

EXCERPTS FROM FDA DEPOSITIONS OF JOHN JENKINS, FLORENCE HOUN AND SUSAN WOOD

JOHN JENKINS (Director of Office of New Drugs)

DEPOSITION

August 14, 2006

Steven Warshawsky (DOJ): Now, in your testimony previously you testified -- and I'm now looking at Page 18 -- "They" -- referring to Dr. Woodcock and Dr. Galson, and I'm quoting now, quote -- "described that Dr. McClellan, the Commissioner at the time, was not in favor of approving the Application and felt that the Application should not be approved on that cycle, so that's how they explained it." Do you recall giving testimony of that type?

Jenkins: Yes.

Warshawsky: Let me ask you a few questions about that testimony. First of all, do you specifically recall Dr. Woodcock or Dr. Galson mentioning Dr. McClellan by name at this lunch meeting?

Jenkins: Yes.

Warshawsky: And did they tell you that Dr. McClellan had reached a final decision with respect to Plan B or was leaning in the direction of non-approval at that time?

Jenkins: I took what they told me at that time, that it was a final decision, that the Application could not be approved on that cycle.

Warshawsky: I'd like to direct your attention to another piece of testimony. I'm looking now at Page 51. To give you the context for your testimony here, you were describing how, as you, as you saw the development during this 2003 and 2004 period, it looked to you like Dr. Galson may initially have been on the side of disagreeing with Dr. McClellan's views about the deficiencies of the Application but then, over time, moved to his own position, agreeing that there were I guess too many deficiencies for an Approval Action to be the right position, and you were asked some questions about what, in your opinion, drove that transition.

Jenkins: Uh-huh.

Warshawsky: And part or one piece of testimony that you gave, you said, quote, "I got the sense that he didn't feel he had a voice." Now, I believe the transcriptionist got that wrong. It should have been "a choice."

Jenkins: Right.

Warshawsky: And I guess -- well, my question is: What did you mean by "he didn't have a choice," and how did you get that sense?

Jenkins: I would back up for just a second and say that during the time that we were reviewing the Application before we went to the Advisory Committee, I never had any indication from either Dr. Woodcock or Dr. Galson that they felt that the product should not be available over the counter without age restriction, so nothing in their

communications with me ever led me to think that they were thinking that this should not be approved or should not be available.

Jenkins: Over the course of the time after the lunch meeting that occurred sometime around the end of December 2003, early January 2004 that we talked about earlier and then the subsequent meeting with the Review Division in January and with Dr. McClellan in February, as we were working through the Application, getting towards the Action, there were occasions where, in conversations with Dr. Galson, that he told me that he felt he didn't have a choice, and he characterized that in a sense that he wasn't sure that he would be allowed to remain as Center Director if he didn't agree with the Action.

Warshawsky: You also testified about how the Non-Approvable Action, I believe, was viewed by Dr. Galson as a compromise that would pave the way toward some sort of non-prescription status later. Is that basically right?

Jenkins: That's not exactly how I characterized it.

Warshawsky: Okay.

Jenkins: It was, it was conveyed to myself that -- and to others -- that the Not Approvable Action was necessary to address the constituents who were opposed to approval of Plan B over the counter, and that in some way down the road that hard-line position that the Agency had taken on the first cycle would in some way pave the way toward some sort of a compromise that would lead to an eventual approval that was more restricted.

Simon Heller (CRR): Did you by any chance read or look at the portion of Dr. Houn's deposition where she testified about receiving a telephone call from Dr. Woodcock around the time of the January 15th, 2004, meeting?

Jenkins: I saw that in her deposition, and I was aware of the phone call, yes.

Heller: When did you become aware of that phone call?

Jenkins: I think I may have -- Sandy Kweder and myself may have actually suggested to Dr. Woodcock that she call Dr. Houn, so I may have been aware of it before it occurred and probably was aware in reasonable proximity to when it occurred that Dr. Woodcock had actually called her.

Heller: Were you aware at that time -- well, were you aware at that time, around the time of January 15th, that Dr. Woodcock had conveyed to Dr. Houn that the Plan B process was occurring as it was to appease constituents of the Presidential Administration?

