



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT
Opening Remarks and Executive Director's Report

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DR. GUTMANN:

Good morning everybody. I'm Amy Gutmann, President of the University of Pennsylvania and Chair of the Presidential Commission for the Study of Bioethical Issues. On behalf of myself and Vice Chair Jim Wagner, who is President of Emory University, I would like to welcome you to day two of our Fourth Meeting here in the nation's capital.

We had a series of informative discussions yesterday about advancing applications in genetics in neuroimaging. Today we turn to a very different project: human subjects protection in scientific studies funded by the U.S. federal government.

Last November, Wellesley College Professor Susan Reverby announced that she would be publishing a research article regarding a U.S. government funded medical study in Guatemala between 1946 and 1948, where vulnerable men and women were intentionally infected with syphilis. The article Normal Exposure was published in the Journal of Policy History in January of this year. As more details emerged about this research project, President Obama directed the Commission, and I quote, "to oversee a thorough fact-finding investigation into the specifics of the PHS-supported research." The President also directed the Commission with input from an international panel convened by me as chair to conduct a review of the adequacy of human subjects protection across the international field of research today.

The Commission's staff began the investigation of the historical case earlier this year. As the investigation was getting underway, I had an opportunity to meet with Vice President of Guatemala, Dr. Rafael Espada and we discussed the efforts that his country is taking in its own investigation.

Vice President Espada is a former cardiothoracic surgeon who has deep understanding of medical research practices during the time period and an abiding concern for the people of Guatemala. He will be serving as Senior Advisor to the Chair of the Commission, that is myself, during this effort. And we are very grateful for his support and input.

I needn't tell you all, but it does not go without saying, that a civilization can be judged by the way that it treats its most vulnerable individuals. There is no position of vulnerability that is greater than to be a subject of a medical experiment. When it has come to light, as it has in Guatemala and as it has over and over again far too many times, that human individuals who are themselves already in a vulnerable position -- prisoners, patients -- are treated unethically, which is an understatement in the case of Guatemala, as it was in Tuskegee, as it was in the New York Chronic Disease Hospital case, as it was in countless and too many times, we have a problem on our hands.

We are charged by President Obama to make sure that what happened in Guatemala, what happened in Tuskegee, what has happened in Staten Island in Willowbrook, in Brooklyn where I was born & it doesn't matter whether it was where you were born, where I was born, whether these people look like us, whether they don't look like us, they are human beings with certain rights that medical doctors, scientists are expected to respect and to abide by the highest standards.

So this should go without saying but clearly it doesn't and it is our responsibility as a Commission to recommend to the President on the basis of both a retrospective fact-finding which I will ask our Executive Director in one moment to tell us about what we are doing, but also a contemporary look at what are the existing standards. Are they adequate? And what are the existing practices? Are they adequate for international clinical trials moving forward?

So at this time I would like to invite Valerie Bonham, the Commission's Executive Director to brief the Commission on the progress of the historical investigation. Welcome, Val.

Let me just say a few words about Val because I had introduced her as our Designated Federal Officer, but Val does much more than make these meetings legal. Val joined us this past summer from the National Institutes of Health branch of the Department of Health and Human Services General Counsel's Office. In that role, she served as lead counsel for a variety of high priority NIH initiatives and she was involved in ensuring that federal scientific and biomedical programs were implemented and managed in a legally, socially, and ethically responsible manner.

Prior to her work and very relevant to this current topic, Val was a staff member for the President's Advisory Committee on Human Radiation Experiments and she focused her research on the ethics, standards and policies applicable to research in the 1940s and 1950s. She also has studied research with captive populations, including prisoners. Val.

MS. BONHAM:

Thank you, Dr. Gutmann and thank you for those kind words. Dr. Wagner and the members of the Commission, thank you for giving me the opportunity to brief you on the progress of the staff's investigation into the Guatemala activities and thank you also for the lead that reminds us all of why we are here.

I want to briefly remind everybody of how we got here. In October 2010, as Dr. Gutmann alluded, following the revelations in Dr. Reverby's paper, the United States disclosed the Public Health Services' activities

from 1946 to 1948 involving intentional infection of vulnerable populations in Guatemala. The research focused on syphilis and other sexually transmitted diseases.

