT: Yes, I know all about.

1 MR. AMANAT: -- it goes back to Londoner v. Bi-  
2 Metallic frame in the 1920s and the Supreme Court.

3 THE COURT: I know all about it.

4 MR. AMANAT: You know --

5 THE COURT: We're going in a circle. It's my  
6 view that as long as the Secretary adheres to her  
7 position, there's no relief that will be granted on a  
8 remand and that's basically my view, and if you want to  
9 argue this, if you think this is a successful argument  
10 that something different will happen, the Yiddish word is  
11 "gezunterhait," good health.

12 MR. AMANAT: Would your Honor like me to  
13 address the harms to the government and public interest  
14 now?

15 THE COURT: Oh, yes.

16 MR. AMANAT: In our brief, we articulate  
17 essentially two types of harm, irreparable harm. And  
18 while the harm is --

19 THE COURT: One type of irreparable harm will  
20 occur because I'll do what the FDA wanted to do to begin  
21 with; that's your first form of irreparable harm.

22 MR. AMANAT: Not exactly, your Honor. While  
23 the harms that we describe in our brief are admittedly  
24 somewhat conceptual in nature, that doesn't make them any  
25 less real.

1 THE COURT: Tell me what they are.

2 MR. AMANAT: Or any less consequential.

3 THE COURT: Tell me what they are.

4 MR. AMANAT: So first there's the irreparable  
5 harm that would ensue from substantial market and  
6 consumer confusion.

7 THE COURT: Oh, right now -- and what you're  
8 about to do is not going to result in substantial market  
9 confusion?

10 MR. AMANAT: Well --

11 THE COURT: I mean I --

12 MR. AMANAT: No, because the agency has taken  
13 an administrative --

14 THE COURT: This is what the plaintiff's say in  
15 their brief about what you're about to do now. And I  
16 think it's on --

17 MR. AMANAT: Hold on. Let me --

18 THE COURT: It's at page 11. This is how  
19 you're going to confuse the process. "In eliminating the  
20 dual marketing regime for Plan B Step-One, the defendants  
21 have replaced it with a convoluted triple tiered  
22 marketing scheme that will only increase confusion that  
23 already prevents women from obtaining timely access to  
24 the Levonorgestrel based products."

25 Specifically, we're going to -- so we're going

1 to change what goes on right now where you basically go  
2 to the counter and you present proof of age for a  
3 prescription. We're going to change that now.

4 First of all, you can't even -- you'll not be  
5 able to get Plan B One with a prescription. That's first  
6 of all, so --

7 MR. AMANAT: That's correct.

8 THE COURT: "Specifically, women and retailers  
9 across the country will be forced to operate on the  
10 following set of nonsensical rules: First, women fifteen  
11 years of age or older with adequate proof of age will be  
12 permitted to purchase Plan B Step-One, which will only be  
13 available on the shelves in stores with onsite  
14 pharmacies. Other Levonorgestrel-based products will  
15 remain behind the counter but will be available without a  
16 prescription to women seventeen years of age who have  
17 government issued proof of age. And three, women who  
18 lack adequate proof of age or are under the age of  
19 fifteen will not have access to Plan B Step-One and must  
20 obtain a prescription for Plan B Step-Two, rather the  
21 two-pill version."

22 That's very -- that's really -- that's not  
23 causing confusion, this change in policy that you're  
24 putting in place right now. That's not going to cause  
25 confusion.

1           What's going to cause confusion -- tell me  
2 what's going to cause confusion? If I should get  
3 reversed, we'll go back to the way we were. So you're  
4 changing right now, you're authorizing a complete change.  
5 You're actually depriving women who want Plan B Step --  
6 who can get a prescription and who need a prescription  
7 from getting it.

8           MR. AMANAT: Again, that's because that's the  
9 way Teva structured their application.

10          THE COURT: Yes, but you --

11          MR. AMANAT: But --

12          THE COURT: You just didn't take Teva's  
13 structured application, even though you had all of the  
14 underlying scientific studies, you didn't just take it,  
15 and go with it, otherwise this would have been done in  
16 March of last year.

17          MR. AMANAT: But --

18          THE COURT: If you were going back and forth  
19 with them -- in fact, you wanted to be sure that they  
20 were going to get photo Ids, you specifically asked the  
21 question in one of your letters.

22          MR. AMANAT: There was a back and forth as your  
23 Honor said --

24          THE COURT: There was a back and forth and --

25          MR. AMANAT: Yes.

1 THE COURT: -- there was about a nine month  
2 hiatus of back and forths from about --

3 MR. AMANAT: As your Honor --

4 THE COURT: And I think my recollection is from  
5 June of 2012 until April of this year, there was nothing  
6 -- there was no exchange of anything between you and  
7 Teva. You were just stalling.

8 MR. AMANAT: There was no stalling of all that.

9 THE COURT: There was. You understood where I  
10 was going the first time and when I told you that I was  
11 going to have a decision by the end of March, all of the  
12 sudden things started moving.

13 MR. AMANAT: Your Honor --

14 THE COURT: I told you at a hearing that we  
15 had, you know, before this that I thought that the  
16 Secretary's decision wreaked with bad faith. Where did  
17 you think that was going to lead in terms of the result  
18 in this case?

19 MR. AMANAT: So getting back to the issue of  
20 market confusion, your Honor --

21 THE COURT: Yes, tell me about market  
22 confusion.

23 MR. AMANAT: The issue for the government is  
24 that if the Court's directive with regard to the status  
25 of emergency contraceptives were to be put in place --

1 THE COURT: Right.

2 MR. AMANAT: -- during the interim --

3 THE COURT: Right.

4 MR. AMANAT: -- only to be reversed by the  
5 Court of Appeals, that kind of a decision in the agency  
6 action that would have to be taken in response to it --

7 THE COURT: Right.

8 MR. AMANAT: -- would result in their being  
9 multiple products on the market with different -- you  
10 know, different configurations and statuses and it will  
11 be confusing to consumers.

12 THE COURT: But I don't understand. You would  
13 have to do -- you would just go back to what it was  
14 before; if you succeed in reversing me which the more I  
15 listen to you, the more I think this isn't likely, but  
16 you've just done that right now.

17 MR. AMANAT: Well --

18 THE COURT: You've just done that right now.

19 MR. AMANAT: What --

20 THE COURT: You've changed the whole thing.  
21 All of the sudden, Plan B One is -- it's not available by  
22 prescription. I've read to you their description of  
23 what's in place, so from a system where you basically had  
24 people going to the pharmacy counter and either showing  
25 their prescription or age ID, you've gone to this whole

1 new system that's totally confusing. It's confusing  
2 until people get used to it.

3 MR. AMANAT: Well, but the plaintiff's  
4 characterization doesn't entirely mesh with the reality  
5 of the market at the present time because currently as I  
6 understand it, the one-pill product has an eight-five  
7 percent market share and the two-pill product has a very  
8 small and rapidly diminishing market share, which is  
9 probably understandable.