Warshawsky: I'm going to object to that question. I think that --

Heller: Let me rephrase it a little bit.

Warshawsky: I object to the way you phrased that, because I think we know from the record who was on that telephone call, so I think the question is more about what he was told by one of these people.

Heller: Well, did either Dr. Houn or Dr. Woodcock tell you that during the course of that telephone call a statement was made about appeasing the constituents of the Presidential Administration?

Jenkins: I have a vague memory that that's how Dr. Houn communicated back to me the substance of the call with Dr. Woodcock, that that was her interpretation of what she had heard.

Heller: Around the time of the phone call?

Jenkins: Yes.

Heller: Putting aside the phone call itself, just information or the proposition that, that the Agency's handling of Plan B was occurring the way it was to appease the constituents of the Presidential Administration, have you heard anyone else express that proposition or that idea?

Jenkins: Well, there's been lots of speculation within the Agency that that was the reason for a lot of the events, but I think the only places that I've heard from my supervisors was in relation to the, uh, the need for the Not Approvable Letter to take a hard stance that would then later pave the way to some sort of acceptable compromise.

FLORENCE HOUN (Director of Office of Drug Evaluation III)

DEPOSITION

July 18, 2006

Simon Heller (CRR): In the course of the Agency's process regarding Plan B, did you observe any departures from normal practice?

Frank Amanat (DOJ): Objection. You can answer the question.

Heller: You can answer.

Houn: Yes.

Heller: Can you tell me -- I don't know if there were one or many, but can you tell me whichever -- whatever things that were departures that you recall?

Houn: Well, I think that there were a number of events that I felt were questionable. And I think the most striking event was related to our January 15th meeting with Steven Galson in which he conveyed that the data for age group 14 to 16 was insufficient to support approval for OTC switch; that either the company would have to conduct a study in that age group or they could propose restricted marketing to 18-year-olds or older. And he described this decision as sincere, not ideologic. But that begged the question of should we complete our reviews or not. And so I asked that question at the meeting. And we were instructed to complete our reviews. But I think that by conveying that this decision was a concern of the Commissioner's, it might have made our further evaluation superfluous. So I do know that some of the reviewers finished their reviews soon after that meeting. But in the Office of Drug Evaluation 3, in order to try to capture all the data that the reviewers were aware of that supported the OTC switch, they continued working with the principal investigators, Melanie Gold and others to obtain the data and document it for the record.

Heller: At that January 15th meeting did Dr. Galson convey that the Commissioner's Office believed that the SNDA could not be approved?

Amanat: Objection. You can answer the question.

Houn: I believe so.

Heller: Why was what Dr. Galson said at that meeting or -- why was it as you said sort of the most striking of the questionable things you noticed?

Amanat: Object to the form of the question. You can answer the question.

Houn: Could you repeat it?

Heller: Yes. Let me ask it a little bit differently. Why was it striking at all that the head of CDER was coming to tell people that the data was insufficient? Why would that be striking?

Houn: Well, I think what was very unusual is that we had not finished the evaluation process, and we were in the middle of getting data on the question of adolescent use of emergency contraception. So if we were to continue an evidence-based approach, we would hope to have all the evidence in hand before an evaluation and decision was made.

Heller: So was it your sense that at that meeting a decision had been made, in essence?

Amanat: Objection. You can answer the question.

Houn: It was my sense that a decision had been made, and that I also sensed within the room and then subsequent discussions that we should meet with Dr. McClellan, present him with new information and perhaps it could be altered. Some people had that view.

Heller: Did you have that view?

Houn: I think I had that hope.

Heller: Wouldn't it be sort of standard that if there was additional evidence that could be presented to alter someone's view, that you would be, of course that could alter that view? Isn't that -- let me rephrase the question, because I don't know if that was even a question. There was a January 15th meeting, and then some people believed that they might be able to present additional evidence to the Commissioner that might alter his view, is that right?

Houn: Yes.

Heller: And some people didn't have that view?

Houn: Right.

Heller: Does that mean that there were some people who thought it's not going to do any good to present the Commissioner with additional evidence?

Houn: Right.

Heller: There were some people who felt that way?

Houn: Yes.

