



Presidential Commission  
*for the Study of Bioethical Issues*

TRANSCRIPT  
Executive Director's Report

**Valerie H. Bonham, J.D.**  
Executive Director

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**DR. GUTMANN:**

Great. So, I would like to invite our Executive Director Val Bonham to give us a brief update on where we are and what the Commission has been doing between the last meeting and this meeting. Welcome, Val. I think it's on, but why don't you test it and begin? No, it's not on.

**DR. WAGNER:**

Push the gray button and see what happens.

**DR. GUTMANN:**

Try again. Nope.

**DR. WAGNER:**

I can't tell how to – here we go. Now we have sound.

**MS. BONHAM:**

All right, thank you all. Sorry about that. Dr. Gutmann, Dr. Wagner, Members of the Commission, thank you very much for the kind introduction and for the opportunity to speak with you and update you on the work that we've been doing. Thank you for the kind words about what the staff has been doing. We have been working very hard and I think that we have been able to produce for you some useful information that will really help you with your charge going forward.

**DR. GUTMANN:**

Can you hear back there? Just raise your hand or put a finger up if you can't.

**MS. BONHAM:**

So, I'm here to update you on our work with regard to the fact finding mission and then a little bit with regard to the contemporary human subjects project. As you know, in January, we began a deep dive into identifying and understanding the facts of the U.S. Public Health Service Inoculation Studies in Guatemala. We are here because President Obama asked for a complete and independent accounting of what happened at that time.

I speak for all of my colleagues on the staff when I say that we are humbled by the seriousness of this responsibility and we are grateful for the confidence that you have shown in us. As Dr. GUTMANN explained – excuse me – the staff has reviewed over 125,000 records, and collected nearly 14,000. I bring you the latest numbers – of documents from 13 different archival sources. We've found and reviewed documents from the National Institutes of Health, the National Academy of Sciences, the National Library of Medicine, Departments of Defense and Veterans Affairs, Pan-American Health Organization, several branches of the National Archives and the Archives of four major universities – housing,

individual personal records of some of the individuals involved in the story.

In addition, we have identified and reviewed nearly 400 published works of relevant historical scientific and legal scholarship. Additionally, as part of the investigation, the Commission staff members and I visited Guatemala from April 30th to May 3rd. I went along with Dr. Lombardo, who is here today, and Brian Eiler and Kayte Spector-Bagdady, who many of you know.

**WOMAN 1:**

Would you just speak up?

**MS. BONHAM:**

We came at the invitation of Vice President Dr. Rafael Espada, who also serves as Chair of the Government of Guatemala's Investigation Commission looking into the facts of the case. As Dr. GUTMANN explained, the Vice President was unable to be with us today due to unrest in his country. But, I spoke yesterday with his office and they asked that I convey to you the Vice President's heartfelt regret, his great appreciation for the work that you are doing and his promise to participate with you at a future meeting.

We appreciated the Vice President's invitation to visit the country. There, we received a very warm reception from the Guatemalan government and its people. The trip served to introduce our work to the members of the Guatemalan Investigation Commission and to gather information about their activities.

We learned a great deal both about the efforts of the Guatemalan government to investigate this historical event as well as the country and the people today.

For example, when we were in Guatemala, we toured the Central American archives. We learned about its records, some of which go back over 500 years, and we met with archivists including directors from both the Central American archives, as well as their Police and their Peace archives. It's important to remember, they have and have had a very different country in some ways than our own and the Police and the Peace archives down there are deep sources of information. And we learned a great deal from speaking with those individuals who have been managing a substantial and broad undertaking on their part to confirm and understand as well from their own records, the information contained in the records that prompted our investigation.

We also sought to locate historical sites relevant to these events. Obviously some of these sites are no longer standing. There have been

fires. There have been earthquakes. But, we did find a public health service building still in use that helped orient us to the physical relationship in the country at the time between, for example, the hospital and the prison where this research occurred.

After nearly five months of intensive research, we remain on track to complete the fact finding this summer. As you know, the work by Dr. Cutler and his partners in the public health service venereal disease research laboratory originally came to light through the diligent efforts of Professor Susan Reverby of Wellesley College, who is here with us today.

DR. GUTMANN: Susan, would you please stand up? We would not be here without Susan's really path breaking work.

MS. BONHAM: Thank you. She has given generously of her time to assist us in our efforts. And we have been aided in our work by many thoughtful researchers and individuals who have taken time to speak with us over the past four months, and for that, we are grateful.

The task given to you and us in the time in which it was given is somewhat extraordinary, if that word works. And, but for the assistance of many, many people, we would not be here.

While I'm not prepared to report out any final findings at this time, I can affirm, as discussed and as you all are well familiar, that what we have found is deeply disturbing. The basic facts of this story are known from Dr. Reverby and the Centers for Disease Control and Prevention reports last fall.

Briefly, as you know in 1946, a team of U.S. funded investigators began research designed to test prophylaxis for certain STD's. And soldiers, prisoners, mental asylum patients, children and commercial sex workers were used in this work. Many were intentionally infected with sometimes life threatening diseases. The record suggests that many were treated, but not all. No evidence of consent exists, and affirmative evidence demonstrates efforts to deceive.