10 THE COURT: I don't want to talk -- I don't  
11 know what the--

12 MR. AMANAT: Uhm.

13 THE COURT: There's nothing before me on market  
14 shares and the only thing that talks about prescription  
15 sales of prescription and non-prescription drugs is  
16 considered to be confidential. They blacked it out,  
17 remember on that -- on the document that I asked you  
18 which the Secretary said she relied. They said that was  
19 confidential.

20 MR. AMANAT: Well, not specifically referring  
21 to Teva's product but collectively Teva and it's or Plan  
22 B One-Step and its generic equivalents, the One-Step  
23 product and the Two-Step product as you can imagine, is  
24 likely to continue losing market share to the one-pill  
25 product because consumers are going to gravitate towards

1 the simpler product.

2 THE COURT: Well, it's also a question of  
3 advertising. I don't know how much free advertising my  
4 decision has given Plan B; priceless. Priceless. You  
5 can't even put a figure on it because when the media  
6 reports on it, they only say Plan B. You would never  
7 know that there are generic -- there are comparable  
8 products on the market at cheaper rates because all you  
9 see in the media is the Plan B, your box.

10 MR. AMANAT: Let me move on if I may to the  
11 second species of harm that we --

12 THE COURT: Is that your best one? You started  
13 with a strongest first?

14 MR. AMANAT: Well, we have two arguments with  
15 regard to harm; first related to consumer confusion, the  
16 second relates to exclusivity which we've talked about a  
17 bit earlier.

18 THE COURT: That's only -- I told you about  
19 exclusivity. My view on exclusivity is that that actual  
20 use study is -- they were entitled to relief without it  
21 and I relied on it in my opinion because at the time that  
22 I wrote my opinion, they weren't entitled to exclusivity  
23 since you hadn't granted any application, to grant them  
24 any relief and therefore under the law, they weren't  
25 entitled to exclusivity. So, I felt fine relying on it.

1           And contrary to what -- the baloney you were  
2 giving me, there was stuff in the administrative record  
3 that reflected what was in that study. And you had the  
4 nerve to argue to me that practically would be a  
5 violation of the Confidential Trade Secrecy Act for  
6 anybody to disclose it.

7           MR. AMANAT: Well, our positions with regard to  
8 that were presented to the Court and were based on the  
9 relevant law and regulations.

10          THE COURT: That actual use study was in  
11 PowerPoint form but in relevant part was part of the  
12 administrative record that was prepared in this case.

13          MR. AMANAT: The --

14          THE COURT: According to you, that violated --  
15 whoever prepared that administrative record violated the  
16 Confidential Trade Secrecy Act.

17          MR. AMANAT: No, because we had permission from  
18 Teva to release that PowerPoint presentation.

19          THE COURT: You did? You gave them permission  
20 to do that?

21          MR. AMANAT: In the administrative record.  
22 Everything that was in the administrative record was  
23 vetted with Teva before it was published.

24          THE COURT: Oh, I see, so before you prepared  
25 the administrative record in this case you consulted with

1 them.

2 MR. AMANAT: With regard to any materials in  
3 the record --

4 THE COURT: That's very nice. It's a wonderful  
5 way to operate.

6 MR. AMANAT: -- as to which they may have a  
7 proprietary interest, of course; the government is  
8 obliged to vet it with the sponsor.

9 THE COURT: So in other words, what was in the  
10 administrative record in this case -- in this case -- the  
11 Citizen's Petition case, you first cleared with Teva.  
12 That's what you just told me.

13 MR. AMANAT: Any document that's in the  
14 administrative record --

15 THE COURT: No, I just want to know.

16 MR. AMANAT: Yes, yes.

17 THE COURT: So the administrative record in  
18 this case you cleared with Teva first. That's very  
19 interesting. It's a wonderful way for an agency to  
20 operate.

21 MR. SHUMSKY: Your Honor?

22 MR. AMANAT: No, I --

23 MR. SHUMSKY: If I can just put a slightly  
24 finer point on that.

25 THE COURT: Yes.

1           MR. SHUMSKY: We were not given the entire  
2 administrative record to vet We were given the portions  
3 of the administrative record that contained information  
4 that under well-settled FDA regulations are deemed to be  
5 proprietary and confidential (indiscernible) and which by  
6 law and the agency's own regulations it cannot publicly  
7 disclose without the consent of the party who has that  
8 proprietary interest. Those portions of the record were  
9 provided --

10           THE COURT: That's all a lot of nonsense  
11 because all of that stuff -- those studies were published  
12 -- were published -- in medical journals. There was no  
13 confidentiality. You did nothing to preserve the  
14 confidentiality of those and they had no business giving  
15 you a veto power of what you put in the administrative  
16 record in this case.

17           MR. AMANAT: Your Honor, to the extent that the  
18 Court's decision can be read to deny the FDA the  
19 authority to grant Teva marketing --

20           THE COURT: I'm not denying. You can give them  
21 whatever you want. I am just telling you that it was my  
22 view in deciding on this Citizen's Petition that they  
23 were entitled to the relief without that one actual use  
24 study. And I didn't feel any compunction about citing  
25 that actual use study, even though I didn't think it was

1 necessary for me to grant them relief because they was no  
2 exclusivity at the time that I decided this case.

3           And there was no exclusivity because you were  
4 dragging your feet for a year after they filed their  
5 application; on March 9th, they asked you for this relief  
6 of 2012.

7           MR. AMANAT: And --

8           THE COURT: And I'm convinced that the only  
9 reason it was decided -- you decided it when you decided  
10 it was because you needed to sugarcoat this appeal of  
11 yours.

12           MR. AMANAT: The fact remains, your Honor, that  
13 although it's true that at the time your --

14           THE COURT: And quite frankly, I'm really  
15 shocked that you gave them veto power over the -- what  
16 was in the administrative record in this case.

17           MR. AMANAT: Your Honor? Your Honor?

18           THE COURT: That's a total and complete  
19 corruption of the process.

20           MR. AMANAT: The statute requires us to.  
21 Nobody --

22           THE COURT: It did not. It did not because  
23 they disclosed it all. They disclosed it all. It was  
24 all -- they let the people who did the study for them  
25 publish the study.

1 MR. AMANAT: There are --

2 THE COURT: You even acknowledged that it was  
3 no longer a matter of confidentiality.

4 MR. AMANAT: Notwithstanding the fact that  
5 portions of the study had been published in the  
6 (indiscernible).

7 THE COURT: Not portions. All the relevant  
8 parts of it --

9 MR. AMANAT: The studies themselves, the data  
10 themselves remained confidential. And Teva has a  
11 proprietary right in that and there can be significant  
12 penalties to government employees who breach that  
13 confidentiality. Understandably, government employees  
14 don't want to be penalized. So, they take the precaution  
15 of vetting with the proprietor of the information, the  
16 potential release of those documents before they get  
17 released, even in the context of an administrative record  
18 for court cases.

19 THE COURT: Even those that have been  
20 published. The underlying data was not significant. The  
21 studies, they published -- Teva took no steps -- when you  
22 hire somebody to do a study, and you pay them, you could  
23 have a provision saying you can't disclose anything in  
24 the study without my consent. Teva did not do that.

