Priority Issues Identified by the Ex Officio Agencies and Departments

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DR. McCABE: Sarah's going to make this presentation. Lana Skirboll is Director of the Office of Science Policy for the NIH and Sarah is basically detailed to us out of that office. That's who Sarah works for, and Lana had some obligations at the NIH today that precluded her being available to us.

So Sarah, if you would?

MS. CARR: I also want to just address the point Reed made. If you'd like, the Committee can ask for a briefing, and I think even David Feigal might be prepared today to say a few words about where FDA is, but we could have a briefing, a more in-depth briefing, at the October meeting. Dr. Sundwall mentioned that the CLIAC is going to be looking at the CLIA regulation and how they want to move forward with whether to augment it for genetic testing. So that would be timely to hear from them in October about their deliberations. So that might be a way to bring you up to date on what's been happening in the time since the SACGT made its recommendations, if you'd like to do that.

Well, as Ed said, Lana couldn't make it today and she regrets it very much, and so do I because I think she would have made this presentation more fun than I'm going to. But anyway, we hope it'll be helpful to you.

What I'm going to present is the summary information about the perspectives of the ex officios, the 16 agencies that are represented on this Committee, and their perspectives on what issues they think are important for this Committee to consider.

I first want to tell you a little bit about the complicated process and how we harassed the ex officio agencies to request their help on this, but what we did was in March, we sent an email request to all of them asking them to identify the high-priority issues they thought, as I said, warranted this Committee's attention, and we used the seven areas of inquiry or functional categories that are set forth in your charter to organize the request. In each of the seven categories, we listed specific issues and we also suggested some other considerations that might be relevant in identifying priorities, and we indicated, though, that they were under no obligation to use this information. They were certainly welcome to think of the issues on their own.

As I said, we organized the request according to the seven functional categories, and I'm sure these are getting to be very familiar to you by now, but let me go through them. The first one is assessing the integration of genetic technologies into health care and public health; studying the clinical, ethical, legal, and societal implications of new medical applications and emerging technological approaches to clinical testing; identifying opportunities and gaps in research and data collection efforts; exploring the use of genetics in bioterrorism; examining the impact of patent policy and licensing practices on access to genetic technologies; analyzing uses of genetic information in education, employment, insurance, and the law; and serving as a public forum for the discussion of emerging ethical, legal and social issues raised by genetic technologies.

Now, I mentioned that we also suggested some other considerations that the ex officios might want to think about as they were identifying priorities and these might also be relevant for the Committee to

consider as you go forward in thinking about priorities. So what we suggested was to think about these questions.

Will the Committee's advice on the issue, on any given issue, significantly benefit society? Conversely, will failure to address the issue prolong any negative impacts it may be having? Is federal guidance or regulation on the issue warranted? Is there a governmental interest in receiving advice on the issue? Is there media attention or public concern about the issue? Is there a need for public discussion and understanding of the issue? Do sufficient data exist on the issue so that the Committee can develop informed policy advice? Is there another body addressing the issue or another body better equipped to address the issue? Does the Committee possess the expertise necessary to undertake a study of the issue?

Now, we had a very good response from the ex officios and I just want to commend all of them for the effort they made and the time they took to respond and they were very thoughtful in how they went about it.

Here you see the responses that we got, and I think it's important to note, though, that the ex officios used a variety of approaches in responding to the request. One of them ranked the seven functional categories in priority order. Some sent back priority issues that were on the list that we prepared. Others selected some of the issues from that list and then added some of their own and then some developed an entirely unique set of issues, and I have to say that this variety actually made the task of summarizing the data rather challenging.

Now, this slide shows the number of specific issues that the ex officios identified within each of the seven functional categories. So you can see that in the first one, integration into health care and public health, they identified 23 specific issues. With regard to uses of genetic information in education, employment, insurance, and law, they identified 19, 17 in the area of research and data collection. On emerging issues, they identified 11. On ELSI issues raised by new health applications and emerging technologies, they identified five, and on the use of genetics in bioterrorism, four, and finally three on patents and licensing practices.

Now, these final two slides that we're going to go through will show you which issues were most often selected by the agencies. As you can see, the use of genetic information in insurance, employment, education, and law was selected by eight agencies. The ethical, legal, and social implications associated with the use of genetic technologies to screen for traits as opposed to diseases was selected by six agencies. Then the following six issues -- standards for clinical readiness, the ELSI implications in new health applications, gene banking, the use of genetics in bioterrorism, impact of patenting and licensing on access, and genetic literacy of the public -- each were identified by five agencies. The last two top 10 pertained to the need for additional oversight and the impact of the privacy rule and they were selected by four agencies.

I just want to make one final point about this list of top 10, which is that they were distributed rather evenly through all seven functional categories.

Now, just one last thing. All of this information is in Tab 6 of your briefing book, including the individual by agency list, so you can see what DOD and Commerce identified in the first table in Tab 6, and then there's also another table in there that shows the priorities that were given, and we just hope this information might be helpful as you begin this important discussion of what you think the priorities are.