



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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Commission Chair

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Meeting 9, Welcome and Opening Remarks
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DR. GUTMANN: Good morning, everybody. I'm Amy Gutmann. I'm President of the University of Pennsylvania and I have the privilege of serving as Chair of the Presidential Commission for the Study of Bioethical Issues, and I welcome you all here this morning.

On behalf of myself and our Vice-Chair Jim Wagner, who will say a few words in a minute, I would like to welcome you. This is our ninth meeting of the Presidential Commission and we have some important work to do.

Before we continue, I want to note the presence of our Designated Federal Official, who is our new Executive Director of the Commission, not so new actually, she's been hard at work with the Commission on our two projects, Lisa M. Lee.

Lisa, would you please stand up so we can recognize you? Welcome. And we on the Commission would like to welcome Lisa as our Director.

(Applause.)

DR. GUTMANN: We have a full day ahead of us and we're going to cover two very important and timely issues.

This afternoon, the Commission will continue its discussion of the issues related to privacy and access to whole genome sequence data but, first, this morning, we're going to begin our work in response to a charge we received from the Secretary of Health and Human Services, Kathleen Sebelius. We received the charge earlier this year.

In January, the Commission received a letter from Secretary Sebelius asking for ethical advice on the development of medical countermeasures for children. In her letter, Secretary Sebelius reminded us that HHS is responsible for developing and stockpiling safe and effective medical countermeasures to protect the nation from

bioterror attacks.

The Secretary noted that HHS has made significant progress towards this goal for adults but acknowledged that developing appropriate measures for children lags, in part due to challenges in conducting studies with pediatric populations.

Herein lies our task. This issue garnered particular public interest last fall when another federal advisory committee, The National Biodefense Science Board, recommended pediatric testing of an anthrax vaccine that would be used in the case of an attack.

The Board, whose chair, Dr. John Parker, we will hear from later today, recommended that HHS move forward with such a study before a public health emergency occurs. It also recommended that such testing occur only after the ethical considerations are adequately addressed and reviewed and that's what we're going to do: carefully and transparently review the ethical considerations surrounding the development of medical countermeasures for children.

In our most recent report *Moral Science*, the Commission thoroughly reviewed human subjects protection standards and concluded that the current U.S. system generally serves to protect people from avoidable harm or unethical treatment in research supported by the Government.

The Commission also found several important areas where improvement of the current system is not only possible but desirable.

As a result of this work, we're very familiar with ethical considerations that arise when conducting human subjects research and, given our limited time today, we're not going to review that. We'll refer anybody to our report and we're very proud of the report and pleased that it was well received.

In preparation for our discussions, though, Commission members reviewed a summary article on key issues in research ethics and like to put this on the record. It's Chapter 11 of the Oxford Textbook of Clinical Research Ethics. It's entitled An Ethical Framework for Biomedical Research. That article is available on our website, bioethics.gov.

We're now focusing in on a specific type of human subjects research: clinical trials of medical countermeasures with children. It is important that we're clear about the scope of our charge upfront. We're not reviewing the overall ethics of vaccine research and use.

Rather, our charge is to focus on medical countermeasures and the specific considerations that arise in testing them for pediatric use.

Of course, medical countermeasures include some vaccines but also include other products, like antibiotics and antivirals. I want to be sure we keep this in mind throughout our deliberations.

We invite comments from the audience and we've always had really helpful comments from the audience and here is how we take public comments. At the Registration Table out front or from any staff member here, there are comment cards. We ask you to write down any comments you have on those cards and hand it to any staff member. The staff members are wearing badges, so I ask staff members to stand up so people can see who you are. There you go.

And the staff members will give me cards throughout the session and as long as we have time, we always begin with questions from Commission members, I'll read them out loud. We take very seriously our commitment to public deliberation and invite you really to ask any questions and those we can't get to at the meeting, we are

happy to respond to after the meeting by e-mail or by letter.

Before I ask our wonderful Vice-Chair to say a few words, I'd like to just have members of the Commission introduce themselves.

Raju, would you please begin?

DR. KUCHERLAPATI: Raju Kucherlapati, Harvard Medical School.

DR. ALLEN: Anita Allen, University of Pennsylvania Law School.

DR. GARZA: Alex Garza, the Department of Homeland Security.

DR. ATKINSON: (inaudible)

DR. MICHAEL: Nelson Michael, Walter Reed Army Institute of Research.

DR. GRADY: Christine Grady, NIH Clinical Center.

DR. SULMASY: Dan Sulmasy, the Medical School and Divinity School at the University of Chicago.

DR. ARRAS: John Arras, University of Virginia.

DR. FARAHANY: Nina Farahany, Vanderbilt Law School and Vanderbilt Philosophy Department.

DR. HAUSER: Stephen Hauser, University of California, San Francisco.

DR. WAGNER: And I am Jim Wagner with Emory University and want to welcome our Commissioners. It's good to be together again. Welcome the experts that will be addressing us today.

Amy and I've had a chance to chat and chatted with several of you, as well. The task before us this morning, I think, is especially fascinating and I hope not confounding. There are issues that involve -- and I'm talking specifically about the countermeasures issue for children -- issues involving risk of biological threat, risk of

anticipatory testing of countermeasures for safety and efficacy, and a whole other bucket of risks around the safety and efficacy associated with applying an untested countermeasure.

None of us, I believe, will have, you know, personal expertise in any of those areas but the service perhaps that we can provide, we're imagining that would be responsive to the Secretary's challenge to us would be to imagine how it is we link those things together in an ethical construct and ethical framework, if you will, into which expert judgment of others could be inserted in order to guide action.

I think if we can focus on that, we'll have a wonderful, wonderful deliverable today, and with that, why don't we get underway?