THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOV 27 2002

The Honorable Henry A. Waxman
House of Representatives
Washington, DC 20515

Dear Mr. Waxman:

Thank you for your recent letter raising your concerns about scientific decision making at the Department of Health and Human Services (HHS). I would like to begin by saying that I agree with your statement that this Department has a long tradition of employing the best scientific information for internal decision making.

In your letter, you asked for specific information relating to the Department's updating of scientific information on web pages, how the Department has handled scientific advisory committees, and how the Department audits various programs. Enclosed is a response to your six specific requests.

I hope that this information will help clarify that I am committed to maintaining and strengthening the Department's reputation for excellence and scientific integrity. Please call me if you have any further questions or concerns. I will send this reply to the co-signers of your letter.

Sincerely,

Tommy G. Thompson

Enclosure

Response to Six Questions

Response to Question #1:
Scientific information we provide to the public must be the best available. That is why it has been made clear to all top Departmental officials that they need to continually assess the information they disseminate to the public to ensure it reflects the latest and best scientific data available.

To this end, the National Cancer Institute (NCI) removed information on the NCI website relating to the relationship between abortion (spontaneous and induced) and breast cancer, to review the accuracy and completeness of the content. Updated information will not only reflect the most current data available, but will also advise the public regarding further steps we are planning to help clarify the relationship. As you know, research regarding this relationship has produced mixed results, and a number of published studies have methodological imperfections. The NCI is planning to hold a scientific meeting in early 2003 to review the published data on the relationship between hormonal reproductive events and breast cancer and to identify future research opportunities that will improve our understanding of these complex interactions. I have been advised that a statement describing the upcoming meeting will be posted shortly on the NCI Web site.

With regard to the Centers for Disease Control and Prevention (CDC) "Programs That Work" website, here again the website was removed for updating. Programs listed on the website were limited, and it was determined that other proven programs that are effective in helping young people avoid risky sexual behavior ought to be added. CDC is exploring new and appropriate means to identify and characterize interventions that have scientifically credible evidence of effectiveness. This is another case where information will not be removed, but merely supplemented and updated, and this website will reappear next year following CDC's identification of additional effective programs.

Finally, the reason that the fact sheet regarding the effectiveness of condoms was removed from CDC's website was that some of the scientific information on the fact sheet had become out of date. CDC and NIH scientists have worked to update the fact sheet and it will appear on the CDC website shortly. This fact sheet will be based on the NIH workshop report and additional studies that were not reviewed in that report or were published subsequent to the workshop.

Response to Question #2:
The Food and Drug Administration proposed to eliminate the Advisory Committee on Pharmacy Compounding because of a Supreme Court decision making the functions of this Committee obsolete. The National Institutes of Health (NIH) absorbed the functions of the Cancer Advisory Panel for Complementary and Alternative Medicine into the National Advisory Council for Complimentary and Alternative Medicine for a more holistic approach toward treatment. Additionally, there are several Congressionally-mandated committees that are slated to terminate when their charters expire. One of

those is the Negotiated Rulemaking Committee on Joint Tribal and Federal Self-Governance. The Department has also been successful in merging two Special Emphasis Panels that perform the same function at the Substance Abuse and Mental Health Administration. Because of duplication, NIH has merged the Acquired Immune Syndrome Research Review Committee with the Microbiology and Infectious Diseases Research Committee (MIDRC). All of these mergers and terminations will be included in the GSA's 2002 Annual Report and available for review at www.facadatabase.gov.

Response to Question #3:
All discussions, including internal or external speculations in the press, regarding the naming of a Chair for the FDA Reproductive Health Drugs Advisory Committee have been premature. All potential candidates who conditionally accept a position on a board or a committee must complete a financial disclosure form, which is then vetted for potential conflicts of interest. If a conflict of interest exists, then that individual cannot serve on a Federal Advisory Committee. No decision has been made on the make-up of the Committee or on the determination of a Chairperson. The Office of the Secretary has received no written recommendations for this position.