25 MR. AMANAT: Your Honor, with due respect, FDA

1 does not rely on the descriptions of the studies  
2 published in academic journals and whatnot.

3 THE COURT: No, it's --

4 MR. AMANAT: It looks at the actual underlying  
5 data and makes it own analysis. And --

6 THE COURT: What underlying data did yo u look  
7 at that wasn't published?

8 MR. AMANAT: The underlying data that  
9 underlay --

10 THE COURT: No, specifically. Specifically.  
11 Don't tell me the underlying data that underlay.

12 MR. AMANAT: Well, I'm not at liberty to  
13 disclose the data. It's the data that was part of the  
14 actual use study.

15 THE COURT: Well --

16 MR. AMANAT: The data that Teva spent money to  
17 collect.

18 THE COURT: Yes.

19 MR. AMANAT: And the FTC and Congress -- in the  
20 FTCA and --

21 THE COURT: Oh, you could -- well, actually you  
22 could tell me now because you've -- I assume that you may  
23 have relied on it to grant them relief now.

24 MR. AMANAT: Congress in the FTCA authorized  
25 FDA to grant --

1 THE COURT: I'm not --

2 MR. AMANAT: -- marketing exclusivity because  
3 it wanted to --

4 THE COURT: This is a phony argument.

5 MR. AMANAT: -- because it wanted to encourage  
6 companies --

7 THE COURT: Yes, good, good. It's a wonderful  
8 policy. It's wonderful. I don't know what it has to do  
9 with the price of eggs here.

10 MR. AMANAT: Well, because it --

11 THE COURT: I just told you over and over again  
12 that my granting of the Citizen's Petition would not --  
13 did not require me to rely on their actual use study.

14 MR. AMANAT: But the --

15 THE COURT: My granting of the Citizen's  
16 Petition because I thought what they had -- not only what  
17 they had was enough but your denial of the Citizen's  
18 Petition in multiple respects violated the policies of  
19 the FDA that it had followed. That's the bottom line  
20 here.

21 MR. AMANAT: But --

22 THE COURT: And you're giving them exclusivity  
23 now? That's between you and them and whoever wants to  
24 challenge it.

25 MR. AMANAT: But --

1           THE COURT: And I don't even know whether they  
2 might not even be bound by what I said here because they  
3 participated in all this.

4           MR. AMANAT: Focusing again on the remedy that  
5 the Court order --

6           THE COURT: Okay.

7           MR. AMANAT: -- the remedy that the Court order  
8 directed FDA to make all emergency contraceptives that  
9 contain Levonorgestrel including the products  
10 manufactured by the generic competitors of Plan B One-  
11 Step to make them available --

12           THE COURT: But don't you think it's perfectly  
13 consistent with my finding that they were entitled to  
14 relief without regard to that actual use study.

15           MR. AMANAT: But --

16           THE COURT: And they -- how would you have  
17 wanted me to have limited it?

18           MR. AMANAT: But if the Court is directing FDA  
19 to make all Levonorgestrel containing EC drugs --

20           THE COURT: Right.

21           MR. AMANAT: -- including the ones manufactured  
22 by Teva's generic competitor for the one-pill product, it  
23 is in reality in the practical effect of the remedy that  
24 the Court is ordering, denying Teva the marketing  
25 exclusivity with regard to its product to which it's

1 entitled under the statute.

2 THE COURT: The issue is if I am right and  
3 their actual use study was not necessary for me to grant  
4 the Citizen's Petition, then that's the end of it.

5 MR. AMANAT: But if the Court is wrong about  
6 that --

7 THE COURT: Well, if I'm wrong, then I'll be  
8 reversed but the question here is and basically, you  
9 know, the -- you haven't disputed anything that I said  
10 about all of these violations of FDA policy that have  
11 been engaged in here and have never been explained but so  
12 I'll be reversed. But that has nothing to do with  
13 anything.

14 MR. AMANAT: Well it does because in the  
15 meantime, the reason the harm that ensues from that is  
16 irreparable is because in the meantime --

17 THE COURT: It's not irreparable --

18 MR. AMANAT: -- during the period of time when  
19 Teva's marketing exclusivity is lost, the generic  
20 competitors could presumably come and attempt to sell  
21 their product on the basis that the --

22 THE COURT: Well, but if you ultimately prevail  
23 and I get reversed by my conclusion that the Citizen's  
24 Petition did not stand or fall on that actual use study,  
25 then they'll get their three years of exclusivity. They

1 had three years of exclusivity on Plan B -- on the first  
2 one and then they -- you know, this is a game they  
3 played. They took two pills and then they had  
4 exclusivity on the two pills for three years and when  
5 that ran out, they took the two pills and they made it  
6 one pill and now they have three more years of price  
7 gouging.

8 MR. AMANAT: Well, your Honor, it is the  
9 government's position --

10 THE COURT: This is a joke.

11 MR. AMANAT: -- that the lost marketing  
12 exclusivity causes harm to the FDA's interest in  
13 promoting innovation and promoting public health.

14 THE COURT: I know but that jest down to the  
15 merits of your appeal and you have not told me why that  
16 study was essential to my approving -- to saying that the  
17 denial of the Citizen's Petition was arbitrary,  
18 capricious and unreasonable.

19 MR. AMANAT: The question --

20 THE COURT: In fact, the most important thing  
21 that the FDA relies on is the ability of people to  
22 read --

23 MR. AMANAT: Right.

24 THE COURT: -- and understand. And that study  
25 they said was not essential. And the basic fact is is

1 that if you're capable of reading and understanding,  
2 there's no reason why a simple pill like this cannot be  
3 taken -- you can't assume that it will not be used the  
4 way it's supposed to be used.

5           This is not a bottle of aspirin. Somebody who  
6 goes in and spends \$60 or \$35 for a single pill is going  
7 to take it when they're supposed to take it. You know,  
8 you get a bottle of aspirin -- take a look at the label  
9 on a bottle of aspirin and compare it to the label on  
10 Plan B. This is -- aspirin is a terrible hazard to  
11 adults, as well as children.

12           MR. AMANAT: Your Honor, if I may conclude my  
13 presentation with just a few comments on the public  
14 interest with regard to a stay because that's one of  
15 the --

16           THE COURT: Yes, tell me about the public  
17 interest. Is there a public interest in unwanted  
18 pregnancies?

19           MR. AMANAT: No, to the contrary.

20           THE COURT: Is there -- which can often result  
21 in abortions? Is there a public interest in that?

22           MR. AMANAT: Let me address that, your Honor.

23           THE COURT: No, is there? Can you answer that?

24           MR. AMANAT: Yeah, FDA does not question that  
25 there's a strong public interest in preventing unwanted

1 pregnancies --

2 THE COURT: Right.

3 MR. AMANAT: -- especially among teens.

4 THE COURT: Right.

5 MR. AMANAT: FDA also doesn't question the  
6 corresponding public interest in the availability of safe  
7 and effective emergency prescriptions.

