



Presidential Commission  
*for the Study of Bioethical Issues*

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**TRANSCRIPT**  
**Opening Remarks**

**Amy Gutmann, Ph.D.**  
Commission Chair

**James Wagner**  
Commission Vice-Chair

Meeting 6, Day 1 Opening Remarks  
August 29, 2011  
Washington, DC

1           DR. GUTMANN: Good afternoon, everybody. I'm  
2 Amy Gutmann, and I'm President of the University of  
3 Pennsylvania, and Chair of the Presidential Commission  
4 for the Study of Bioethical Issues.

5           On behalf of our Vice Chair Jim Wagner, who's  
6 President of Emory University, and myself, I welcome  
7 everyone to this, our Sixth Meeting of the Commission.

8           It is -- before we continue, let me note the  
9 presence of our designated federal official, Commission  
10 Executive Director Valerie Bonham. Val, will you  
11 please stand up so people can recognize you? Thank  
12 you.

13           We, as a commission, are now well into our  
14 work responding to President Obama's charge on the  
15 topic of human subjects protection. As you'll recall  
16 last Fall, we learned that the United States Public  
17 Health Service conducted intentional exposure studies  
18 involving STDs, sexually-transmitted diseases, with  
19 vulnerable populations in Guatemala between 1946 and

1 1948.

2           Following this revelation, President Obama  
3 charged us to do a study of both the historical and the  
4 contemporary situation with human subjects research.  
5 So there are two tasks.

6           One, to do a thorough fact-finding  
7 investigation in to the events in Guatemala to  
8 determine what happened and also to decide what our  
9 ethical position is on what happened, and the second is  
10 to determine if contemporary human subjects protections  
11 adequately guard the health and well-being of  
12 participants in scientific studies supported by the  
13 Federal Government.

14           We're pleased to report that the historical  
15 investigation is near completion. The Commission staff  
16 has devoted the last nine months to conducting  
17 comprehensive independent research into the Guatemala  
18 studies. This is and will be, when we bring it out,  
19 the most comprehensive study of this series of  
20 experiments to date.

21           During this time period, they reviewed over a  
22 125,000 documents. They also created an inhouse

1 document library of over 13,000 documents that inform  
2 most of the facts in this report.

3 The staff reviewed documents compiled from  
4 nine archives, three libraries, and five government  
5 agencies. Source included institutions, such as the  
6 National Archives and Records Administration,  
7 PanAmerican Health Organization Headquarters Library,  
8 and the Bureau of Prisons.

9 From all of that information, this report was  
10 drafted and today we'll discuss some of the answers  
11 we've uncovered to key questions about the studies in  
12 Guatemala. The best thing we as Americans can do when  
13 faced with a dark chapter in our government's history  
14 is to bring it to light. It is important that we  
15 accurately document this clearly unethical episode of  
16 historical injustice.

17 We also have called on our sense and  
18 sensibility, if you will, about bioethics and added a  
19 careful and, I would say, unvarnished ethical analysis  
20 to the historical investigation. We do this, to put it  
21 as simply as possible, to honor the victims and to make  
22 sure it never happens again.

1           Before we turn to the historical  
2           investigation, which will be the topic for the meeting  
3           today, I'd like to take a moment to talk about the  
4           Commission's other activities.

5           The second part of the President's charge on  
6           human subjects protection is to review current rules  
7           for human subject protection and determine if these  
8           rules, coupled with the practices that accompany them,  
9           protect people participating in federally-funded  
10          research from harm and unethical treatment.

11          In carrying out this part of the human  
12          subjects assignment, the Commission has done a number  
13          of things since we last met. An international research  
14          panel was set up as a subcommittee to the Commission.  
15          That panel consisted of international experts on human  
16          subjects protection standards and international  
17          research. The panel members came from all over the  
18          world.

19          Since the Commission's last meeting, the  
20          international panel held its second and third meetings  
21          and it's poised to complete its work. The panel has  
22          reported its findings and recommendations to the full

1 Commission in the form of a report entitled Research  
2 Across Borders.

3 We have sent this report to be published in  
4 the Federal Register and we look forward to taking  
5 public comments on it. The panel report will be on our  
6 website tomorrow.

7 I'm very grateful to Commission Members John  
8 Arras, Christine Grady, and Nelson Michael, who sat on  
9 the international research panel, and they will report  
10 to us. Christine and Nelson will take the lead and we  
11 will have a report tomorrow on the panel and its work  
12 and a discussion on it, as well.

13 We're also collecting data from government  
14 agencies that support research involving human  
15 subjects. What we're going to do with this information  
16 is to be able to describe to the President the  
17 landscape of human subjects research that is supported  
18 by the Federal Government, domestically and  
19 internationally.

20 There is no such set of empirical data  
21 available at the moment and there is nobody in the  
22 process of collecting it. So we decided this was a

1 very important first step which will accompany our  
2 investigation into the adequacy of the rules and  
3 practices concerning human subjects research.