Response to Question #4:
The Department has not replaced anyone on any advisory committee whose term has not expired, and has not asked for any committee member's resignation. The only people who have been replaced, prior to fulfilling their term, resigned on their own personal reasons (e.g. they were a foreign agent and could not serve on the committee, they moved, or changed jobs that created a conflict of interest). Membership is reviewed upon expiration of service for the individual whose term has been completed. The Department does not project replacements for those expirations, rather Departmental staff review candidates for either reappointments or consider other individuals for service. Upon their termination date, the Secretary has the discretion to appoint new members or reappoint members. This is a process that has been followed by previous Administrations regardless of political party.

Response to Question #5:
The Office of the Inspector General (OIG) is responsible for conducting independent audits of Departmental programs and operations, including groups that receive HHS funding. The OIG auditors follow generally accepted government auditing standards, issued by the Comptroller General of the United States, which are intended to ensure the integrity of the audit process. The audit process used by the HHS OIG, which is typical of that employed by most other federal audit organizations, entails due professional care in the gathering and documenting of evidence in support of audit findings and rigorous reviews of audit findings, conclusions, and recommendations by audit supervisors, managers, and Assistant Inspectors General. The OIG's work meets the highest standards of integrity and objectivity. Furthermore, the OIG has an ongoing program of internal quality control review that is subject to regular external peer review by another OIG in accordance with guidelines established by the President's Council on Integrity and Efficiency.

With regard to the selection of audit projects, the OIG follows an annual work plan, publicly available on its website, as the guide for deploying audit resources by program issue area. This plan is developed by the OIG in consultation with the Secretary and various Assistant Secretaries, the Office of Management and Budget, and Congressional committees with jurisdiction over Departmental programs. The plan takes into account the results of prior work and other factors, such as increases in program budgets, major program changes, and patterns of recent problems. The OIG work plan process ensures the deployment of its scarce resources on the highest priority in terms of Administration and Congressional interest and our responsibility to protect the interest of the taxpayers.

In addition, apart from the official audit process, the CDC Financial Assistance Manual requires CDC to conduct routine monitoring and oversight of all CDC cooperative agreements and to follow-up with grant recipients when problems or potential problems are detected. CDC attempts to have the recipient take corrective action and provide needed technical assistance when issues are first identified. Part of the monitoring may include a site visit to the program where CDC officials may ask for information or updates on the grantees' progress in meeting program requirements outlined in the cooperative agreement and agreed to by the grantee. This information may include, but is not limited to, an evaluation of the grantee's accounting system, budgetary controls, property management, purchases, travel expenses, and internal controls.

Response to Question #6:
Since the latter part of 2001, the OIG has initiated five audits of four non-profit CDC HIV/AIDS prevention grantees, as follows:

- Two audits of the San Francisco-based Stop AIDS Project, Inc. (SAP)—one in the Fall of 2001 after Congressional concerns surfaced about the appropriateness of materials being used in workshops, and the second audit currently being completed to ascertain at action SAP has taken since the issuance of the first audit;

- One audit in Washington, DC at Us Helping Us, initiated in the Spring of this year to assess how the grantee is complying with applicable federal financial management criteria and carrying out the activities agreed to in its grant application;

- Two audits in Boston, Massachusetts: one at the Fenway Community Health Center and the other at the Multi-Cultural AIDS Coalition. The objective of these audits is also to assess how well the grantees are complying with applicable federal financial management criteria and carrying out the activities agreed to in their grant applications.

The OIG plans to review up to six additional grantees in FY 2003, but they have not yet been selected. Factors considered in selecting grantees for audit include size of grant, location of grantee, and previous financial or program problems.

In addition to the Department's work in the CDC HIV/AIDS prevention area, as part of a request from the Senate Finance Committee, the OIG has a significant effort underway to audit grantees of the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, which is a program administered by the Health Resources and Services Administration. During FY 2002, the OIG conducted audits of the financial management and program operations of CARE Act service provider grantees in Baltimore, Indianapolis, Kansas City, Houston, and Puerto Rico; and it plans similar reviews in the larger cities and states for FY 2003. Some CARE Act grants may also receive CDC HIV/AIDS prevention funds.

The OIG is not conducting, nor does it have plans to conduct, audits of sex education grants that do not fall under CDC's HIV/AIDS prevention program, whether they are groups that oppose abstinence-only policies or which operate abstinence-only programs.