8 THE COURT: Right. And it doesn't question the  
9 fact that Plan B is safe and effective.

10 MR. AMANAT: For use generally.

11 THE COURT: Yes.

12 MR. AMANAT: Yes, that is correct.

13 THE COURT: Yes, absolutely.

14 MR. AMANAT: The FDA has never questioned any  
15 of those things --

16 THE COURT: Right.

17 MR. AMANAT: -- during the twelve years that  
18 Plan B has been on the market.

19 THE COURT: And they've stalled -- and during  
20 which they've stalled the ability to make it more  
21 generally available to people to avoid either unwanted  
22 pregnancies or abortions.

23 MR. AMANAT: Your Honor, let me present a  
24 different take on that. The government, as I said, hasn't  
25 questioned that aspect of the public interest. In fact,

1 it is precisely in recognition --

2 THE COURT: And what it's doing is undermining  
3 that public interest.

4 MR. AMANAT: Well, we would disagree and I  
5 would like to explain why.

6 THE COURT: Yeah, tell me why.

7 MR. AMANAT: It's precisely in recognition of  
8 this public interest that FDA has taken the action it is  
9 taking now in approving in its latest action Plan B One-  
10 Step for OTC access by some ninety-nine percent of the  
11 market for the drug.

12 THE COURT: I'm sorry.

13 MR. AMANAT: No --

14 THE COURT: Could you tell me again?

15 MR. AMANAT: Because fifteen -- the approximate  
16 market for Plan B fifteen and over is considered about  
17 ninety-nine percent of the people who would potentially  
18 buy the drug.

19 THE COURT: So you agree with me that it's  
20 infinitesimal in the number of people who would --

21 MR. AMANAT: And --

22 THE COURT: -- who were below that who would  
23 buy --

24 MR. AMANAT: And in recognition --

25 THE COURT: And you agree with me that it's

1 infinitesimal the number of people under that age who  
2 would buy this drug; is that right?

3 MR. AMANAT: That is correct, your Honor.

4 THE COURT: And because of that infinitesimal  
5 number who might buy that drug, you're putting this  
6 burden on everybody over that age. That's what you're  
7 saying.

8 MR. AMANAT: Your Honor, no, that's not what I  
9 am -- let me address that. Keep in mind that FDA's  
10 actions in approving Plan B and Plan B One-Step for OTC  
11 access are unprecedented in an important respect, in a  
12 different respect than the Court has focused on.

13 In 2006, when FDA approved Plan B for non-  
14 prescription availability to consumers aged eighteen and  
15 over at the time, that was the first time --

16 THE COURT: Took a long time to do that.

17 MR. AMANAT: But that was the first time,  
18 your Honor --

19 THE COURT: It took a long time-- how many  
20 years did it take to --

21 MR. AMANAT: But --

22 THE COURT: -- how many years did it get you  
23 there -- to get there?

24 MR. AMANAT: But, your Honor --

25 THE COURT: How many years did it take to

1 approve it for eighteen and over?

2 MR. AMANAT: I don't know where -- what the  
3 starting point is. It came on the market in 1999.

4 THE COURT: Right.

5 MR. AMANAT: The Citizen Petition was 2001.

6 THE COURT: Right. And there were other  
7 petitions --

8 MR. AMANAT: But the --

9 THE COURT: Barr, their predecessor --

10 MR. AMANAT: -- was in 2004.

11 THE COURT: Right. And the only reason they  
12 did it then was because of pressure on the --

13 MR. AMANAT: But --

14 THE COURT: Because it became clear that the  
15 Commissioner of the FDA would not be confirmed.

16 MR. AMANAT: But your Honor, let me explain;  
17 this was the first time FDA allowed any orally ingested  
18 contraceptive to be sold without a prescription --

19 THE COURT: Right, right.

20 MR. AMANAT: -- to any consumer in the United  
21 States.

22 THE COURT: And do you know when they did that?

23 MR. AMANAT: Hold on one second.

24 THE COURT: About five days after you told me  
25 that it was against the law to do that. You sat here in

1 this courtroom a few days before the FDA did it and you  
2 said that it couldn't be done. It was either over-the-  
3 counter or by prescription. That's one of the  
4 nonsensical things that you said to me.

5 MR. AMANAT: They --

6 THE COURT: You may have been right on that one  
7 by the way.

8 MR. AMANAT: At the point in time in which I  
9 made that, your Honor --

10 THE COURT: Yes.

11 MR. AMANAT: -- the --

12 THE COURT: They didn't tell you what they were  
13 doing.

14 MR. AMANAT: -- determination as to what the  
15 FDA's authority was in that regard had not been fully  
16 made. It was made shortly thereafter. But I would like  
17 to --

18 THE COURT: You didn't express much doubt about  
19 it.

20 MR. AMANAT: I would like to take what I just  
21 said a step further. Plan B is, as the Court pointed  
22 out, a safe and effective drug to be sure. But it is  
23 also a powerful systemic hormone. It's a metabolic  
24 steroid. So, 2006 was the first time that any metabolic  
25 steroid was allowed to be sold without a prescription to

1 any consumer in the United States, adult or adolescent.  
2 And to this day, Plan B and Plan B One-Step and their  
3 equivalents, are still the only metabolic steroids to be  
4 available without a prescription.

5 THE COURT: You know, you could give it these  
6 fancy names. The bottom line is is that there's no harm  
7 that could come --

8 MR. AMANAT: Well --

9 THE COURT: -- from the use of this drug.

10 MR. AMANAT: What I am trying to emphasize  
11 though, your Honor, is that FDA took these --

12 THE COURT: The FDA was totally governed by  
13 politics. The only reason they took it was because they  
14 wouldn't have confirmed, what was the name Von Eschenbach  
15 or -- as head of the FDA. That was the only reason they  
16 took it.

17 MR. AMANAT: I understand that that's the  
18 Court's view.

19 THE COURT: They were playing the same game  
20 that the Secretary was playing.

21 MR. AMANAT: Look --

22 THE COURT: They were playing politics.

23 MR. AMANAT: Your Honor, I know that this Court  
24 has been frustrated with the pace at which FDA has taken  
25 its actions in this case but sometimes --

1           THE COURT: It's not a question of frustration.  
2 It's a question of what it says about the way the agency  
3 is operated.

4           MR. AMANAT: But, your Honor, I would --

5           THE COURT: And then you finally get a  
6 professional who is in charge of that agency, Dr.  
7 Hamburg, and she does the right thing and the political  
8 appointee of the President who is covering his political  
9 back, overrules her. That's what happened here.

10          MR. AMANAT: Dr. Hamburg is also a political  
11 appointee of the President, your Honor.

12          THE COURT: I know but some are more principled  
13 than others.

14          MR. AMANAT: Your Honor, the point I am trying  
15 to make is that sometimes the people are better served  
16 when the government acts deliberately and incrementally.  
17 And that's essentially what happened here. Teva  
18 submitted a series of applications requesting incremental  
19 approvals of its products based on new data and  
20 information as they've become available.