President Obama asked the Commission to oversee the most accurate historical account of what the U.S. Public Health Service did in Guatemala as it researched sexually transmitted diseases. He will get it and you, I believe, will be pleased with the work that we've done on your behalf.

Turning now to the contemporary project, the President asked you to examine current standards to protect human subjects, and the bulk of this meeting is about that. You'll be hearing from experts across the globe as they discuss where domestic and international rules and guidelines for human subjects stand today.

The work of the international research panel, whose membership in terms of reference we announced at the last meeting has begun. And we are collecting valuable input from federal research funders. President Obama charged the Commission to determine if federal regulations and international standards adequately guard the health and well being of participants in scientific studies supported by the federal government.

To respond, the Commission, quite rightly, seeking to understand the landscape of scientific studies supported by the Federal Government, what that means. So, you've asked the federal agencies to provide basic, relatively straight forward project by project data of research involving human subjects such as study title participants and funding amounts to the extent that the agencies are aware of that information.

This request is designed to answer some key questions like, how many studies involving human participants are supported by the Federal Government domestically and internationally? How many people are enrolled in this research? And how much funding does the Federal Government expend on research involving human subjects?

I'm happy to report that we have begun to receive the luminous data back from the federal agencies in response to this request. We are working on preparing a database that will enable everyone to sort of understand what is contained in these reports. And we are also collecting from the agencies their perspectives on the regulations that guide them and the documents that direct the protections that they employ for human subjects.

So with that said, if you have any questions I'd be happy to answer them.

**DR. GUTMANN:**  
So, Lonnie?

**MS. ALI:**  
I just want to know.

**DR. GUTMANN:**  
Lonnie Ali, since I think people in the audience can't necessarily see, just introduce yourself.

**MS. ALI:**  
I have a loud voice.

**DR. GUTMANN:**  
Yeah, right.

**MS. ALI:**

A really loud voice.

**DR. GUTMANN:**

I just wanted them to know your name as well.

**MS. ALI:**

Is this database that you speak of, is this going to be a public database that will be accessible to the public or is it just for the Commission?

**MS. BONHAM:**

At this point, it's just for the Commission. And I should add, we're in a relatively preliminary stage. And so, I think in part, you all will decide in part thinking about that at the end of the day, how much data can be gathered. It's a big enterprise, the Federal Government, as you all are well familiar, funds an extraordinary volume of research and this has never been done before.

**DR. GUTMANN:**

Yes, Nita? Nita Farahany.

**DR. FARAHAANY:**

Yeah. Thank you for this update. It's amazing, the amount of work that the staff has done so far, and the briefings that you've provided us have been extraordinary.

I just have a quick question about this empirical study. I know we'll have an opportunity to talk about it in greater depth later today. But, given that there's a question at least with what constitutes human subjects research and how broad that definition is, what was the definition that was given to the organizations in asking them to supply information about human subjects research?

**MS. BONHAM:**

That the agencies report based on their own rules with regard to what constitutes the human subjects generally. The definition is uniform across most agencies and rather than second guessing or investigating that question, which as you say, is the subject of debate at times, the rather straight forward desire was to simply try to get a picture of what the current perception is.

**DR. GUTMANN:**

John Arras? You're on.

**DR. ARRAS:**

Okay, thank you. In the past, there's been some talk about perhaps doing some site visits to federally supported research sites abroad. Is that still in the cards or is there funding to –?

**MS. BONHAM:**

I think that's the Commission's call.

**DR. GUTMANN:**

Any other Commission questions? I would just like to ask Susan, since we have the privilege of having Susan here, if Susan, you wanted to ask anything or make any comment? That's okay. Come on up. This is Susan Reverby. She was the author of the article that first exposed the Guatemalan experiments between 1946 and '48 to public attention.

Susan?

**DR. REVERBY:**

Thank you. I first want to just say thank you for all of the work that you're doing. It's an unusual experience for a historian to then have a federal agency go back over what she did and then to be able to expand it in the way that your staff has done. And I've had two fabulous meetings with them about how to think about the historical material. So, I'm very grateful.

And the only thing that concerns me now because I've been speaking so widely on this since October when the story broke, is I have one of two thoughts. One is that I think it's really important that you listen to the way in which people sort of think this happened rather than actually how it happened. So there tends to be these narratives that get created. And obviously you can't answer all of the sort of conspiratorial theories that come up, but my experience in more than two decades now writing on the Tuskegee studies suggests that there will be these kinds of conspiratorial ideas about how all this happened. And as much as you can explain why Cutler was not really a rogue, but was doing what he thought actually was good science, I think is really crucial, but also to remember what stories can be told as much as possible, if you can address them.

And then, secondly, I think the important thing is for people to be really reassured about the importance of medical research. One of the things that would make me feel terrible about this would be if in the end, people were afraid to participate in what makes a huge difference in the lives of every person on this planet.

And my worry, frankly, is that in fear of what could happen, people won't also understand why the risks sometimes are really, really worth it. And that's really crucial. So, thank you.

**DR. GUTMANN:**

Thank you. Those are two very important points. And I can assure you, the Commission will take both to heart. Thank you.