At the time it disclosed the story, the government announced plans for a thorough fact-finding investigation to be conducted by the Institute of Medicine.

At the same time, the government released a report prepared by the Department of Health and Human Services reviewing the records of Dr. John Cutler, who was the principal investigator of the Guatemala research, which the government recovered from the University of Pittsburgh following Dr. Reverby's research.

Shortly after this, the government learned that the Institute of Medicine had identified a potential conflict of interest owing to an historical overlapping personal relationship between its leaders and funders of the research in Guatemala. Consequently, to ensure the integrity of the investigation and to assure its independence, President Obama asked the Commission to oversee a thorough fact-finding investigation into the facts of the research in Guatemala. He detailed this request to Dr. Gutmann on November 24th in a memorandum which you all have and as you know is available on our website for anyone who would like to review it.

When we began our work, we spoke with many of the most knowledgeable sources in this area, including Dr. Reverby. We had her come brief the staff, explain her perspective and talk with us about the areas of interest that she thought we ought to be pursuing.

From these discussions and after reviewing very carefully the paper that the Department of Health and Human Services prepared, we identified four overarching questions for review that are guiding the investigation. Those questions are:

What happened in Guatemala between 1946 and 1948 as part of a series of inoculation studies on venereal disease sponsored by the United States Public Health Service?

Second, to what extent did the U.S. government and the medical establishment of the time was it aware of the protocol? And to what extent did they actively facilitate and/or assist in the conduct of these studies?

Third, what was the historical context?

Fourth, how did the studies comport with or diverge from the relevant medical and ethical standards and conventions of the time?

As I mentioned, these questions formed the framework. They are guideposts and as you can imagine, numerous additional questions flow from them.

Essentially what we are pursuing are fundamental questions of who knew about Dr. Cutler's Guatemala studies; what did they know; when did they know it; and what did they do about it?

In probing these basic details, we are looking to explain the context in which the research occurred. We believe that it is important to understand not only the details of Dr. Cutler's work but also how the inoculation study in Guatemala fits within the wider context of venereal disease research at the time. As many of you know, syphilis and other venereal diseases were among the most serious public health problems of the day and researchers leading these efforts were, at the time, among the nation's leading scientists.

We are focusing as well on understanding intentional infection protocols, understanding international studies, understanding venereal disease research as I mentioned, and understanding research involving vulnerable populations with a focus on context of the day.

I am leading a staff of approximately 12 people working on this project. Several senior academic advisors with deep experience in medical ethics and history of the Public Health Service and its activities at the time are helping us with this work. These include Doctors Paul Lombardo & 8212; they are here with us today, Dr. Paul Lombardo, Dr. Jonathan Moreno, and Dr. Jeremy Sugarman.

Dr. Lombardo is a historian and a lawyer currently serving as a Professor of Law at Georgia State University College of Law in Atlanta. Dr. Moreno, whom you had a guest speaker in your meeting in September, is a Professor of Medical Ethics, History and Sociology of Science at Penn.

Dr. Sugarman is Professor of Bioethics in Medicine, Professor of Health Policy and Management and Deputy Director for Medicine at the Berman Institute of Bioethics at Johns Hopkins.

Both Dr. Sugarman and Dr. Moreno served as senior staff members to the Advisory Committee on Human Radiation Experiments which, as Dr. Gutmann has explained, in many ways provides the closest analog to what we are doing investigating the research in Guatemala.

To date, we have reviewed approximately 477 boxes of materials, which comprise hundreds of thousands of pages of documents. From my days doing litigation, it brings fond memories but it doesn't for everyone. We anticipate that we will review hundreds of boxes more.

Briefly, we have looked at the documents of Dr. John Cutler, primary investigator of the study originally archived at Pittsburgh, now housed at the National Archives and what constituted the records upon which HHS built its review last summer.

We have reviewed the archives at the National Archives in Morrow, Georgia, which include United States Public Health Service records from the time period at issue.

I mentioned already records from the Advisory Committee on Human Radiation Experiments. ACHRE, again to recall, spent approximately a year and a half reconstructing applicable government and medical establishment standards for the ethics of research during World War II, relevant time period to what we are doing here. We don't want to repeat what they did. What we are trying to do is build on and leverage that.