21                 FDA in determining and assessing these drugs  
22 has proceeded with baby steps rather than a full gallop.  
23 Reasonable minds may differ as to what pace the decision  
24 making ought to have been but one thing seems certain,  
25 now that FDA has taken what we consider to be a fairly

1 significant step forward --

2

3 THE COURT: Which is that?

4 MR. AMANAT: -- which is the approval of Plan B  
5 One-Step for ages fifteen and above --

6 THE COURT: It's not significant at all. It's  
7 meaningless, largely.

8 MR. AMANAT: We don't think that the public  
9 interest would be well-served --

10 THE COURT: It's not only meaningless but it  
11 has a disparate affect on African Americans, on younger  
12 people and on lower income people. You could take a look  
13 at the study by the Brennan Center. That's basically the  
14 bottom line. Those are the people who have had the most  
15 difficulty in getting photo IDs and it's sort of ironic  
16 to me that the poor, young and African Americans are the  
17 ones who are going to be put in a position of not having  
18 ready access to this safe and effective drug. And that  
19 this position is taken by a representative of the  
20 Department of Justice in this case; it's just shocking.

21 Do you need to say anything?

22 MS. CREPPS: Your Honor, if you don't mind, I'm  
23 going to switch mics because I have kind of a soft voice.

24 THE COURT: Sure.

25 MS. CREPPS: I think that it's clear where your

1 Honor stands on most of the issues related to the stay  
2 and so I just wanted to make a couple of points and, of  
3 course, answer any questions if you have any for me.

4           Your Honor has stated and we obviously agree  
5 that there is clearly ongoing irreparable harm here and  
6 that the approval of the amended SNDA does not eliminate  
7 that. It doesn't even significantly diminish the ongoing  
8 harm. And so rather than belabor that point, I would  
9 like to point out one thing that hasn't been mentioned as  
10 much which is the balance of equities in this case is  
11 somewhat unique because the granting of a stay will  
12 actually exacerbate delay and that is one of the harms  
13 that has been clearly identified by the plaintiffs  
14 throughout this case. And so from that perspective, the  
15 balance of equities on top of irreparable harm clearly  
16 tips --

17           THE COURT: It's not only that, denying the  
18 stay, if I do it -- I'm going to write an opinion in this  
19 case. I'm not deciding this today. The irony of this  
20 all is that I would be allowing what the FDA wanted to do  
21 and an exercise of its best scientific and expertise, to  
22 be done.

23           I mean this is got to be one of the most  
24 unusual administrative law cases I've ever seen and is  
25 anybody here from the FDA?

1 MR. AMANAT: My colleague, Mr. Kaplan (ph.).

2 THE COURT: I would even be surprised -- you  
3 know the way the Solicitor General's office operates, I  
4 know because I was there for two years, they get  
5 recommendations from Mr. Amanat, from the civil division,  
6 from HHS, and from the FDA, assuming the FDA was allowed  
7 to submit its independent views, or whether it was  
8 precluded from doing that. I would be surprised that --  
9 if the FDA was permitted to submit its views to the  
10 Solicitor General, that it recommended an appeal. In  
11 fact, I would be started to know that that is so. You  
12 know, he could tell me that I am wrong but I would be  
13 surprised and then the Solicitor General would normally  
14 meet with interested parties and listen to arguments  
15 about -- you know, there's not always agreement within  
16 the government on issues and the Solicitor General then  
17 makes a decision. And I suspect in this case, the  
18 Solicitor General probably conferred with someone at the  
19 White House. And I don't think there's anything wrong  
20 with that. It's one thing for the FDA's work to be  
21 dictated by politics, I don't -- you know, it would not  
22 be unusual in a case like this for someone to have been  
23 in touch with -- someone in the Solicitor General's  
24 office to have been in touch with the President, even  
25 though he said that he didn't -- he left it totally up to

1 the Solicitor General.

2 But I would be surprised if the FDA was  
3 permitted to put in its own views that it recommended an  
4 appeal. In fact, I would think that on the day that I  
5 handed down on my opinion, they were drinking champagne  
6 in the FDA.

7 MS. CREPPS: Well, your Honor, I think -- and  
8 this goes to the public interest -- I would certainly  
9 think that --

10 THE COURT: Of course, I mean --

11 MS. CREPPS: -- the public interest here where  
12 the FDA has said this is a safe and effective product --

13 THE COURT: And they wanted -- you know, the  
14 net effect if --

15 MS. CREPPS: -- to go over-the-counter --

16 THE COURT: -- I denied the stay is to let the  
17 -- to give effect to what the agency charged with the  
18 responsibility for making this decision wanted to do and  
19 if I grant the stay, I will be giving effect to what some  
20 political appointee in the Justice Department with no  
21 expertise, who is not even qualified to be Commissioner  
22 of the FDA, imposed. I mean, it's astonishing.

23 MS. CREPPS: It is, your Honor, and just going  
24 for a moment to the issue of market confusion, it's our  
25 position that any benefit of the doubt on the issue of

1 market confusion has got to be given to women to have  
2 immediate access.

3 THE COURT: Not only that, the market confusion  
4 will not result from my denying the stay. It would only  
5 come about if they win on appeal. I mean that's the only  
6 way there's going to be market confusion. The market  
7 confusion and then -- so that's sort of tied to their  
8 likelihood of success on appeal. There's not going to be  
9 any market confusion from my -- under their theory from  
10 my denial of the stay.

11 MS. CREPPS: No, it would be elimination of  
12 market confusion.

13 THE COURT: Exactly.

14 MS. CREPPS: And as you said --

15 THE COURT: It would be a total simple process.

16 MS. CREPPS: That's right. And at the end of  
17 that process, if you would be overruled, then certainly  
18 the --

19 THE COURT: And then we'll go back to the way  
20 it was. And just -- they're introducing market confusion  
21 right now by changing the method of Plan B. They're  
22 introducing market confusion right -- it doesn't bother  
23 them. There's market confusion right now. But if this -  
24 - by the change that they've put in place.

25 MS. CREPPS: I agree, your Honor. I would

1 hazard a guess that the current model of access to  
2 Levonorgestrel products has got to be the most convoluted  
3 in the history of drugs approved by the FDA.

4 THE COURT: That's what happens when you let  
5 politicians instead of scientists make these decisions.

6 MS. CREPPS: But also just going for a moment  
7 to the merits, I think your Honor has covered the issues  
8 of the likelihood of their success on appeal quite well  
9 but a couple of things that have jumped out at me as we  
10 discuss this; one thing that they seem to be suggesting  
11 is that there could be a fair process. I note they never  
12 said there could be an expeditious process. If this  
13 Court were to remand with discretion, this Court has  
14 remanded with a --

15 THE COURT: I know, I did it once.

16 MS. CREPPS: -- with directions that the  
17 Citizen's Petition be granted but to allow them any  
18 discretion would simply just I think perpetuate the delay  
19 and one thing that they said in their brief that I found  
20 surprising is that not only would a remand give them an  
21 opportunity for further agency consideration or  
22 elaboration of their decision, it would also give them as  
23 experts an opportunity to -- this is a quote, "The agency  
24 alone has the necessary information and scientific  
25 expertise to make a determination that a drug is safe and

1 effective."

