

## EXCERPTS FROM DR. JANET WOODCOCK AND DR. STEVEN GALSON DEPOSITIONS

### *Dr. Janet Woodcock Deposition*

April 26, 2006

### PAGE 64-65

**Bonnie Scott Jones, CRR attorney (speaking to Dr. Woodcock):** To your knowledge, in January of 2005, was Dr. Galson planning to issue an approval on the Plan B dual status application?

**Dr. Janet Woodcock:** The plan was if all—any remaining regulatory and legal issues could be resolved, that the product would be approved under dual marketing status the sponsor had submitted an application for.

**Jones:** So that was his plan at that time?

**Woodcock:** That's my understanding.

**Jones:** What derailed that plan?

**Woodcock:** My understanding is that the legal and regulatory issues were not resolved in the minds of those who were evaluating this application.

**Jones:** Whose minds were those? Whose minds are you talking about?

**Woodcock:** As I said, I was not really privy to that decision or who was, you know, giving opinions on that.

**Jones:** Well, you said that some—at least someone perceived that the legal and regulatory issues were not resolved. To your understanding, who was it that perceived that the legal and regulatory issues were not resolved?

**Woodcock:** By the Commissioner or Acting Commissioner at the time.

**Jones:** Which was Dr. Crawford?

**Woodcock:** Yeah.

**Jones:** Did Dr. Crawford say to you anything about that?

**Woodcock:** No. I asked him.

**Jones:** You asked him?

**Woodcock:** Repeatedly about status of the application and he just said it was under evaluation.

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## **PAGES 72-73**

**Jones:** When were you first informed about the possibility that the Agency would initiate rulemaking prior to deciding on the Plan B dual status application?

**Woodcock:** I believe it was the day before the notice issued, but as I said, I'm not very good at time, dates.

**Jones:** But it was very close in time to the public announcement of that decision, is that right?

**Woodcock:** Yes, yes.

**Jones:** So would it be fair to say that you were informed of the decision itself, rather than included in the decision-making process in that regard?

**Woodcock:** That's correct.

**Jones:** Was that unusual that you would not be informed of a decision of that nature until the day before its announcement?

**Woodcock:** Ordinarily, I would have been more involved, but not in all cases. In this case, I was not involved.

**Jones:** Was it Dr. Crawford himself who told you about—

**Woodcock:** Yes.

**Jones:** Why weren't you involved?

**Woodcock:** I don't know.

**Jones:** You still don't know?

**Woodcock:** No.

**Jones:** Did you ever ask Dr. Crawford why you weren't involved?

**Woodcock:** Yes. He said he was, you know, going to take this decision himself, and that's what he told me.

**Jones:** Did he give you any other answer than that?

**Woodcock:** No.

## **PAGES 77-78**

**Jones:** 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.

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## ***Dr. Steven Galson Deposition***

April 26, 2006

### **PAGES 186-187**

**Simon Heller, CRR attorney (speaking to Galson):** In January of 2005, were you planning to issue an approval for the Barr application?

**Dr. Steven Galson:** We don't make regulatory decisions until all the documentation is together, so planning to make—I don't think like that. It's—I was tending that direction. What happened around that time frame is that Dr. Crawford, who was the Acting Commissioner then, told me that he was concerned about where we were heading because he knew that I was heading towards this recommendation, and he told me that he was going to make the decision on what to do with the application.

**Heller:** So he removed your authority to make the decision?

**Galson:** Right, right.

**Heller:** Had that ever happened before?

**Galson:** Not to me.

**Heller:** Do you know if it's ever happened—do you know of it happening to anyone else who was in your position?

**Galson:** No.

**Heller:** When did he tell you that he was going to remove that authority?

**Galson:** I don't remember the exact time, but it was, it was winter, you know, January, February time frame. That's the closest I can come to it.

### **PAGES 200-202**

**Heller:** When—maybe you answered this already, tell me if you did. When the decision was taken away from you, at whatever point that occurred, were you given a reason why it was being taken away from you?

**Galson:** Yeah, Dr. Crawford was concerned about this packaging configuration, that this was something new, and despite the fact that I saw a clear path to approve it, he had those concerns.

**Heller:** Do you believe his concerns were valid?

**Galson:** I don't make—I don't second-guess the opinions of our attorneys in the Agency. That's their expertise.

**Heller:** I'm talking about Dr. Crawford's views.

**Galson:** Well—

**Heller:** Were they valid?

**Galson:** Yeah, I think he had an educated view of it, based on discussions I wasn't in, but I assume -- he's not an attorney either, so I assume that he had discussions that informed him, and so it wasn't, it wasn't really my role.

**Heller:** He had no scientific basis to disagree with your intended goal—intended decision?

**Galson:** No, and he didn't, didn't attempt to bring science into the question.

**Heller:** Okay. And why were you not included in these other discussions that he was having about Plan B?

**Galson:** I don't know.

**Heller:** Have you ever—

**Galson:** I don't know for sure. I'm speculating that he had—that his concerns were informed by discussions, but since I wasn't in those discussions, I didn't hear about them, I don't, you know, I don't know, I don't know for sure that I was excluded from anything.

**April 27, 2006**

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## **PAGES 269-270**

**Heller:** During the period from when your authority to take action was withdrawn, or the delegation was withdrawn by the Commissioner, through when he resigned, that particular individual resigned, were you unhappy with the process that had evolved with respect to Plan B?

**Galson:** I think that's fair to say, yeah.