Records from the Pan American Health Organization, successor organization of the Pan American Sanitary Bureau which served as the grant recipient in this case. Papers of Thomas Parran, the United States Surgeon General from '36 to '48, archived now at the University of Pittsburgh. Papers of Hugh Cummings, U.S. Surgeon General 1920 to 1936, Director of the Pan American Sanitary Bureau 1936 to 1947, archived now at the University of Virginia. Records also from the National Research Council housed at the Institute of Medicine containing historically relevant information on government efforts to combat syphilis and other diseases.

We are also, as Dr. Gutmann relayed, working with the government of Guatemala to obtain from them relevant material that they have uncovered in connection with their independent investigation.

In addition, we have asked the Departments of Defense, State, Health and Human Services, and Veterans Affairs to assist us to gather relevant information from within their files that is not already housed in the sources I have previously mentioned.

For example, Defense is reviewing records for information on venereal disease research and studies involving intentional infection protocols during that time period.

The investigation is obviously not limited to these activities. My goal in reviewing it for you this morning was to give you a sense of the breadth,

the comprehensiveness, and I believe the thoroughness with which we are taking on the task. We anticipate expanding as appropriate, focusing as appropriate. The investigation will proceed where the evidence leads.

In closing, I would like to acknowledge the incredibly hard work of our advisors and staff. We began this work just eight short weeks ago and our progress since then, in my opinion, is remarkable. In rotating teams of three to four reviewers, many of the staff have spent most of the last two months in the National Archives, carefully reviewing documents and gathering relevant materials, meeting together regularly, meeting with our advisors to make sure we are asking the right questions, pursuing the right leads, and bringing back to you the information that you need. It is my hope and expectation that you will have a report at the beginning of the summer. The report will provide, as I mentioned, an independent and comprehensive examination of the facts and the context in which this research occurred.

Thank you.

DR. GUTMANN:

Thank you very much. Do the Commission Members have any questions for Val? Anita.

DR. ALLEN:

I have not so much a question but just a desire to be absolutely clear about one important fact. President Obama, in his memorandum, clearly indicated that in his view the experiments were unethical. So I want to confirm that the point of this comprehensive review, which I am sure will be conducted with utmost care, is not to excuse or to justify the experiments but rather to simply understand them and to understand them in context.

MS. BONHAM:

Absolutely. There is in fact &8212; generally our plan is to provide little in the way of judgment, for lack of a better expression, but in fact to get the facts out, tell a complete and comprehensive narrative. But I don't think there is any question that &8212; of any reopening of the judgment that President Obama has already given and as you all have discussed quite clearly here.

DR. GUTMANN:

Thank you very much. Any other questions? John.

DR. ARRAS:

Yes, this is really a follow-up to the last question.

You emphasize that you are going back into the past to look at the normative standards operative at the time. Can you give us a preview of what you are finding there?

In other words, I mean because when you go back to these historical epochs, you know, we often find dissenting voices. We find a mix of opinion. We found that to be true with regard to Willowbrook, with regard to the Jewish Chronic Disease Hospital case. There wasn't uniformity of opinion at the time. So you know, what are you seeing in that historical record? Are you seeing voices at the time opposing this research?

MS. BONHAM:

Yes. Beyond that, I am not really in a position to elaborate &8212;

DR. ARRAS:

Okay.

MS. BONHAM:

&8212; a lot more but that is a fair statement.

DR. ARRAS:

Yes, I figured you would.

DR. GUTMANN:

Yes, thank you very much.

So we had two charges. We have two charges from the President. One is to do a staff-led investigation of the historical record. And the purpose of that is to get the facts out and to understand what happened.

The meeting that I had with Vice President Espada I can report that the first thing that we said to each other was, what happened was clearly wrong. It was clearly terribly wrong and we want to get the facts out and the record out there for the public in Guatemala and in the United States and all over the world to know.

The second charge that we had is focused on contemporary research. President Obama asked me to convene an international panel to consider current U.S. government regulations and international standards to guard the health and well-being of participants in scientific studies supported by the U.S. government.

I am pleased to report that the international panel, a working group of the Commission, will include 14 eminent members whose origins come from around the world, including the U.S., although the majority of members are from outside the U.S., coming from the international

bioethics and medical and science communities and we will begin our work shortly.

