

**REMARKS BY  
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I am glad you are all here today. I am delighted to have a chance to meet you. I have known about you in many ways from different perspectives for a long time but I do not know all of you personally and it is a great delight for me to be here today. I sort of envy Harold for his opportunity to work with you because this is quite an extraordinary group of individuals and professionals, and Americans, and it has just got to be fun. As much and as hard as you work, I know that the discussions you have must be incredibly interesting and I know from the work that you have done, which is considerable, that somehow you are able to do this in a way that is efficient and actually moves forward. I know that is a tribute to all of you but also to Harold's leadership so we very much appreciate it.

Jack Gibbons, my predecessor, did an extraordinary job in the White House. He certainly considered the establishment of NBAC one of his great triumphs. He did many outstanding things as science advisor in the White House, but he certainly looks at this particular accomplishment as a special one. I think Jack opened the first NBAC meeting three years ago and had a chance to speak with you about how important these issues are and how much the President was going to rely on the Commission. And now, as we look back, we can see that the President has relied on the excellent advice he has gotten from you. We really appreciate the commission's timely and very important contributions to the national debate on what are clearly some of the most controversial issues in science policy that we face today. Certainly your work reflects well on the wisdom of establishing this commission and we know you spend a lot of your time and effort on it.

Twice, the President has called upon you to interrupt your deliberations and take up highly charged questions that define the intersection of science and ethics. What happens when scientific breakthroughs challenge our views of nature and humanity? The crux of the challenge is how we can best square our newest technologies with our oldest values. Cloning, as was mentioned a few years ago, and stem cell research, both of which came during my relatively short time in the White House, are really good examples of how we have to look at our fundamental values and make some very difficult choices about how we proceed as a society. I want to express my personal appreciation and certainly that of the President for the sensitivity and for the scholarship and the wisdom that you brought to your deliberations on both of these topics. The reports that you write are fascinating as well. They are well written. They are interesting. They have considerable depth, which

will make them last. I know their impact will last well beyond the immediate considerations of policy that they receive in the White House.

When you take on such weighty issues you have to accept in advance that probably not everyone is going to embrace your conclusions in their entirety. I do not know if that has been the case, but I could well imagine that it might be, given the difficulty of all these matters. But I think it is a testament to your hard work and Harold's leadership that you are lauded for listening and for being especially sensitive to the range of America's views and emotions that accompany these thorny ethical issues that lie at the nexus of humans and technology.

This commission has also submitted two other reports to the President. It is really quite incredible the work that you have done and the products that have come out. I must say I am very impressed. The two reports, *Research Involving Persons with Mental Disorders that May Affect Decision Making Capacity*, and the second, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*, both make landmark contributions to ongoing discussions regarding human research subject protection.

The Capacity Report ably addresses a longstanding need for special measures to protect a particularly vulnerable segment of volunteers in the research enterprise, namely those with conditions that may reduce their ability to make informed decisions. The Human Subjects Research Subcommittee of the NSTC Committee in Science has now been tasked to put together a set of policy options that are based on the 21 recommendations of your human biological materials report. That is our mechanism for getting your recommendations translated into policy.

The Human Biological Materials Report is significant in that it describes the terms under which it would be ethically permissible to use the more than 300 million human tissue specimens that are currently stored in various repositories throughout the country, some of which have been in storage for 100 years. Given the powerful genetic tools that might be used to identify inherited traits, protecting the privacy of the people from whom this tissue was derived and their descendants is particularly important. This report also provides an excellent analysis of the question as to when the source of a biological specimen should be considered to be identifiable.

The President has just asked NBAC to continue its work for the next two years. No good deed goes unpunished in our business. This makes it a really auspicious time for me to have the opportunity to meet with you. Instead of coming to you with another quick turn around request - I cannot, of course, promise that that might not happen again. I wish I could but at least that is not happening today. I ask you instead to recall the original charge from the President to examine the current federal system of human research subject protections.

Several recent events have drawn attention to what is largely a decentralized system with great responsibility placed on individual investigators and their sponsoring institutions. The Department of Health and Human Services, and within that department, the NIH, has

taken several actions to strengthen their oversight capability and forestall situations in which subjects could potentially be harmed. Other agencies have also made changes and instituted policies and procedures that address their role in overseeing human subject research. The Department of Veteran Affairs is one example. The Department of Justice is another and I know you are going to have a look at what they are doing.

So while there has been increased attention paid to this area I think it is increasingly clear that a comprehensive examination is in order. I would expect that such a study would include: an assessment of the adequacy of the current federal system of protections; a review of the relevant statutes and regulations, with particular attention to the effectiveness of the Common Rule and its applicability to the full range of government sponsored research activities involving human subjects; and an examination of the strengths and the weaknesses of the infrastructure responsible for ensuring the entire system's integrity.

The most important component of this task is to provide detailed recommendations for changes necessary to ensure that our ethics are as good as our science. You are all aware that it took ten long years to promulgate the Common Rule in 1991 and yet even at that time it was agreed that additional work needed to be done to provide adequate coverage for every research subject, including special populations. One of the driving forces behind NBAC's establishment was the desire to accelerate progress towards the goal of ensuring such coverage. The comprehensive report that you will consider today should be constructed so as to fulfill that desire.

You will probably note that I focused solely on federally sponsored research and not research carried out with private funds. I understand that NBAC has passed a resolution recommending that human subject protections be extended to all research subjects regardless of the source of funding. I fully expect that the bulk, if not all of your recommendations, will have equal relevance for research carried out in the private sector and you might want to make note of that in your report. However, it is important to recognize that the initial audience of your reports is the National Science and Technology Council chaired by the President and made up of agencies including those that are involved in human subjects research.

These agencies, through the work of the Council, are well positioned to make immediate use of your recommendations through the administrative actions in their respective program areas. I have outlined how that happens. We get the recommendations from you and we put together a working group. We translate your recommendations into policy options, which are considered at the appropriate policy levels of the President's Council. So it makes sense for you to focus most of your energies on the advice that can be incorporated into the government's ongoing efforts to enhance human subjects protection.

When I sought Harold Shapiro's wise counsel earlier this week, as I often do, we talked about this proposal and I conveyed the strong sense of the President and Secretary Shalala that human subject protection is a critical element of our research enterprise. The

President has addressed this in the past, most notably in his commencement speech at Morgan State University.

The Secretary is currently engaged in efforts to bolster protections including, for example, protecting medical records privacy. These and other ongoing activities make this an opportune time for the commission to take on what is admittedly a very challenging task.

So, in conclusion, we are particularly grateful to you not only for your four scholarly valuable reports, but also for the stimulating balanced discourse that I commented on earlier, for involving and educating the American public, which is extremely important, and for undertaking this challenging assignment, even under somewhat constrained time frames.

The President, his Administration, and the American public look forward to receiving the fruits of your labors and I look forward to getting to know all of you better.