TRANSCRIPT
Closing Remarks

Amy Gutmann, Ph.D.
Commission Chair

James Wagner, Ph.D.
Commission Vice-Chair

Meeting 6, Day 1 Closing Remarks
August 29, 2011
Washington, DC
DR. GUTMANN: Alas, because of time, and I know we're pressed for time, I'm going to wrap this up and ask Jim to make some concluding comments, as well. Our discussion was sobering to say the least but necessary to bring facts to light and what we're planning on putting forward publicly as our report.

Let me try and not in any way comprehensive way but to outline some of the things on the ethical analysis side that we have agreed upon as a commission and you'll see that in the report we do this in a much more detailed way, drawing upon some of the historical facts that we've just in a very summary way have just brought to light.

So a civilization, we've said, can be judged by the way it treats its most vulnerable individuals and it is our moral responsibility to care for those who cannot protect themselves and clearly in this history, we failed to keep that covenant.

The research specifically included populations that were vulnerable and thereby deserving of additional safeguards to ensure their adequate protection. The researchers knew that that was the case, as indicated in the Terre Haute experiments.
Prison inmates in Guatemala, institutionalized and mentally-disabled individuals and children were among the groups most frequently included in the Guatemala experiments. Federal regulation, international codes and the ethics literature all acknowledge that research involving these groups raises unique issues requiring additional attention.

That said, many of the institutional codes and federal regulations that exist today did not exist at the time, although the Nuremberg Code had contemporaneously come out, and I'll say something more about three of the standards that were articulated in that Code which are not unique to Nuremberg but are really ethical standards that have been with us for centuries.

The research team in Guatemala and their immediate supervisors appear to have had considerable latitude in the design and conduct of individual experiments with no evidence of substantive independent review of the conduct of the research. Again, as Raju has pointed out, there could have been more review than there was.
On the contrary, substantial evidence reflects efforts by the researchers to limit knowledge of the Guatemala activities as much as possible outside of those conducting it or directly authorizing it.

The experimenters in Guatemala, both the Americans and their local colleagues, consistently failed to act in accordance with minimal respect for human rights and morality in the conduct of research. It's even more disturbing for us as a commission to find that the blame lies with medical doctors and scientists who hold professional positions that carry with them special privileges and responsibilities, expected to do no harm, and to abide by the highest professional standards of ethics.

In the Commission's view, the Guatemala experiments involved basic violations of ethics, even as judged against the researchers' own recognition of the requirements of the medical ethics of the day, although some of those researchers clearly rejected those requirements.

Many of their actions violated principles widely accepted as applicable at the time as well as the standards of our own time that are embodied in the
ethics and regulation of biomedical research today. These standards include the following:

First, treating people fairly and with respect. The voluntary consent of human subjects is absolutely essential. That is the first sentence of the Nuremberg Code.

Second, one ought not to subject people to harm or risk of harm, even with their consent, unless the risk is reasonable and there is a proportionate humanitarian benefit to be obtained. Careful and scientifically-sound research is an essential condition for medical ethics.

And third, one ought not to treat people as mere means to the ends of others. Subjects must not only give informed consent but they also must be free to withdraw and they certainly ought not to be deceived unless they have been informed of possible deception and consented to that.

The Guatemala experiments could not be approved under current human research protections for U.S.-funded research. That is clear. Widely-discussed cases in the post-World War II era with some similar features have led to a greater appreciation and
articulation of the moral principles underlying medical research.

We hasten to add that in judging and assessing these experiments as morally wrong and assigning blame to the individuals, we in no means, by no means mean to say this was the only example, far from it, of unethical experiments and blameworthiness not only in the 1940s but in the '50s, '60s and forward.

A clear consensus has emerged that medical research must not violate human dignity or undermine the very human flourishing it seeks to advance in future patients. The Guatemala experiments and other troubling violations of this norm that have come to light in the last 60 years shock the conscience. They should shock the conscience, not in spite of their medical context but precisely because of it.

