

EXCERPTS FROM FDA DEPOSITION OF DR. SANDRA KWEDER

Vivien Labaton/Center for Reproductive Rights: Okay. Thank you. Do you recall a lunch meeting you had in late 2003 with Dr. Woodcock, Dr. Galson and Dr. Jenkins?

Kweder: Yes.

Labaton: Where did that meeting take place?

Kweder: Amalfi Restaurant.

Labaton: And that's a restaurant --

Kweder: It's right down the street, yeah.

Labaton: And was it just the four of you?

Kweder: Yes.

Labaton: And what happened at that meeting?

Kweder: They had asked to -- they had asked for Janet and Steven and us -- John and I -- to have lunch with them. We were expecting to discuss the outcome -- I'm not sure. We weren't clear. It was clear that they wanted to talk to us about something. We were just -- we saw it as an opportunity to share with them some of the details of the discussion at the Reproductive and OTC Advisory Committee meeting that had occurred a few weeks before. And when we began -- it was during the course of that discussion that -- we never even really got much into the detail of the Advisory Committee meeting itself, but they informed us that the Plan B could not be approved on this round, and that, that phrase was used, "on this round."

Labaton: What does that mean, "on this round"?

Kweder: That meant that if there were another round of review, another resubmission or "cycle" of review, we call it, there could be approved, it might be able to be approved at some point, but not this time, not on this clock, as we had our deadline. So it couldn't be approved on this round, and that the reason was really rooted in the concern about two things: One, that the -- there was concern about adolescents, its availability to adolescents, and also that it, it takes -- we, society -- the public is not ready to have this kind of contraceptive so widely available over the counter, and that it's going to take time for the public to adjust to this idea. They also told us that they were -- this was part -- that it had to be a Non-Approvable Action and not an Approvable, which -- and the reason for that was because the NA Action sent a stronger message to the public

that FDA was being tough on safety and concerns about reproductive issues in adolescents.

Labaton: At the time of this meeting, the reviews of the Plan B Application, had they been completed?

Kweder: No. However, the general findings of the review staff had been shared and were – at the Advisory Committee meeting a few weeks before and had been presented.

Labaton: Did either Dr. Houn or Dr. Woodcock communicate to you that during the course of that phone call, a statement was made about appealing the constituents of the Presidential Administration?

Kweder: I don't recall being told that that was part of the conversation, but that was certainly implied in the lunch meeting that I had with Janet and Steven was that Dr. McClellan -- you know, this recommendation had -- was not one that Dr. McClellan had made on his own but was in -- the White House was involved is what we were told, and that it was made very clear that there were a lot of constituents who would be very unhappy with the, an over-the-counter Plan B, and those were part of -- in addition to the public, that was part of the public that needed to have the message that we were taking adolescents and reproductive issues seriously. I don't know who those were or anything more about it.

Labaton: You said earlier that at the lunch with Dr. Woodcock, Dr. Galson and Dr. Jenkins, that they said that Dr. McClellan hadn't made his decision with regard to Plan B on his own and that the White House was involved. Who said that? Was that Dr. Woodcock or Dr. Galson?

Kweder: Woodcock.

Labaton: And did Dr. Galson indicate his agreement with that?

Kweder: He didn't disagree with it. I would say he just -- it was more of a nodding in agreement.

Labaton: And when you were told that by Dr. Woodcock, did you ask anything further about the White House's involvement?

Kweder: I didn't. What I asked was, I said – I asked where was, where was this decision coming from? And I expressed -- John and I expressed surprise, since, when we had previously briefed Dr. McClellan, and even earlier I think we had probably briefed

Dr. Crawford at some point, I don't know, but we had previous briefings with the Commissioner's Office on this subject, or conversations with him. Concerns about the Application had never -- or what might be issues that we would need to consider had never been raised, so where was it coming from? And I asked whether Dr. McClellan had specific concerns about the data, and it was at that point that Dr. Woodcock said this is coming from -- this isn't -- she said I don't think this is specifically Scott -- I mean Mark -- but this is coming from the White House and supporters of the White House who are weighing in, and I don't know -- she never shared, nor did she seem to know, anything -- she certainly didn't share with me and John anything more specific than that.

Labaton: When -- do you know when the White House started getting involved?

Kweder: I have no idea.

Labaton: Other than this lunch that you talked about and the conversation between Dr. Woodcock and Dr. Houn, did you ever hear anything about any other instance of the White House's involvement in the FDA's handling of the Plan B Application?

Kweder: I, I don't think specifically I did. There were other occasions after that meeting where I -- I always had the distinct impression that when we would have a discussion within the Center with Dr. Galson about the Application on that first round of review and he would take the discussion back to Dr. McClellan or report back to Dr. McClellan, that there were other parties outside of the Agency, at least at the Department, that were being, being provided the opportunity to express a perspective, but I can't be specific about who or in what exact circumstance. That's to the best of my recollection.

Labaton: And what gave you that impression?

Kweder: Dr. Galson.

Labaton: How did he give you that impression?

Kweder: He would -- he would say things that would -- say, "Well, I will have to run this by -- I will" -- he would say, "I'm going to make this decision, yeah, and I'll run that by Mark, and I'm sure he'll have to -- you know, there may be -- he may have other considerations after he talks to others." But, you know, it was always very vague. It was always very vague.

Labaton: And when he said -- he would talk to Dr. McClellan, and Dr. McClellan may have some concerns after he speaks with others?

Kweder: Yes.

Labaton: Do you know who those "others" were?

Kweder: No, I have no idea. I have no idea, and I never had the impression that Dr. Galson knew either. And actually I don't think that -- yeah, I don't think he did know, and I don't think that Dr. Woodcock did either.