2 THE COURT: Right. And they made that  
3 determination already.

4 MS. CREPPS: Many, many years ago and --

5 THE COURT: They made it last year.

6 MS. CREPPS: But the suggestion --

7 THE COURT: It's the agency -- he likes to make  
8 the Secretary part of the agency for the purpose of  
9 getting some sort of deference. The agency made the  
10 decision and the Secretary said no. And there's no way  
11 that they can say yes again unless the Secretary changes  
12 her views.

13 And by the way, I just found this section of  
14 Teva's application that they made on March 12th on your  
15 argument about voluntariness. "We are amending our  
16 application" --

17 MR. SHUMSKY: Your Honor, I'm very sorry to  
18 interrupt but as you know, both Teva and the government  
19 have taken the position that those documents are  
20 proprietary, confidential, protected by federal statute  
21 and by --

22 THE COURT: No, no, no, no.

23 MR. SHUMSKY: -- (indiscernible).

24 THE COURT: The government hasn't taken that  
25 position at all. The government's position is that they

1 will decide what could be made public and just because  
2 you say that every word in here is confidential, doesn't  
3 make it so. And I'm about to read it and you could take  
4 whatever you want.

5 MR. SHUMSKY: Your Honor, if I --

6 THE COURT: "We are amending our application to  
7 address the Secretary's stated concerns."

8 MR. SHUMSKY: Your Honor, we would --

9 THE COURT: That's confidential?

10 MR. SHUMSKY: We would be pleased to file a  
11 letter brief with the Court explaining our position on  
12 confidentiality.

13 THE COURT: Go ahead.

14 MR. SHUMSKY: We also would appreciate an  
15 opportunity because I can assure you this issue of a  
16 broader significance. It's not a Teva issue. It's an  
17 entire pharmaceutical industry issue; generic, branded,  
18 biotech and we would like an opportunity --

19 THE COURT: I am not -- I told you, I am going  
20 to give you an opportunity to.

21 MR. SHUMSKY: He --

22 THE COURT: Mr. Amanat said in his letter,  
23 first of all from what I understand that you couldn't --  
24 you had no reasonable expectation that they wouldn't make  
25 any part of this public. I'm just relying on his

1 representation. I haven't researched it. He said that  
2 normally, the agency would decide what portions of it  
3 would be made public.

4 As I understand it, that's different from when  
5 they deny an application. This is where they've granted  
6 an application. And they've granted an application and  
7 they've relied -- they specifically refer -- the only  
8 reason I know that this exists is because they describe  
9 it and the notion that they could keep every line of it  
10 secret is startling to me.

11 MR. SHUMSKY: Your Honor, if I may very briefly  
12 address that and I can assure you we'll elaborate that on  
13 a letter --

14 THE COURT: I'm not making it public until you  
15 --

16 MR. SHUMSKY: Fair enough.

17 THE COURT: -- have your opportunity.

18 MR. SHUMSKY: But just very briefly, so that  
19 you understand, there are FDA regulations following an  
20 approval --

21 THE COURT: Mr. Amanat -- I'm relying on  
22 Mr. Amanat which may be a mistake. He didn't cite any  
23 regulation in his letter and he said that generally,  
24 after it grants the application it decides what documents  
25 it will release and what information from the documents

1 it will release and they just haven't had enough time to  
2 read these fifteen pages or so --

3 MR. SHUMSKY: Your Honor?

4 THE COURT: -- and decide what they want to  
5 release or not release.

6 MR. SHUMSKY: If I can explain, when FDA  
7 approves --

8 ESR OPERATOR: Pull the microphone closer.

9 MR. SHUMSKY: When FDA approves an application,  
10 it prepares a document that's called a summary basis of  
11 approval.

12 THE COURT: Right.

13 MR. SHUMSKY: It contains a general description  
14 of the clinical data that the agency relied upon when it  
15 made a decision of whether or not to approve the  
16 application. It also details some of the review history.  
17 There's a Web site. It's called Drugs@FDA. You can look  
18 up a brand name drug. You will often find a summary  
19 basis of approval document that a company's approved --  
20 and so you can see the kind of information that's  
21 provided.

22 THE COURT: You made the --

23 MR. SHUMSKY: But --

24 THE COURT: I told you, I relied on what  
25 Mr. Amanat said and that's what he said. And besides, I

1 don't know how the disclosure of that line hurts you  
2 because it's quite obvious.

3 MR. SHUMSKY: Your Honor, allow me to say --

4 THE COURT: Do you deny that the only reason  
5 you proposed this was because the Secretary vetoed your  
6 application?

7 MR. SHUMSKY: Your Honor, I'm not going to get  
8 into the company's motivations for filing an application.  
9 I want to make a very simple point which is we believe we  
10 have a legal entitlement to keep that correspondence with  
11 the agency confidential.

12 THE COURT: Well --

13 MR. SHUMSKY: We'll prepare a letter brief and  
14 you can consider those arguments. The only thing I would  
15 ask is that you treat this issue the same way that you  
16 would treat an assertion of attorney/client privilege,  
17 work product privilege, and not disclose the information  
18 until we've had an opportunity to --

19 THE COURT: I'm not going to do that.

20 MR. SHUMSKY: -- decide our views --

21 THE COURT: I'm not going to do that.

22 MR. SHUMSKY: And if necessary --

23 THE COURT: I don't think I --

24 MR. SHUMSKY: -- take the issue then publicly.

25 THE COURT: -- I've disclosed anything that's a

1 secret or violates the policies that you've just  
2 described. And that's basically my view and, you know, I  
3 think it's quite shocking that some of the stuff could be  
4 kept secret and when it does not undermine the policies  
5 that you're talking about.

6 MR. SHUMSKY: Your Honor, our letter will make  
7 an effort to explain that.

8 THE COURT: Good.

9 MR. SHUMSKY: And I hope that we will have  
10 amici who will add emphasis to those points and explain  
11 why that's so.

12 THE COURT: Good.

13 MR. SHUMSKY: If you could provide us with a  
14 reasonable opportunity to prepare that.

15 THE COURT: Go ahead.

16 MR. SHUMSKY: We'll get it --

17 THE COURT: I have no plans to immediately  
18 disclose it. I'm going to have it filed under seal.

19 MR. SHUMSKY: Thank you, your Honor.

20 THE COURT: But what I wanted in terms of  
21 looking at it, I got. And he disclosed some of it  
22 anyway. But I was just relying on what the government  
23 had told me and the first argument was was that when they  
24 deny an application, everything was a secret but when  
25 they grant it, not everything is a secret and they just

1 didn't have enough time to decide which parts of it were  
2 secret, so that they would give you complete control over  
3 what was shown to me or not. And you were kind enough to  
4 let them give it to me. Am I misstating what he said?

5 MR. AMANAT: I just wish to clarify,  
6 your Honor, when I said we didn't have enough time, I was  
7 referring to the short period of time between your  
8 Honor's order yesterday and when you wanted the  
9 documents.

10 THE COURT: It basically took me -- I'm not  
11 interested in any of the attachments -- it took me about  
12 fifteen minutes to read those letters.