It is clear that many of the actions undertaken in the Guatemala experiments were grievously wrong and that the individuals who approved, conducted, facilitated, and funded these experiments are morally culpable to various degrees for these wrongs.

Although some individuals are more blameworthy than others, the blame for this episode cannot be said
to fall solely on the shoulders of one or two individuals. The unconscionable events that unfolded in Guatemala in the years 1946 to 1948 also represented an institutional failure of the sort that modern requirements of transparency and accountability are designed to prevent.

In the final analysis, institutions are comprised of individuals who are expected to exercise sound judgment in the pursuit of their institutional mission. This is all the more important when those individuals hold privileged and powerful roles as professionals and public officials.

One lesson, just one lesson of the Guatemala experiments is never to take ethics for granted, let alone confine ethical principles, confuse ethical principles with burdensome obstacles to be overcome or evaded.

This lesson should be a sobering one for our own and all subsequent human research experiments. We all know of rules that feel burdensome to comply with and we all believe that rules shouldn't be any more burdensome than they need to be to protect us from
unethical experiments, but we should be ever vigilant
to ensure that such reprehensible exploitation of our
fellow human beings is never repeated.

In the charge to the Commission last November,
President Obama said, and I quote, "While I believe the
research community has made tremendous progress in the
area of human subjects research protection, what took
place in Guatemala is a sobering reminder of past
abuses. It is especially important for this Commission
to use its vast expertise, spanning the fields of
science, medicine, policy, ethics, and moral and
religious values to carry out this mission. We owe it
to the people of Guatemala, to future generations of
volunteers at home and all around the world who
participate in medical research."

As a commission, we shall report back to the
President with our findings on the research and our
analysis of the ethics of this shameful piece of
medical history.

That's all I have to say for now and I would
like to turn the floor over to Jim Wagner for some
concluding comments before we adjourn.
DR. WAGNER: Amy, there's very little that needs to be added to that statement. Thank you so much. But maybe to highlight one point or two.

The purpose for doing this was not simply to put a moment of history to bed so that it could be sealed with some form of sealing wax that says we've done it, we understand it, and we condemn it, but, rather, it's to inform what we need to do going forward and what we recommend going forward, and, of course, that will be the purpose of our conversations tomorrow.

The challenge, of course, is how to implement the kinds of principles that you spoke about, Amy, in such a way that they are for the well-intentioned researcher seeking how to pursue viable research, that they are an illuminating aid and not, as you said, some sort of onerous burden.

On the other hand, for the other kind of individual or group of individuals, who understand somehow intrinsically that the value of their work is so meritorious that it is to be -- it can rise above restraints and restrictions and ethics, these do need to be horribly burdensome, in fact impenetrable, if
possible, and how do you do all of this without unduly restricting the imperative that we have to pursue biomedical research in the service of humanity, I think, is the big challenge.

And I'm pleased to be working with this group, to roll up our sleeves and take that as our next move going forward.

So thank you very much.

DR. GUTMANN: Thank you. I would like to ask the staff members of the Presidential Commission for the Study of Bioethical Issues who have worked on the historical report and they've worked assiduously, the 125,000 pages of documents doesn't even come close to capturing all of the work and the drafts which we are still refining but will soon be put out there for the public to read, if you would all stand up so we can thank you for your work, I'd really appreciate it.

(Applause.)

DR. GUTMANN: Tomorrow, we will reconvene and we will discuss contemporary human subjects protections standards. This will be our third meeting addressing this subject and we will look forward to a full day of
speakers and discussion.

I want to thank everyone who's attended again and we will reconvene tomorrow at 9 a.m.

Thank you very much.

(Whereupon, at 3:13 p.m., the meeting was adjourned, to reconvene tomorrow morning, Tuesday, August 30th, 2011, at 9:00 a.m.)

* * * * *