Houn: And it sounds like you had a hope, but you weren't exactly sure that it was going to be successful either?

Amanat: Objection.

Houn: That's correct. Oh --

Amanat: Go ahead. You can answer that.

Houn: That's correct.

Heller: Why -- it seems to me that why would it be that people wouldn't sort of all feel, oh, of course if we have additional evidence, that could be persuasive to the Commissioner, who's a scientist and so forth?

Houn: I think --

Amanat: I object. You can answer the question.

Houn: I think since at least in 2000, we are – we in HHS, Health and Human Services, are aware that then Secretary Tommy Thompson's goals and strategic objectives for the Department, when they involved unintended pregnancies, was the -- was the advocacy of abstinence. And under the president's management agenda, the Department's strategic plans and goals are cascaded down to agencies, to supervisory heads in our performance evaluation. So I think that the availability of Plan B over-the-counter raised concerns on whether this was counter to the strategic goals of the Department.

Heller: Continuing on with other things that may have occurred that you viewed as questionable, are there any others that come to mind?

Amanat: Object to the word "questionable" once again. You can answer the question.

Houn: Well, going back further, I guess the December -- let me get the dates right -- it was December 2002, appointments of the Reproductive Health Drugs Advisory Committee members was also very unusual.

Heller: In what way?

Houn: Usually nominations received from the Division, received by the Division from different sources, Division members put together a panel of nominees and send those names up for clearance. In this case names were sent down, and this was in 2002, because we were --

Warsawsky: I'm sorry, can I ask you to speak up? I'm having a hard time hearing you.

Houn: Okay. This was in 2002 because I remember we wanted to try to constitute the Advisory Committee to discuss the findings with estrogen and hydroxyprogesterone acetate on cardiovascular risks that became known in July 2002, because we wanted to hold an Advisory Committee in the fall of 2002 to deal with the cardiovascular risks of the post-menopausal estrogen agents. And so in trying to constitute that committee, a compromise was reached which some of the members were names that the Division had put forward and others were not. And that --

Amanat: Go ahead.

Houn: And that full committee was signed off by Associate Commissioner Linda Skladany late December in 2002.

Amanat: I'm going to object and move to strike the entire answer as being nonresponsive to the question posed.

Heller: I thought it was completely responsive.

Amanat: Well, it doesn't have anything to do with Plan B, which is why it was not responsive.

Houn: Well, I think that in --

Heller: Please explain further.

Houn: I think that everybody knew the application would be coming in either late 2002, which I think the company made public announcements. The Washington Post -- or was it the New York Times had a summer article about the impending application.

Heller: And certainly within the Agency you knew that the application was coming?

Houn: Yes. Yes. And so I think that the constitution of the panel was important, and that these OTC switch applications are heard before advisory committees. So I thought it was irrelevant.

Heller: Let me ask a different question because yesterday I did -- no, I guess my colleague conducted the deposition of Dr. Griebel, who you know. And she talked about there being contention around the composition of this Advisory Committee. And what I'm trying to get a sense of is, was the contention about some of the names that were nominated from higher up in the Agency, or was the contention also about people who were nominated from sort of the more normal process for nominations?

Amanat: I'm going to object to the word "contention" and object to the characterization of the testimony of the witness who testified yesterday, and object to the form of the question as compound, vague and ambiguous.

Heller: You can answer the question.

Houn: Well, from my perspective, the contention was over the constitution of the panel, the type of experts needed, and the lack of expertise in some of the nominees relevant to the function of the Reproductive Health Drugs Advisory Committee.

Amanat: Object to the response. Move to strike as nonresponsive to the question posed.

Heller: Which of the nominees did you view as having a lack of expertise relevant to the function of the Committee?

Houn: Well, I was concerned that the appointment of Dr. Susan Crawford -- Crockett was not reflective of the desire to have expertise recognized on a --

Warshawsky: I'm sorry, expertise what?

Houn: Expertise recognized on a regional or national level or specialty field that would help our deliberations.

Heller: Anyone else you were concerned about?

Houn: I was concerned about the expertise of Dr. Joseph Stanford, being that of natural family planning as you don't have any drugs being developed in that area, and we don't use natural family planning as a control arm in our trials. So I wasn't sure about his expertise being, again, relevant to the functions of the Advisory Committee.