13 MR. AMANAT: Myself as well, your Honor, but I  
14 didn't --

15 THE COURT: And, you know, the notion that it  
16 could take longer for the FDA to make a judgment on what  
17 should be disclosed or not is ridiculous. But I don't  
18 want to -- this is all a diversion.

19 MS. CREPPS: Your Honor, I just have a couple  
20 of more points, if I could. One, while we're talking  
21 about the letters and I'm not talking about the merits of  
22 disclosure or not disclosure, it does sort of go back to  
23 the point about the administrative record in this case  
24 and it just can't be the case that the scope of the  
25 administrative record on the Citizen's Petition can be

1 dictated by a private interest.

2 THE COURT: I agree with that. I'm fine with  
3 tracking.

4 MS. CREPPS: The end result of course being  
5 that information that the FDA considered underlying -- in  
6 considering the Citizen's Petition may not be disclosed  
7 as part of the administrative record and we would never  
8 even know about it.

9 THE COURT: Exactly.

10 MS. CREPPS: But I would like to go just for a  
11 moment to the issue of what the appropriate remedy here  
12 is. We feel that the Court was clearly within its scope  
13 to issue an order that covered the one-pill products.  
14 That they fairly come within the Citizen's Petition but  
15 also it was necessary in order to grant the plaintiff's  
16 relief and remedy the defendant's conduct here.

17 And they seem to be saying well, we can bring  
18 the Plan B One-Step SNDA into this process in a way that  
19 makes these two things inextricably entwined and then  
20 when it comes to remedy, we can try to untie them if it  
21 results in something that we don't like.

22 And what they seem to be trying to do here is  
23 an end run about -- around their own arbitrary and  
24 capricious conduct by saying that they shouldn't be held  
25 fully accountable for it. That their actions concerning

1 Plan B One-Step shouldn't be taken into account in the  
2 end result and that just can't be the case where they are  
3 the ones that have created this problem.

4           And again, I think that once the Court  
5 correctly in this case determined that a discretionary  
6 remand was not appropriate, that the remand had to  
7 include specific directions by this Court that you  
8 clearly had the authority to fashion the appropriate  
9 remedy and the only remedy here that really could address  
10 the plaintiff's harm and the defendant's conduct under  
11 this Citizen's Petition included the Plan B or the One-  
12 Step -- the one pill products.

13           And as to remand, I think here again the  
14 defendant's own arguments explain exactly why a  
15 discretionary remand was not appropriate because they  
16 can't say what they would do or when they would do it and  
17 so the remand itself step -- point-by-point addresses the  
18 harms, grant the Citizen's Petition, make these products  
19 available and do it within thirty days. Each of these  
20 are in direct response to the problems that have been  
21 established here and this is a straightforward order.

22           The defendants aren't saying they couldn't have  
23 done it. They are just saying that they don't want to do  
24 it but nothing less would have given the plaintiffs  
25 actual, rather than hypothetical relief because what the

1 defendants are saying is the plaintiffs are going to get  
2 hypothetical relief at some unknown point in the future  
3 and we've waited, and waited, and waited.

4 THE COURT: You're saying that but it's not  
5 true. I don't want to repeat and I'm going to say this  
6 for the last time.

7 MS. CREPPS: Am I giving him too much of the  
8 benefit of the doubt?

9 THE COURT: As long as the Secretary takes the  
10 position that she has taken, they can't grant you the  
11 relief that you want. That's the bottom line. And  
12 everything he says to the contrary just undermines his  
13 credibility as a lawyer and as a member of the bar of  
14 this Court.

15 MS. CREPPS: Your Honor, I don't have any other  
16 remarks unless you have questions.

17 THE COURT: No.

18 MR. AMANAT: May I respond to just a couple of  
19 things very briefly, your Honor.

20 THE COURT: Go ahead.

21 MR. AMANAT: With regard to Ms. Crepps'  
22 argument with respect to the remedy, regardless of what  
23 remedy the plaintiffs sought by their complaint or how  
24 they characterized their addendum, ultimately under the  
25 Monsanto decision from the Supreme Court, even in the

1 face of a determination by the Court that the agency's  
2 action was arbitrary and capricious, the Court is obliged  
3 to tailor and limit its remedy to that which is  
4 specifically unnecessary to cure the harms the plaintiffs  
5 themselves have.

6 THE COURT: So if I follow the logic of your  
7 argument, this could go on endlessly. I could remand,  
8 which I did. I was very conservative in what I did the  
9 last time. And the same thing happened that happened the  
10 first time and you want me to remand it again even though  
11 it's absolutely clear that if the Secretary adheres to  
12 the position, you cannot grant -- you won't do anything  
13 other than deny the Citizen Petition.

14 MR. AMANAT: Is --

15 THE COURT: And please, don't keep repeating  
16 this double-talk about what could be done. It just can't  
17 be done because they do not have any more than Teva had,  
18 the figures relating to this one percent and it can't be  
19 gotten.

20 MR. AMANAT: Is --

21 THE COURT: And if that's what the Secretary's  
22 position is -- now if you want to write me a letter  
23 saying the Secretary has changed her position, she's  
24 willing to get out of the process and let the FDA do what  
25 it wants, then I will reconsider but that's not the --

1 but right now, a remand would be totally pointless and it  
2 cannot be the law that I can remand it again -- suppose  
3 you did the same thing? Listen to me. I'm asking you a  
4 question.

5 MR. AMANAT: I'm listening.

6 THE COURT: Suppose they did the same thing  
7 again and then it came back and you would tell me what?  
8 Could I then order the FDA to grant the relief? Yes or  
9 no. Please answer my question.

10 MR. AMANAT: There may come a --

11 THE COURT: There may --

12 MR. AMANAT: In that hypothetical, sure, there  
13 may --

14 THE COURT: There may come a time when I could  
15 do this -- I could order it.

16 MR. AMANAT: Well, except for the fact of --

17 THE COURT: Yes or no?

18 MR. AMANAT: Well, I --

19 THE COURT: You started to say it. Why don't  
20 you finish it?

21 MR. AMANAT: I --

22 THE COURT: There may come a time when enough  
23 is enough in terms of remands; right?

24 MR. AMANAT: Yes, but --

25 THE COURT: Good. So now that we've

1 established there's --

2 MR. AMANAT: But --

3 THE COURT: -- no absolute bar to my doing  
4 this.

5 MR. AMANAT: Yes, there are times when courts  
6 have held that enough was enough with regard to remands.

7 THE COURT: Good.

8 MR. AMANAT: However --

9 THE COURT: Do you have the cases for me by the  
10 way?

11 MR. AMANAT: However --

12 THE COURT: Did you cite them in your brief?

13 MR. AMANAT: This -- well, we're not aware of  
14 any case, however, where any court has directed FDA to  
15 change the prescription status of a drug that's on the  
16 market based on a review of the Citizen petition and with  
17 that kind of a mandatory directive.