4 In December, we will complete the second part  
5 of the President's human subject protection assignment  
6 and we will deliver our report about contemporary human  
7 subjects research to the President in December.

8 Finally, we're making progress on our next  
9 project, called Genes to Genomes: Collecting, Using  
10 and Governing Genome Sequence Data.

11 This project will address how the growing  
12 amount of collected and available genetic data raises  
13 the bar on data protection, privacy, consent, issues of  
14 individual counseling, among other important issues,  
15 and we will devote the Fall and Spring to this subject  
16 and produce a report next summer.

17 Following this project, so when I said  
18 finally, I was not telling the truth, I will  
19 now -- since I'm a truth-telling person, that was  
20 penultimately, following this project, a project we  
21 haven't started working on, so it's true that I've just  
22 said everything that we've been working on to date, but

1 following this project, we are going to begin another  
2 topic called Neuroimaging and The Self which focuses on  
3 advances in neuroimaging and the implications for moral  
4 and legal responsibility. So we have a very full year  
5 coming up.

6           Unfortunately, due to the hurricane this  
7 weekend, Dr. Rafael Espada, Vice President of  
8 Guatemala, who was planning on being with us, planning  
9 on flying up yesterday, you can understand why he was  
10 unable to travel to Washington to be with us as  
11 scheduled. He sends his regrets.

12           I am very sorry that he couldn't be with us  
13 today. We have enjoyed a very good working relationship  
14 with Dr. Espada throughout our investigations. We very  
15 much appreciate all that he has shared with us.

16           I would like to say a few words about how we  
17 will take comments from the audience at this meeting  
18 before we get started.

19           We are -- we have a lot to accomplish today  
20 and tomorrow and a short amount of time to do it. So  
21 what we've done at the Registration Table out front,  
22 there are comment cards and we ask that anyone who

1 wishes to make a comment write down any comments you  
2 have on the cards, hand the card to any staff member,  
3 and they're all wearing badges. Would staff members  
4 stand up so people can recognize you? Okay.

5           So any staff member can take a card and the  
6 staff will give Jim and me cards throughout the session  
7 and, time permitting, we will read them aloud and we  
8 will engage in responses. All I ask is that any  
9 questions or comments you make be relevant to the  
10 sessions that we are engaged in.

11           And with that, I think we've done all the  
12 preliminaries. We know our beginning. I'm going to  
13 turn to Jim Wagner, our Vice Chair, and see if he has a  
14 few opening remarks.

15           Thank you all for being here, and let me just  
16 thank -- there will be opportunities later, and I will  
17 thank the staff for the incredible work they've done,  
18 especially on the historical report, but let me also  
19 thank all the commission members who traveled to get  
20 here today, for getting here. Somebody once said 90  
21 percent of success in life is showing up. Well, I'm  
22 glad you've showed up. We have a lot more to do

1       besides that, but thank you for being here.

2                     Jim.

3                     DR. WAGNER: Very good. Amy, thank you so  
4 much. Let me also thank the staff for the hard work on  
5 what we're about to discuss, the historical report of  
6 the Guatemalan incident, and thanks to all the  
7 commissioners for all of their work, mostly offline  
8 work.

9                     This is an opportunity this afternoon to be  
10 overheard as we talk to ourselves about the -- thank  
11 you -- as we talk to ourselves about the report now in  
12 draft form and, as you heard Amy say, that we want to  
13 discuss the facts and, as well, as have some  
14 conversation about our ethical analysis.

15                    In fact, the ethical analysis will be the  
16 second piece in Session 2. Now we're going to spend  
17 some time talking about the historical investigation  
18 into the inoculation studies in Guatemala. Our  
19 investigation is to document a couple things, a number  
20 of things, but it documents the actual events, first  
21 and foremost, and tries to explain these events in the  
22 context in which they occurred.

1           It's important to understand not only the  
2 details of the work that Dr. Cutler and colleagues did  
3 but also how the study in Guatemala fit into the wider  
4 context of what was going on in venereal disease  
5 research at that time.

6           To set the stage, we know that syphilis,  
7 gonorrhoea, and other venereal diseases were among the  
8 most serious public health problems of that day and  
9 researchers leading these efforts were at the time some  
10 of our nation's very best scientists. So what happened  
11 is the first question and why, and then the second  
12 question in our second session is about the ethical  
13 appropriateness of that.

14           I think, Steve, you're going to lead us, are  
15 you not? Steve Hauser is going to lead us in an  
16 initial discussion on the facts where we'll talk. We  
17 hope to touch on such things as what were the  
18 scientific questions involved, what methods were used,  
19 what populations were involved, was the methodology  
20 sound, and not just by our standards but all in the  
21 context of the standards of that day.

22           So if you'd open our first session with your

1        comments, Steve, I'd appreciate it.

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