I will chair the panel. The members of the panel I am happy to announce this morning are as follows. John Arras, and I will mention their countries of origin, the United States. John is a member of the Presidential Commission. Julius Ecuru, whose origin is Uganda, is the Assistant Executive Secretary at the Uganda National Council for Science and Technology, UNCST. Christine Grady, also U.S., is also a member of the Presidential Commission. I'm afraid I don't speak Portuguese. So it is Dirceu Greco from Brazil; is the Director of the Department of STD, AIDS, and Viral Hepatitis in the Ministry of Health of Brazil. He is also a Professor of Medicine at UMFG and he is also a member of the National Institute of STD and AIDS in Brazil and he founded the first hospital department specialized in treating HIV in Brazil in 1985. Myself. Unni Karunakara, whose origin is Indian, was the Deputy Director of Health for the Millennium Villages Project at the Earth Institute between 2008 and 2010. Currently, he is an Assistant Clinical Professor at the Mailman School of Public Health of Columbia University. Nandini Kumar, India, is a consultant for the Indian Council of Medical Research who works with physicians creating ethical trial designs involving vulnerable populations. She is the former Deputy Director General, National Institute of Epidemiology, Indian Council of Medical Research. Sergio Litewka, Argentina, is the International Programs Director at the University of Miami ethics program and an Assistant Professor at the UM ethics program. He is Project Director for the Pan American Bioethics Initiative. Luis Lopez, Guatemala, sits on the Board of Directors for the Latin American Forum of Committees for Ethical Research and Health, and is a faculty member at the University of San Carlos. He also serves as a Clinical Trials Assessor for the Guatemalan Ministry of Health. He is an editor for The Center for Health Science Research magazine and he is a legal representative of a foundation whose name I cannot pronounce. Adel Mahmoud, Egypt, is the former President of Merck Vaccines and an expert on disease control in the developing world. He is a Professor of Molecular Biology presently at Princeton University. Nelson Michael, U.S., is a member of the Presidential Commission. Peter Piot, Belgium, is the Director of the London School of Hygiene and Tropical Medicine. He is the former Undersecretary General of the United Nations and the former Executive Director of UNAIDS. He is also the former President of the International AIDS Society and former Assistant Director of the World Health Organization's global program on HIV/AIDS. Piot also co-discovered the Ebola virus in 1976.

Dr. Huanming Yang co-founded the Beijing Genomics Institute, from China I should say, and current President of BGI. He made significant contributions to the Human Genome Project.

And finally, 14th, these are in alpha order, Boris Yudin, Russia, is at the Department of Comprehensive Problems of Human Studies at the Institute of Philosophy, the Russian Academy of Sciences. And he is the Russian representative in the Steering Committee on Bioethics for the Council of Europe. He is also Vice Chairman of the Russian National Committee on Bioethics of the Russian Academy of Science.

So this panel will meet at least three times in the next five months and at least once overseas. It will focus on contemporary issues and international ethics research. We are very grateful for the members, for their willingness to serve.

Our review of contemporary scientific studies comes at a critical time. Nearly a decade has passed since the last national bioethics commission report on questions about international research and domestic policies for human subjects protection. In that time, medical research around the globe has expanded rapidly. The current system for protection of research subjects based largely on policies developed three to four decades ago, may not be keeping pace.

The Commission began its deliberations today by bringing together experts from clinical research & begins. The Commission begins its research today by bringing together experts from clinical research, from medicine, from ethics, and other fields, together with you, the concerned public, and we are also webcasting this, to begin discussing these issues. We are here today to learn about the global landscape of medical research, the historical context of the development of current policies for the protection of human subjects, and the ethical concerns, and concrete problems that arise in practice. Finally, we will hear about prior commissions' efforts to address these issues.

This Commission is an inclusive body that encourages the exchange of well-reasoned perspectives with the goal of making recommendations that will serve the public good. Medical research's aim, ultimate aim, is to serve the public good. In order to do that, it also has to treat its subjects in an ethically responsible way. Deliberative commissions such as ours can contribute to the quality of public debate and to the quality of governmental policy. We are here today because we believe that a concerned citizenry deserves nothing less.

The work before us demands very careful deliberation. Before we continue, I just want to say a word of thanks to the Commission members for their hard work and for their commitment to these very important principles. And with that, I would like to ask our first presenters to come up and I turn the floor over to my wonderful Vice Chair, Jim.