Heller: Do you know who makes the final decision about the composition of the Advisory Committee?

Houn: The Secretary or Assistant Secretary or delegate.

Heller: In this case, in the case of the composition of the Committee that you're talking about in 2002, do you know who made -- was there someone --

Houn: The deciding official was Dr. Linda Skladany in this case.

Warshawsky: I'm sorry?

Amanat: Dr. Linda Skladany, Assistant Secretary of the Agency.

Houn: No, she is the Associate Commissioner.

Heller: How long do people serve on the Advisory Committee? Is it sort of constituted when it's needed or do people get appointed for ten years? How is that done?

Houn: Four-year -- maximum membership is four-year and would have to be renewed. And then you can have shorter membership appointments. So I think in this case we tried to come up with a compromise that Dr. Kweder and Dr. Skladany negotiate in terms of length of time, who would be on it.

Heller: And so Dr. Kweder might know even more about these negotiations and the constitution of the Committee than you do?

Houn: Dr. Kweder would know more, and Dr. Igor Cerny, who's head of the Advisory Committee staff for CDER, also has knowledge.

Heller: Do you know if Dr. Crockett -- I hope I have the name right -- Dr. Susan Crockett, wound up being on the Committee?

Houn: Yes.

Heller: She was on the Committee?

Houn: Yes.

Heller: And what about Dr. Stanford?

Houn: Yes.

Heller: And Dr. Hager?

Houn: Dr. Hager, yes.

Heller: Were there any other names that were proposed from higher up in the Agency that you can recall, or was it just those three?

Amanat: I object to the question. You can answer.

Houn: I don't recall, but like I said, they were in e-mails responsive to your request.

Heller: Do you know who outside the Office was communicating these proposed nominees or conveying that these people were proposed for the Committee?

Amanat: Objection. You can answer.

Houn: Well, we interacted with the Advisory Committee staff, and they provided us with the latest news. We interacted with Dr. Kweder and she would provide us with feedback. So we were not the direct recipients of interactions. We were the recipients of names. And our job was to look at the name, research their credentials, their publications. And we felt if there was a question of qualification, we should raise it with our senior managers, which we did.

Heller: Do you recall receiving or seeing the names of any individuals proposed for the Advisory Committee from outside the Office, like sort of in the way you saw Dr. Hager, Dr. Stanford and Dr. Crockett's names? Do you recall seeing any other names of individuals whose expertise you didn't question or didn't doubt?

Amanat: Objection. You can answer the question. I'm going to object. I want to make clear I object that your question assumes facts not in evidence because not all of the names -- the witness did not testify that she questioned the expertise of all the names that you mentioned. But your question is objectionable for other reasons as well.

Heller: Didn't you say that you questioned the expertise of Dr. Hager, Dr. -- I'm sorry, maybe you didn't -- did you question the expertise of Dr. Hager?

Houn: No, I did not. I questioned whether he was the -- well, no, I didn't actually tell you why.

Heller: Well, go ahead.

Amanat: My objection was well taken.

Houn: I think Dr. Hager got his training in the Center for Disease Control, Sexually Transmitted Disease. Drugs that treat, prevent sexually transmitted disease are not handled in the Reproductive Drugs Advisory Committee. They're handled in the anti-infectives or antiviral drugs committee. And they approve like vaginal antifungals, STD treatments for chlamydia. But so that's why I objected for his appointment as chair. I thought it was not the right expertise.

Heller: Between that time when you sort of first learned of that and May of 2004, when the non-approvable letter was issued, did you engage in any discussions with Dr. Galson to try to understand why ODE-3 and ODE-5 were not going to make the decision about the application?

Amanat: I'm sorry. What were the dates in your question?

Heller: Between the dates when she first learned that ODE-3 and ODE-5 would not be making the decision, and May of 2004 when Dr. Galson issued the letter.

Houn: I didn't talk with Dr. Galson.

Heller: Was there anyone else you did talk to about that subject?

