Q&A and Discussion of HHS Efforts and Future Directions in Pharmacogenomics

DR. WINN-DEEN: Because these talks have run a little longer than we had budgeted, what I'd like to do is maybe take one or two questions while our next speaker is getting set up for her talk. If I can put you on the spot, Dr. Deverka, to come up and get your slides going. Then we'll take Q&A for all four members of the afternoon panel immediately after her talk.

Is there anybody that has an urgent question you'd like to address to the HHS agency speakers at this point?

Kevin?

DR. FITZGERALD: Just a quick one. Particularly in the FDA presentation, but also in some of the other ones, when you're talking about clinical benefit or therapeutic benefit or something like that, is there a specific definition that is used to apply to that? And I guess in part I'm thinking of something like recombinant human growth hormone for children who are projected to be of a certain height or less, and I know that was very controversial. I presume when we get into this kind of thing, more of those controversies are going to come up. So is there a definition that you're using, or a threshold?

DR. FRUEH: There's no generally applicable definition. I think the definition is looked at on a case by case basis. I mean, you're looking at the outcome, at the benefit/risk ratio every time you're approving a drug, for example. So you're really basing it on an estimate on what at this present time makes the most sense to approve a drug or not. So I think that applies for co-development situations as well as for the regular drug application process as we have it today.

DR. WINN-DEEN: Did you have a question or a comment?

DR. LICINIO: A suggestion.

DR. WINN-DEEN: Okay.

DR. LICINIO: Which is actually to Rochelle, and I should have said this to you before, which is that at the NIH, the National Center for Research Resources has this large program of GCRCs, some of which, just a couple I think, have pharmacogenetics cores. Do you think there's any movement at that level to increase pharmacogenetics within the context of patient-oriented research?

DR. LONG: I think to coordinate with other groups that are doing activities in the same area makes good scientific sense. Insofar as those efforts are possible, we are trying to identify different groups and coordinate them. For example, in the research grant applications you're asked to define who else is doing something at your institution, and reviewers look to see have you formed the right teams and maximized your potential to do good quality research studies. Beyond that, it's a matter of networking, getting the right people together, and if there's benefit to both, they usually do want to start talking.

DR. WINN-DEEN: We'll pause in the Q&A for the agencies right now.