



Presidential Commission  
*for the Study of Bioethical Issues*

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**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

1 DR. GUTMANN: Alas, because of time, and I  
2 know we're pressed for time, I'm going to wrap this up  
3 and ask Jim to make some concluding comments, as well.

4 Our discussion was sobering to say the least  
5 but necessary to bring facts to light and what we're planning on  
6 putting forward publicly as our report.

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

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

19 The research specifically included populations  
20 that were vulnerable and thereby deserving of  
21 additional safeguards to ensure their adequate  
22 protection. The researchers knew that that was the  
23 case, as indicated in the Terre Haute experiments.

1 Prison inmates in Guatemala, institutionalized and  
2 mentally-disabled individuals and children were among  
3 the groups most frequently included in the Guatemala  
4 experiments.

5 Federal regulation, international codes and  
6 the ethics literature all acknowledge that research  
7 involving these groups raises unique issues requiring  
8 additional attention.

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

17 The research team in Guatemala and their  
18 immediate supervisors appear to have had considerable  
19 latitude in the design and conduct of individual  
20 experiments with no evidence of substantive independent  
21 review of the conduct of the research. Again, as Raju  
22 has pointed out, there could have been more review than  
23 there was.

1           On the contrary, substantial evidence reflects  
2           efforts by the researchers to limit knowledge of the  
3           Guatemala activities as much as possible outside of those conducting  
4           it or directly authorizing it.

5           The experimenters in Guatemala, both the  
6           Americans and their local colleagues, consistently  
7           failed to act in accordance with minimal respect for  
8           human rights and morality in the conduct of research.

9           It's even more disturbing for us as a commission to  
10          find that the blame lies with medical doctors and  
11          scientists who hold professional positions that carry  
12          with them special privileges and responsibilities,  
13          expected to do no harm, and to abide by the highest  
14          professional standards of ethics.

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

21          Many of their actions violated principles  
22          widely accepted as applicable at the time as well as  
23          the standards of our own time that are embodied in the

1 ethics and regulation of biomedical research today.

2 These standards include the following:

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

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

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

19 The Guatemala experiments could not be  
20 approved under current human research protections for  
21 U.S.-funded research. That is clear. Widely-discussed  
22 cases in the post-World War II era with some similar  
23 features have led to a greater appreciation and

1 articulation of the moral principles underlying medical research.

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

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

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

21 Although some individuals are more blameworthy  
22 than others, the blame for this episode cannot be said

1 to fall solely on the shoulders of one or two  
2 individuals. The unconscionable events that unfolded  
3 in Guatemala in the years 1946 to 1948 also represented  
4 an institutional failure of the sort that modern  
5 requirements of transparency and accountability are  
6 designed to prevent.

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

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

18 This lesson should be a sobering one for our  
19 own and all subsequent human research experiments. We  
20 all know of rules that feel burdensome to comply with  
21 and we all believe that rules shouldn't be any more  
22 burdensome than they need to be to protect us from

1 unethical experiments, but we should be ever vigilant  
2 to ensure that such reprehensible exploitation of our  
3 fellow human beings is never repeated.

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

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

20 That's all I have to say for now and I would  
21 like to turn the floor over to Jim Wagner for some  
22 concluding comments before we adjourn.

1 DR. WAGNER: Amy, there's very little that  
2 needs to be added to that statement. Thank you so  
3 much. But maybe to highlight one point or two.

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

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

17 On the other hand, for the other kind of  
18 individual or group of individuals, who understand  
19 somehow intrinsically that the value of their work is  
20 so meritorious that it is to be -- it can rise above  
21 restraints and restrictions and ethics, these do need  
22 to be horribly burdensome, in fact impenetrable, if

1 possible, and how do you do all of this without unduly  
2 restricting the imperative that we have to pursue  
3 biomedical research in the service of humanity, I  
4 think, is the big challenge.

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

8           So thank you very much.

9           DR. GUTMANN: Thank you. I would like to ask  
10 the staff members of the Presidential Commission for  
11 the Study of Bioethical Issues who have worked on the  
12 historical report and they've worked assiduously, the  
13 125,000 pages of documents doesn't even come close to  
14 capturing all of the work and the drafts which we are  
15 still refining but will soon be put out there for the  
16 public to read, if you would all stand up so we can  
17 thank you for your work, I'd really appreciate it.

18           (Applause.)

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

1 speakers and discussion.

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

4 Thank you very much.

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

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