Houn: I talked to Dr. Woodcock. She called me at home, either the afternoon of the 15th, or more likely the afternoon of the 16th of January, 2004, to review the impact of the January 15th meeting with me, to find out what did the -- what was the reaction to the team. And she conveyed to me her assurance that this was the only way to go to issue a non-approval letter to appease the administration's constituents, and then later this could be approved.

JANET WOODCOCK (Deputy Commissioner for Operations)

DEPOSITION

April 26, 2006

Bonnie Scott Jones (CRR): Do you have any idea why the Commissioner would have cut you out of his decision-making process regarding the initiation of rulemaking when you had played a significant advisory role on the Plan B SNDA up to that time?

Woodcock: No.

Jones: No idea?

Woodcock: No.

Jones: None at all?

Woodcock: No.

Jones: Has Dr. Galson ever communicated to you his speculation on that question?

Woodcock: Dr. Galson and I discussed the pending application a number of times. He requested to me to request to Dr. Crawford what the status would be and what would be expected. I would do that, and Dr. Crawford would tell me it was under evaluation.

Jones: But Dr. Galson never told you why he might think that Dr. Crawford had cut you out of that decision on rulemaking?

Woodcock: There was—he speculated that there might be pressures on Dr. Crawford.

Jones: And who did he speculate those pressures were coming from?

Woodcock: Congress, the administration, and so forth.

SUSAN WOOD (former Director of Office of Women's Health)

DEPOSITION

July 31, 2006

12:19:51

Vivien Labotan (CRR): Did, did Dr. Steven Galson ever discuss with you the basis for his decision to issue a Non-Approvable Letter?

Wood: Yes.

Labotan: Did that occur in a conversation by phone?

Wood: No.

Labotan: In person?

Wood: In person.

Labotan: And who initiated that conversation?

Wood: Dr. Galson.

Labotan: When did that conversation take place?

Wood: Either the day -- I believe it was the day before or a couple of days before the, um, issuing of the Non-Approvable Letter.

Labotan: And where did that conversation take place?

Wood: In Dr. Galson's Office.

Labotan: And what did Dr. Galson say about the basis for his decision?

Wood: Um, he said that he, um, had reached conclusions about concerns regarding the use by younger teens, um, and he also, uh, said, uh, that he was, um, felt it important to be an effective leader of the Center for Drugs, and that issuing this Non-Approvable Letter was, um, necessary if he was going to be able to be an effective leader of the Center for Drug Evaluation and Research.

Labotan: Did Dr. Galson ever indicate that issuance of the Non-Approvable Letter in May of 2004 might lead to some favorable action related to Plan B in the future?

Wood: Yes.

Labotan: And what did he indicate?

Wood: Well, he really thought that this was a path forward towards approval, at least for older teens and adults.

Labotan: And did Dr. Galson express that in that same conversation with you?

Wood: Yes.

Labotan: Do you have any understanding of why Dr. Galson thought that denial of the SNDA was, was necessary to be an effective leader?

Frank Amanat (DOJ): Objection. You can answer the question.

Wood: Can you ask that question again.

Labotan: Sure. Do you have any understanding of why Dr. Galson thought that denial of the SNDA was necessary to be an effective leader?

Wood: I don't remember the exact words that he said, but my understanding of it was that he felt that he would not be able to work with the leadership of the Agency in an effective manner if this letter -- if this denial did not go through. My understanding from that meeting was that he, he felt that this was necessary if he was going to be, um, an integral part of the leadership of the Agency in terms of being able to work with, um, uh, his supervisors, uh, in, in managing, uh, the Center for Drugs.

12:38:05

Vivien Labotan (CRR): Sure. When you resigned to Dr. Woodcock, what did she tell you about her own feelings about staying at the Agency?

Wood: Um, she said that she, um, was actually very understanding as to why I felt I needed to resign in order to maintain my credibility as someone working in women's health policy and women's health science and research. She was just very, um -- she was very understanding. She asked me if I would reconsider, and she said that she understood the need to maintain your credibility in the outside world and that, um, she, um, wasn't sure, um -- and I have to say I'm very uncomfortable in revealing private conversations of this nature. She wasn't sure how long, you know, that she would be able to feel credible at the FDA herself, and -- but she was certainly understanding how I had reached that point.