From Nancy Ostrove, interviewed by John Swann, 14 June 2013:

One thing that I learned here is that it's like we always said that the industry is not monolithic. FDA is not monolithic either. When I first came in, it seemed like it was a whole bunch of little turfs, and depending on who was the head of the particular office in terms of the Office of New Drugs, for instance you get very different ways of approaching things. When I first started, as I said, we had two very small groups. There weren't enough people in either of those small groups, or even in the medical review groups, to make sure that there was sufficient communication between our division and the medical divisions in terms of labeling. I mean, certainly this was something that was recognized by all the people in what eventually became DDMAC. Obviously, the labeling is the crux. It's the basis of all the judgments that are made about promotional materials. You use the labeling as the basis. Promotional materials need to be consistent with labeling, and they can't be false or misleading.

So, that gets now to more of the regulatory stuff that I got involved with, as opposed to the research. And I did; I got involved in the regulatory stuff, especially when it moved into the patient arena, the consumer arena. But I think that the reviewers in drug advertising and labeling tried their best to give their feedback to the medical reviewers about how labeling could be used to justify promotional material that the reviewers would not want to see. So you have to be very careful about the wording in the labeling. Okay?

But they weren't necessarily, I don't believe that they were necessarily communicators. Most of the people, almost all of them, except, before me, there was Carrie Baum, but beyond

that, all of the people in the regulatory groups really were pharmacists; so they're scientists also. They don't necessarily understand how people interpret stuff. So I think there has been that constant kind of tension between the scientists and the communicators.

But the communicators were this little tiny group that we had of social scientists; there were just a few of us in Lou's group. And then the pharmacists, they'd look at the information and labeling very literally. But even looking at it literally, they often came up with some very good recommendations. For instance, they'd say don't say it this way, because if you say it this way in the labeling, they'll be able to do this in the promotional stuff, and we don't think you want that." Okay?

Now, as time has gone by, that group, which became DDMAC and now it's the Office of Prescription Drug Promotion, got more and more respect, and ability to have a seat at the table with respect to labeling negotiations.

But I do have to say that, when I was involved, it was very difficult for me as a communicator to overrule a medical officer -- to say, "no, they're not going to see it that way." Some of the medical officers really wanted to hear what we had to say, and some of them said, "Hey, I know how people think. I'm a doctor, and I know how the doctors are going to interpret this." You know, just because you're one doesn't mean that you know how everybody else thinks. That's one of the basic tenets that you have to take away from risk communication research -- don't assume you know how your target is going to interpret something. You need to find out, you need to actually ask them, because even the experts make mistakes. So there has been an evolution, I think, over the years, and it's so much better than it was -- I think it is

anyway. By the time I left DDMAC, which was in like 2002, it was better than what it had been when I first started.