World Trade Center Health Program

Scientific/Technical Advisory Committee Teleconference Meeting

28 March 2012

Statement of John Howard, M.D. Administrator, World Trade Center Health Program

Good afternoon to Advisory Committee members in the Eastern and Central Daylight Time Zones, and good morning to members in the Mountain and Pacific Time Zones. Good afternoon and good morning to members of the public, responders and survivors and other attendees at the third World Trade Center Health Program's Scientific/Technical Advisory Committee Meeting. I want to thank each Committee member again for their service on the Committee. Your time and your advice are greatly appreciated.

As I mentioned to you at your inaugural meeting in November of 2011, the Committee has an important role to play in the World Trade Center Health Program. The James Zadroga 9/11 Health and Compensation Act of 2010, codified in Title XXXIII of the Public Health Service Act ("Act") at 42 U.S.C. §§300mm-300mm-61, specifies three general areas of contributions from the Scientific/Technical Advisory Committee, and only three:

(1) Providing Input on Eligibility Criteria for Pentagon and Shanksville Responders and Modified Eligibility Criteria for Responders or Survivors

Section 3311(a)(2)(C)(ii) of the Act *requires* that before making a determination establishing eligibility criteria for responders to the September 11th attacks at the Pentagon and at Shanksville, Pennsylvania, the Administrator must consult with the Scientific/Technical Advisory Committee. As you will recall, the Administrator sought the Committee's consultation on these criteria and the Committee provided its input at its meeting on February 15, 2012.

I want to thank the Committee for its consultation on eligibility criteria for Pentagon and Shanksville responders. At the present time, regulatory language is being prepared to codify the eligibility criteria and will appear in a future Federal Register Notice. Any Notice would also appear on the World Trade Center Health Program website.

If the Administrator decides to consider modifying current statutory eligibility criteria for NYC responders, then, as the Act requires in Section 3311(a)(1)(C)(ii), the Administrator *is required* to consult with the Scientific/Technical Advisory Committee for input on changes in NYC responder eligibility criteria. In the case of changes in survivor eligibility criteria, Section 3321(a)(1)(A)(iii) of the Act requires the Administrator to consult not only with the Scientific/Technical Advisory Committee, but also with the World Trade Center Health Program Steering Committees and Data Centers. At this time, the Administrator is not planning any modification of the current statutory eligibility criteria for responders or survivors.

(2) Identifying Research Needs

Section 3341(c), pertaining to research regarding health conditions related to the September 11th terrorist attacks, *requires* the Administrator to seek advice from the Advisory Committee with regard to identifying research needs for the Program.

I would like to thank the Committee for its consultation provided at the February 2012 meeting on research needs for the Program in preparation for a World Trade Center Health Program research solicitation for 2012. On March 23, 2012, a funding announcement was published for Cooperative Research Agreements Related to the World Trade Center Health Program. The receipt date for applications is May 21, 2012. A link to the announcement can be found at http://grants.nih.gov/grants/guide/pa-files/PAR-12-126.html

(3) Providing a Recommendation Regarding the Addition of Health Condition(s) to the List of Covered World Trade Center-Related Health Conditions

Section 3312(a)(6) of the Act allows the Administrator to request a recommendation from the Committee regarding additions of conditions either at the Administrator's own initiative or following the receipt of a petition. When the Administrator receives a written petition to add a particular health condition to the List of covered World Trade Center-related health conditions, one option is that the Administrator *may* request a recommendation from the Scientific/Technical Advisory Committee regarding the potential addition.

As you are aware, the Administrator received a petition to add cancer to the List on September 8, 2011. Pursuant to Section 3312(a)(6)(B)(i) of the Act, the Administrator requested advice from the Advisory Committee on the petition and subsequently provided a due date for the recommendation of April 2, 2012, or 180 days from the date of the Administrator's request which is the maximum amount of time permitted by the Act for the Committee to submit its recommendation. The Act provides in Section 3312(a)(6)(C) that not later than 60 calendar days after receipt of the Committee's recommendation (which would be June 1, 2012 if the Committee's recommendation is received on April 2, 2012), the Administrator must publish in the Federal Register a *proposed rule* with respect to the Committee's recommendation, or a determination *not to propose such a rule* and the basis for such determination.

As I said at your November 2011 meeting, it is important to keep in mind that the Scientific/Technical Advisory Committee was established by the Act to provide advice of a *scientific* or *technical* nature to the Administrator. Articulating the strongest possible scientific basis for the Committee's recommendation on Petition 001--*including an evaluation of available information about the level of exposure to carcinogenic agents--*will be of greatest value to the Program. The Administrator looks forward to receiving your recommendation on Petition 001 by April 2, 2012 and will give it full and serious consideration.

Finally, some Committee members have asked "what does the Committee do after April 2, 2012?" As just stated, the Act provides only consultative actions for the Committee in relation to the Administrator's determining or modifying eligibility criteria, preparing input for the Program's research solicitations, and determining whether to add health conditions to the List. The Scientific/Technical Advisory Committee has a limited role and meets only at the request of the Administrator based on Program needs. If there is no business to conduct with regard to the Committee's consultative duties, then the Administrator will not request a meeting.

Again, on behalf of the World Trade Center Health Program, thank you for your service on the Scientific/Technical Advisory Committee and I wish you a successful meeting today.