

SUMMARY STATEMENT

SUBJECT: Interim Progress Report on Complementary and Alternative Medicine Policy

PURPOSE: Secretary Signature

SUMMARY: Executive Order 13147 established in the DHHS on March 7, 2000 the White House Commission on Complementary and Alternative Medicine Policy. The Commission was directed to provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The Commission is scheduled to terminate on March 7, 2002, unless extended by the President prior to this date.

The staff office for the Commission, located within the Immediate Office of the Secretary, DHHS, receives logistical/administrative support for their activities from the National Center for Complementary and Alternative Medicine at the National Institutes of Health. In preparing this Interim Progress Report, the staff took into consideration comments and testimony provided by experts in the CAM community, traditional academic research centers, health professional organizations, and the public at the seven issue-specific meetings and four Town Hall meetings convened by the Commission.

This Interim Report provides an overview of the issues presented to the Commission, including the need for an expanded Federal sector effort to coordinate CAM-related activities. The Commission presents no formal recommendations at this time. However, the Commission supports the promotion of rigorous science and the appropriate use of the scientific method in research studies. The Commission also supports making the current evidence for CAM practices and products more widely and easily available to the public and health care providers. The Commission recognizes that recommendations in the Final Report about the appropriate use of safe and effective CAM practices and products must be grounded in sound scientific and ethical principles.

The Final Report will provide detailed recommendations regarding the four topics identified in the Executive Order. The Commission will continue to solicit and consider the advice received from the public after presenting this interim report on the Commission's website.

CONCERNS: None.

RECOMMENDATION: That the Secretary sign the transmittal letter transmitting the Interim Progress Report to the Congress.

CONTACT PERSON: Stephen C. Groft, Pharm.D.  
Executive Director  
301-435-6199  
SG18B@nih.gov



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

**DATE:** August 27, 2001

**TO:** The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
ES \_\_\_\_\_

**FROM:** Executive Director  
White House Commission on Complementary  
and Alternative Medicine Policy, OS, DHHS

**SUBJECT:** Interim Progress Report to Congress

BACKGROUND

Attached is the Interim Progress Report of the White House Commission on Complementary and Alternative Medicine Policy requested by former Secretary Shalala at the swearing-in ceremony held on July 13, 2000. Because of delays in establishing the Commission and the broad scope of activities required by Executive Order 13147, Secretary Shalala, Senator Tom Harkin, and Senator Barbara Mikulski requested an interim report be submitted highlighting the issues identified and discussed during public testimony and received at the seven issue-specific meetings and four Town Hall meetings during the past year.

HIGHLIGHTS

The Commission elected to provide in its interim report a brief overview of its activities and progress to date as it develops recommendations that address the four major topic areas outlined in the President's Executive Order. This report provides no formal recommendations. However, the final report from the Commission, to be submitted prior to March 7, 2002, will make administrative and legislative policy recommendations promoting the public's health and safety when using Complementary and Alternative Medicine (CAM) practices and products. The Final Report will also provide strategies to increase the availability of useful information about the safety and efficacy of CAM practices and products.

The Commission will continue to consider all of the issues discussed in the Interim Progress Report and will solicit advice from the public and other government agencies after the report is made available on the Commission's website (<http://whccamp.hhs.gov>).

Page 2 - The Secretary

If you have any questions on the contents of the report or on future activities of the Commission, I can be reached on 301-435-6199.

RECOMMENDATIONS

I recommend that you accept the attached Interim Progress Report from the Commission and sign the attached letter.



Stephen C. Groft, Pharm.D

Attachments:

Tab A - Letter to the President of the Senate

Tab B - Letter to the Speaker of the House

Tab C - Letter to Senator Tom Harkin

Tab D - Letter to Senator Barbara Mikulski

Tab E - Interim Progress Report, White House Commission on Complementary  
and Alternative Medicine Policy

DECISION:

Approved \_\_\_\_\_

Disapproved \_\_\_\_\_

Date \_\_\_\_\_



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

The Honorable Barbara Mikulski  
United States Senate  
Washington, DC 20510

Dear Senator Mikulski:

Enclosed for your information is the Interim Progress Report submitted by the White House Commission on Complementary and Alternative Medicine (CAM) Policy. Executive Order 13147 requires a Final Report to be submitted to the President prior to March 7, 2002. The Final Report will provide administrative and legislative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine.

This report provides a brief overview of the Commission and its activities. It also discusses the Commission's progress to date in developing recommendations and reflects the diverse perspectives heard from advocates, critics and other expert witnesses.

