



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT
Opening Remarks

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Meeting 5, Day 1 Opening Remarks
May 18, 2011
New York, New York

DR. GUTMANN:

Good morning, everybody. I'm AMY GUTMANN and I'm President of the University of Pennsylvania and Chair of the Presidential Commission for the study of Bioethical Issues.

On behalf of myself and my Vice Chair Jim Wagner, who is President of Emory University, I would like to welcome you to Day 1 of our fifth meeting. We're delighted to be here in New York City. The Commission takes seriously our commitment to be a public forum and for that reason, we have come outside of Washington and had three of our five meetings outside of Washington D.C.

Before we continue, let me please note the presence of our designated Federal Official, Commission Executive Director, Valerie Bonham. Valerie, do you just want to signal? There you are. Thank you.

At our last meeting, we began discussion of multiple topics: the use of emerging genetics and neuroscience technology for research for diagnosis for risk identification and for prevention, and the analysis of the current human subjects protection system. Experts on those topics shared their perspectives. We learned a great deal from their presentations and we also, again, heard public comments.

Since then, I'm very pleased to say, the Commission has set our agenda for the next couple of years. We're going to, for our present and until we complete our report, focus on human subjects protection and begin work on genetics. The human subjects protection questions that President Obama raised at the beginning of this year will be discussed at length over the course of today and tomorrow. We will report back to President Obama as he requested this winter.

Though we will not discuss genetics today, we also are beginning to examine some of the questions about genetics and whole genome sequencing that we raised at our last meeting. We hope to give our full attention to what we are now calling the "Genes to Genomes Project" when we take it up again later this year.

Following that project, we will immediately begin work on "Neuroimaging and the Self." That's our tentative title for the neuroscience and neuroimaging topic. And we will begin that in 2012, which is not that far away-- we should remind ourselves. With regard to human subjects protection, the Commission has been given an extremely important charge by the President to review contemporary ethical standards in clinical trials.

We also have been asked to assure the President that the current rules

for research participants protect people from harm both domestically and internationally. And if we can not assure him that that's the case, to recommend to the government changes.

In carrying out this charge, the Commission has done quite a few things since we last met and I have to commend our staff for really driving this forward with the Commissions' advice and consent. At the last meeting, we announced the formation of our International Research Panel to assist the Commission in fulfilling the President's charge. This panel held its first meeting in April at the University of Pennsylvania and it's poised to complete its work and report to the Commission later this summer. So that's the first step in this multifaceted charge.

Second, the Commission has continued its ongoing historical investigation of the public health service research of sexually transmitted disease in Guatemala, which took place from 1946 to 1948. Not to put too fine a point on it, the egregious treatment of vulnerable populations during that time is both stunning and sobering. It puts in higher elite what is at stake in getting both the standards and the practices of human subjects research correct.

As Val Bonham will describe in a few moments, our staff has carefully reviewed over 13,000 original documents and has been on a fact finding trip to Guatemala, including meeting with their own internal investigation committee in Guatemala. Now, this morning we were planning to welcome Dr. Raphael Espada. Dr. Espada, I think as you all know, is the Vice President of Guatemala, and he was committed and truly wanted to speak at this session. Unfortunately, events in Guatemala got in the way and a national state of emergency in Guatemala has prevented Dr. Espada from joining us, and he sends his sincere regrets.

As I'm sure everyone is aware, there has been a great deal of unrest in Guatemala over the past several days, some truly tragic and troubling massacre, and our thoughts are with Vice President Espada and the whole country as they deal with the aftermath of the violence there.

Had Dr. Espada been here, we would've thanked him for his efforts. And I want to say a few words about that now. He has overseen a very important investigation domestically into what happened in Guatemala between '46 and '48. At my last meeting with Dr. Espada, we talked about the responsibility both of our countries feel and both of us feel professionally and personally to learn from the past. There is a wise saying, "those who don't learn from the past are destined to repeat it." It is a clear aim of President Obama to have our Commission enable our government to learn from the past, so we don't repeat it. The same is true for Dr. Espada and the Guatemalan government.

Our mutual commitment to identifying the full facts in this case will ensure going forward that current rules for research participants protect

people from harm or unethical treatment wherever research sponsored by the government occurs. And I was very impressed by Dr. Espada's commitment to this and by his Commissioning a group in Guatemala to move the investigation forward.

So, I also should say that Dr. Espada has given great support to the mission of our Commission as was clear from our past discussions. Our mutual examinations into the research on sexually transmitted diseases that were supported by the U.S. public health service in Guatemala in the 1940's offers a truly extraordinary opportunity to consider and understand very important issues that are important historically, but important in an ongoing way. And to have both countries doing independent investigations of this is truly, I think, path breaking and important.

So we look forward to reading the full report of the Guatemalan Government Investigation Committee as soon as that's out. So that gives you a sort of background on where we are and also our counterpart in Guatemala.

Before I begin, we begin today's sessions, I want to remind everyone in the room about our practice regarding public comments at our meeting. Given the high volume of requests to speak and interest in this topic, we have reserved a session at the end of the day exclusively for public comment. If you have signed up and been selected to give public comment, we will invite you to speak at that time. If not, we welcome you to observe our full proceedings, and also to provide any written comments that you wish. And now I'm going to turn it over to our Vice Chair, Jim Wagner to say a few words. Thank you Jim.

DR. WAGNER:

In fact, I'll make them very few words. I think it was, thank you for reviewing the conversations with Dr. Espada. And perhaps that's more important to hear than my ruminations going forward. So let me just add my thanks, first to you Amy for your leadership to the staff, reinforcing what you have said about the remarkable job they have done. And also the International Research Panel that advises the conversation today toward this question of what constitutes ethically appropriate and sufficient regulatory policy in practice to ensure as the President charged us globally, that we are able to maximize the benefits to be gained by the advancement of medical science and technology. But, at the same time, minimizing the risk to society in general and to individuals in particular, especially the most vulnerable.

I think as it looks, the rest of my comments, you don't need to hear those. I think we need to stay on schedule. So, let me turn it back to you to introduce Valerie.