18 THE COURT: Well, listen we're going --

19 MR. AMANAT: Your Honor, just said --

20 THE COURT: We're going --

21 MR. AMANAT: -- (indiscernible).

22 THE COURT: So what? We're going around in a  
23 circle here. I'm not ordering in reality whatever  
24 fictions you want to engage in, the FDA to do anything  
25 that it didn't want to do. That's the bottom line here

1 and that's what makes this case so unique and that the  
2 only thing that's going to stand in the way of -- if I  
3 remanded it, is the same impediment now and that is the  
4 political decision of the Secretary. That's basically  
5 it.

6           There will probably be not another case --  
7 since this is basically the first time as far as I  
8 understand that the Secretary has ever intervened and we  
9 never even discussed the issue of her power, by the way.

10           MR. AMANAT: That's not entirely correct, but  
11 -- the -- but it's also besides the point. The point I  
12 am trying to make, your Honor, is that the question of  
13 whether a court should remand rather than take some more  
14 directed action --

15           THE COURT: I did. I was the responsible  
16 conservative judge the last time. They wanted me the  
17 last time to order the FDA to do what I ordered them to  
18 do now and I said no. I said even though what happened  
19 was politically motivated, the process -- the  
20 administrative process was essentially corrupted. I'm  
21 going to remand because we're getting a new FDA  
22 administrator. I forget the name of the administrator --  
23 the commissioner -- is that her title, administrator or  
24 commissioner?

25           MR. AMANAT: Commissioner of Food and Drugs.

1           THE COURT: Commissioner -- a new Deputy  
2 Commissioner and a new President. And so, I said, no,  
3 I'm not going -- I'm going to be the responsible judge.  
4 I'm going to remand it and what happens on remand? The  
5 same thing. And I'm -- I wasn't going to do it again.

6           MR. AMANAT: But regardless of the reasons why  
7 the Court found the process to have been arbitrary and  
8 capricious, and regardless of how many times it had been  
9 previously remanded or how long the process has taken,  
10 the legal standard that the Court has to follow is to ask  
11 itself whether it is definitively true that a remand  
12 would serve no useful purpose.

13           THE COURT: Yes, I have asked myself. Would a  
14 remand serve no useful purpose? Yes.

15           MR. AMANAT: The government disagrees with the  
16 Court.

17           THE COURT: No, but you keep saying that. You  
18 disagree but you cannot tell me how if the Secretary's  
19 position remains unchanged, that they could do anything  
20 else. And I want to draw this to an end because we're  
21 going over the same thing.

22           MR. AMANAT: If I may just briefly address the  
23 question of the administrative record and the  
24 confidential information. I just want to clarify a  
25 factual matter.

1           From the beginning of this case going back to  
2 the 2005 case, when the Court directed the government to  
3 produce the administrative record which spanned 30,000,  
4 40,000pages, I don't recall precisely how long it was but  
5 it was voluminous, in the course of that production, we  
6 consulted closely with Barr, which at the time was  
7 represented by Lenzer Colin (ph.) not Kirkland & Ellis.

8           THE COURT: Good to know.

9           MR. AMANAT: And the documents in the  
10 administrative record as to which Barr asserted a  
11 propriety interest were simply submitted under seal and  
12 made subject to a protective order. It's not that the  
13 sponsor has a veto power over whether they're in the  
14 administrative record or not. They're in the  
15 administrative record -- the administrative record is  
16 what the agency relied on.

17          THE COURT: Right.

18          MR. AMANAT: It is. The administrative record  
19 is what the agency relied on in making its decision.

20          THE COURT: It may be.

21          MR. AMANAT: There may be portions of the  
22 administrative record --

23          THE COURT: I have to rely on you for that and  
24 Teva.

25          MR. AMANAT: Well, there may be portions of the

1 administrative record which may need to be filed under  
2 seal or in a redacted version or which are not suitable  
3 for public submission because of the proprietary interests  
4 of the sponsor but the sponsor doesn't get a veto over  
5 what's in the administrative record or what's not in the  
6 administrative record.

7 THE COURT: Maybe he does and maybe it doesn't.  
8 I don't know. You know, I --

9 MR. AMANAT: So, I just wanted to clarify that  
10 that with regard to for example, the PowerPoint  
11 presentation that your Honor mentioned, that was part of  
12 the administrative record because it was part of what FDA  
13 considered in the course of adjudicating the Citizen  
14 Petition because Teva had a proprietary interest in it.  
15 We consulted with them as to whether it could be part of  
16 the public filing or whether it needed to be submitted  
17 and redacted or under seal.

18 THE COURT: Basically that was -- what was in  
19 that PowerPoint was not confidential because it had been  
20 published. And I want to ask you one more thing, by the  
21 way, because I didn't want to make an issue of it at the  
22 time but you know, this Miriam Kramer affidavit, the  
23 study that she did, it's labeled "Comprehension Study  
24 Ages Twelve to Seventeen --

25 MR. AMANAT: I'm having a hard time hearing

1 you, Judge. I'm sorry.

2 THE COURT: You know, this Miriam Kramer study  
3 on ages twelve to seventeen one of the questions that I  
4 asked was this considered by the agency, right?

5 MR. AMANAT: Right.

6 THE COURT: That could be answered by a yes or  
7 a no, right? Am I correct?

8 MR. AMANAT: We answered that question for the  
9 Court, yes.

10 THE COURT: But not with a yes or a no. Right?  
11 What you told me was that the FDA had come across -- an  
12 FDA researcher had come across it and read it but it was  
13 not part of the docket.

14 MR. AMANAT: Right. That is correct.

15 THE COURT: But it didn't answer the question.

16 MR. AMANAT: If it wasn't part of the docket,  
17 it wasn't considered as part of the --

18 THE COURT: Well, you didn't say that. You  
19 didn't answer the question no. You didn't say it wasn't  
20 considered.

21 MR. AMANAT: Well the --

22 THE COURT: And there was stuff that --

23 MR. AMANAT: I apologize, your Honor.

24 THE COURT: There was stuff that was considered  
25 that was not part of that docket. I mean, I just -- when

1 I asked you whether the Secretary knew that Teva had been  
2 told that they didn't have to submit actual use studies  
3 for eleven to thirteen-year-olds, you didn't answer that  
4 question yes or no either. You said the Secretary wasn't  
5 in the room when they were told that, as if that's the  
6 only way she could have found it out. That could have  
7 been answered by a yes or no too. And so you wonder why  
8 I am cynical and skeptical of you and your arguments.

9           The Solicitor General authorized you to file a  
10 motion for a stay, by the way?

11           MR. AMANAT: Of course, your Honor.

12           THE COURT: I'm really surprised.

13           MR. AMANAT: Thank you, your Honor, for your  
14 time.

15           THE COURT: I hope to have a decision before I  
16 leave for California. Don't charge your client any money  
17 for this brief that you're going to give me. I'm going  
18 to leave it to the FDA to decide what they want to  
19 release.

20           MR. SHUMSKY: Thank you, your Honor.

21                           (Matter concluded)

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## C E R T I F I C A T E

I, LINDA FERRARA, 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 8th day of May, 2013.

  
Linda Ferrara

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