U.S. Department of Health and Human Services
Perspectives on the Revision of the Declaration of Helsinki
World Medical Association Expert Conference
Tokyo, Japan
February 28-March 1, 2013

Oral Statement of James McCormick, U.S. Embassy Tokyo

Good afternoon. I am the Health and Scientific Affairs Officer at the U.S. Embassy Tokyo. I am pleased to be here on behalf of the U.S. Government to present the perspectives of the Department of Health and Human Services (HHS) on the Declaration of Helsinki (DOH). HHS has the lead role in the development of our position on the DOH. Its broad health and human service mission is carried out through, among other HHS agencies, the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections.

A more detailed written statement prepared by HHS was submitted to the World Medical Association (WMA) secretariat at the meeting in Cape Town. HHS has asked that this document be shared with the participants at this meeting as well.

HHS recognizes that the DOH has been an important source of ethical guidance in the conduct of clinical research throughout the world for nearly half a century, and that it is highly regarded and respected for its reflection of fundamental principles and widely-held values. As the process to revise the 2008 version of the document begins, HHS wishes to commend the WMA for the integrity and transparency of its consultative and deliberative processes and for giving due consideration to the perspectives of all stakeholders and interested parties. In these remarks and in its longer written comments, HHS provides its perspectives on the five main ethical topics that are under consideration in this meeting as part of the revision process and raises several other issues that relate to the content and structure of the current DOH.

Biobanks raise many important ethical issues, and they will likely play a role of growing importance in the world of research. However, the debate with regard to the ethical issues surrounding biobanks is ongoing, and there is as yet no consensus on the appropriate ethical course to take. In HHS' view, it is premature to establish ethical requirements in areas where such consensus has not been established.

Regarding **insurance, compensation and protection,** articulating the ethical principle that research participants should not bear the cost of unforeseen harms related to their study participation may be an appropriate addition to the DOH. However, given the different approaches that nations take in addressing this issue, in HHS' view, it would be counterproductive to go further than this by attempting to identify a specific implementation mechanism.

With regard to the issue of **post-study arrangements in resource poor settings**, the current DOH approach, as expressed in Paragraphs 33 and 14, warrants reconsideration and revision, particularly Paragraph 33. The expectation in Paragraph 33 that investigators will provide access to interventions identified as beneficial or to other appropriate care or benefits is a standard that most investigators cannot meet. Certainly, researchers must be attentive to the ongoing health needs of research participants, but establishing a standard that is largely impossible to achieve does not advance the ethical conduct of research. HHS urges WMA to consider a more reasonable articulation of the investigator's obligations to the future well-being of the participants enrolled in their studies. In HHS' view, the WMA should adopt a more measured ethical approach that would call upon researchers to consider the issue of post-trial access in the context of local needs, the local healthcare infrastructure, national regulations and health care policies, and the availability of effective treatments and, where such access is possible, to describe arrangements for access to interventions identified as beneficial in the study, such as continued therapy with an investigational intervention or other appropriate care or benefits.

Concerning **vulnerable groups**, HHS recommends that the reference to disadvantaged populations in Paragraph 17 be deleted. Its inclusion inappropriately characterizes every disadvantaged population or community as incapable of giving or refusing consent for themselves or as vulnerable to coercion or undue influence. Paragraph 17 should also make the point that research participation in itself can be beneficial to a population or community, not just the research results.

Regarding **ethics committees,** from HHS' standpoint the current DOH content is appropriate and, with one exception, sufficient. The one addition that HHS recommends is to specify in Paragraph 15 that Ethics Review Committees should be comprised of members with the appropriate expertise to review the research protocols that are submitted to them.

Additionally, although **broad consent** is not an agenda topic for this meeting, as it was in Cape Town, HHS supports WMA's consideration of the concept of broad consent. The ethical acceptability of the use of broad consent in certain types of research is an important and timely issue. HHS is currently considering changes in its regulations to allow the use of broad consent for research involving biospecimens and data. Such a change will facilitate important research and, if properly designed and implemented, would be in keeping with applicable ethical principles.

I also want to take this opportunity to highlight two areas of the 2008 DOH that HHS views as problematic or in need of clarification.

- First, HHS is concerned that while much of the DOH appropriately remains at the level of broad principles, there are a number of paragraphs that include requirements that, in their specificity, are at odds with national laws and/or regulatory requirements. Excessive specificity undermines the value of DOH as a source of basic ethical guidance and leads to unnecessary conflicts with national approaches that are based on the same fundamental ethical principles. This problem is exacerbated because of language in the DOH that claims moral supremacy over national requirements and standards. As such, HHS urges WMA to modify Paragraphs 10 and 15 which inappropriately call on researchers to

disregard their obligations to follow their national laws and regulations when they conflict with the provisions of the DOH.

- Second, the DOH draws an artificial and confusing distinction between "Medical Research" in Part B and "Medical Research Combined with Medical Care" in Part C. Since it is difficult to find conceptual differences that warrant separate ethical guidance, HHS recommends that the additional principles in Paragraphs 32-35 of Part C be incorporated into Parts A or B and that Paragraph 31 be deleted. In its written statement, HHS makes specific suggestions about where to place those paragraphs.

Finally, HHS also wishes to comment on the topic of **placebo controls in clinical research**. The consensus achieved in 2008 on Paragraph 32 provides appropriate ethical guidance. It allows for the use of placebos when a proven intervention exists if the study has scientific merit and clinical value and does not pose risks of serious or irreversible harm to the study subjects. HHS urges the WMA to preserve the current wording on the use of placebos in medical research.

HHS has elaborated on these topics in written comments that are available to you. The written comments also contain some suggestions on how to improve the readability of the DOH.

I appreciate the opportunity to present HHS' perspectives on the DOH, and want you to know that HHS looks forward to providing further perspectives, as well as more specific comments, during the next phase of the revision process. If you have any questions about the HHS position, I would point you to HHS' written comments which have been posted on the WMA website at:

http://www.wma.net/en/50events/20otherevents/40doh2012_1/HHS_Comments_on_DOH_for_Cape_Town_Conference_12-5-7-2012.pdf

In addition, I would be glad to provide a point of contact at HHS for clarification about the comments or if you have any other questions.