Sincerely,

Tommy G. Thompson

Enclosure

;



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

The Honorable Tom Harkin  
United States Senate  
Washington, DC 20510

Dear Senator Harkin:

Enclosed for your information is the Interim Progress Report submitted by the White House Commission on Complementary and Alternative Medicine (CAM) Policy. Executive Order 13147 requires a Final Report to be submitted to the President prior to March 7, 2002. The Final Report will provide administrative and legislative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine.

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Sincerely,

Tommy G. Thompson

Enclosure

;



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

The Honorable Richard Cheney  
President of the Senate  
Washington, DC 20510

Dear Mr. President:

Enclosed for your information is the Interim Progress Report submitted by the White House Commission on Complementary and Alternative Medicine (CAM) Policy. Executive Order 13147 requires a Final Report to be submitted to the President prior to March 7, 2002. The Final Report will provide administrative and legislative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine.

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Tommy G. Thompson

Enclosure



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

The Honorable Dennis Hastert  
Speaker of the House of Representatives  
Washington, DC 20515

Dear Mr. Speaker:

Enclosed for your information is the Interim Progress Report submitted by the White House Commission on Complementary and Alternative Medicine (CAM) Policy. Executive Order 13147 requires a Final Report to be submitted to the President prior to March 7, 2002. The Final Report will provide administrative and legislative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine.

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Sincerely,

Tommy G. Thompson

Enclosure

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President of the Senate  
Washington, DC 20510

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This report provides a brief overview of the Commission and its activities. It also discusses the Commission's progress to date in developing recommendations and reflects the diverse perspectives heard from advocates, critics and other expert witnesses.

Sincerely,

Tommy G. Thompson

Enclosure

*Doris*  
*OK to Final to*  
*all Four*  
*on OS Stationary.*  
*Thanks*  
*Steve*



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
IMMEDIATE OFFICE OF THE SECRETARY  
EXECUTIVE SECRETARIAT

FACSIMILE  
COVER SHEET

Number of Pages: \_\_\_\_\_  
(Including Cover Sheet)

Date: 8/23

To: Steve Goyt

Fax #: 301 486-1091 Telephone #: \_\_\_\_\_

Subject: \_\_\_\_\_

From: \_\_\_\_\_ Sandra Bart  
\_\_\_\_\_ Mirtha Beadle  
\_\_\_\_\_ Catherine Beck  
\_\_\_\_\_ Katie Burns  
\_\_\_\_\_ LaVarne Burton  
\_\_\_\_\_ Ilka Chavez  
\_\_\_\_\_ Ken Cohen  
\_\_\_\_\_ Patrice Drew

\_\_\_\_\_ Lorraine Fishback  
\_\_\_\_\_ John Gallivan  
\_\_\_\_\_ Cynthia Kenny  
\_\_\_\_\_ Thomas Kuchenburg  
\_\_\_\_\_ Carol Price  
\_\_\_\_\_ Martina Varnado  
\_\_\_\_\_ Ann Stallion  
\_\_\_\_\_ Melvin Whitfield

Sender's Fax #: (202) 205-2135

Office #: (202) 690-7753

MESSAGE: Steve. Here are examples of  
What is needed for your Package  
1- a Summary Statement  
2- a transmittal <sup>memo</sup> to the Secretary  
3- letters transmitting the report to members



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Health  
Office of Public Health and Science  
Washington D.C. 20201

MAY 10 2001

TO: The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
ES \_\_\_\_\_

FROM: Acting Principal Deputy Assistant Secretary Health

SUBJECT: Provisions and Implementation of Section 1003 of the Children's Health Act  
Report to Congress (Public Law 106-310) - ACTION

**BACKGROUND**

Attached for your approval are letters to the President of the Senate (TAB A) and Speaker of the House (TAB B), transmitting a report to Congress on Protections for Children in Research (TAB C).

The United States Congress enacted legislation in October of 2000, known as the Children's Health Act. Section 1003 requires that "By not later than 6 months after the date of enactment of this Act (October 17, 2000), the Secretary of Health and Human Services shall (1) conduct a review of the regulations under Subpart D of Part 46 of Title 45, Code of Federal Regulations, (2) consider any modifications necessary to ensure the adequate and appropriate protection of children participating in research, and (3) report the findings of the Secretary to Congress."

**HIGHLIGHTS**

Section 1003 directed the DHHS Secretary, in conducting the review, to consult broadly with experts in the field including pediatric pharmacologists, pediatricians, pediatric professional societies, bioethics experts, clinical investigators, institutional review boards, industry experts, appropriate Federal agencies, and children who have participated in research studies and the parents, guardians, or families of such children.

The staff of the Office for Human Research Protections took into consideration comments provided by expert consultants, as well as experience acquired during its compliance oversight investigations of research involving children in developing findings and recommendations.

Page 2 - The Secretary

(1) Major Findings

(a) The current DHHS regulations under Subpart D of 45 CFR Part 46 are sound, effective, well-crafted, robust and flexible, and when implemented properly by IRBs and investigators, provide adequate and appropriate protections for children of all ages and maturity levels participating in biomedical and behavioral research conducted or supported by DHHS.

(b) There is a clear need for DHHS to provide detailed guidance relevant to the complex issues inherent in both the conduct of research involving children and the interpretation of the provisions of the regulations under Subpart D of 45 CFR Part 46 to all parties engaged in the conduct and oversight of research involving children.

(c) Further guidance is particularly needed from DHHS regarding specific terms and concepts within the regulations under Subpart D of 45 CFR Part 46.

(d) The DHHS National Human Research Protections Advisory Committee (NHRPAC) provides an appropriate forum for broad public discussions of the complex issues related to the conduct of research involving children and the provisions of the regulations under Subpart D of 45 CFR Part 46.

RECOMMENDATIONS SUGGESTED

DHHS recommends that the regulations under Subpart D of 45 CFR Part 46 not be modified at this time.

DHHS should provide detailed guidance relevant to the complex issues inherent in both the conduct of research involving children and the interpretation of the provisions of the regulations under Subpart D of 45 CFR Part 46 to all parties engaged in the conduct and oversight of research involving children. Guidance regarding the interpretation and implementation of Subpart D should be developed with input from the DHHS National Human Research Protections Advisory Committee (NHRPAC). Such guidance should include:

1. Clarification for interpretation of terms and concepts of Subpart D of 45 CFR Part 46 such as "the prospect of direct benefit for the individual subject," "a minor increase over minimal risk," "disorder," "condition," and the appropriate procedures for recruiting children into research.
2. Instructions to IRBs that when interpreting the definition of minimal risk for research involving children as subjects conducted or supported by DHHS, an absolute standard under which "daily life" is interpreted to mean the daily life of healthy children in the general population should be applied.

Page 3 - The Secretary

3. Direction regarding payment (financial or otherwise) that may be provided to children involved in research as subjects or their parents, under circumstances that minimize the possibility of coercion or undue influence.

RECOMMENDATION

I recommend that you approve the attached Report to Congress and sign the attached letters.

DECISION

Approved \_\_\_\_\_ Disapproved \_\_\_\_\_ Date \_\_\_\_\_



Arthur J. Lawrence, Ph.D.  
Assistant Surgeon General

Attachments:

Tab A - Letter to the President of the Senate

Tab B - Letter to the Speaker of the House

Tab C - Report to Congress on Provisions and Implementation of Section 1003 of the  
Children's Health Act



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

The Honorable Richard Cheney  
President of the Senate  
Washington, D.C. 20510

Dear Mr. President:

Enclosed for your consideration is the report submitted by the Office of Human Research Protections, Department of Health and Human Services under the Children's Health Act of 2000 (P.L. 106-310). Section 1003 required that the Secretary of Health and Human Services conduct a review of the regulations under subpart D of part 46 of title 45, Code of Federal Regulations, consider any modifications necessary to ensure the adequate and appropriate protection of children participating in research and report the findings of the Secretary to the Congress.

This report, "Protections for Children in Research" describes the results of the broad consultation and the findings and recommendations derived from this consultation.

Sincerely,

Tommy G. Thompson

Enclosure



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

The Honorable Dennis Hastert  
Speaker of the House of  
Representatives  
Washington, D.C. 20515

Dear Mr. Speaker:

Enclosed for your consideration is the report submitted by the Office of Human Research Protections, Department of Health and Human Services under the Children's Health Act of 2000 (P.L. 106-310). Section 1003 required that the Secretary of Health and Human Services conduct a review of the regulations under subpart D of part 46 of title 45, Code of Federal Regulations, consider any modifications necessary to ensure the adequate and appropriate protection of children participating in research and report the findings of the Secretary to the Congress.

This report, "Protections for Children in Research" describes the results of the broad consultation and the findings and recommendations derived from this consultation.

Sincerely,

Tommy G. Thompson

Enclosure

OPDIV/STAFF DIV:OPHS/OHRP

DATE: MAY 10 2001

**SUBJECT:** Report to Congress: Protections for Children in Research

**PURPOSE:** Secretary's Signature

**SUMMARY:** Section 1003 of the *Children's Health Act of 2000 (P.L. 106-310)* directs the Secretary of the Department of Health and Human Services (DHHS) to conduct a review of the regulations under 45 CFR Part 46, Subpart D - *Additional DHHS Protections for Children Involved as Subjects in Research*, within 6 months of the Act's enactment. That evaluation should consider if any modifications are necessary to ensure the adequate and appropriate protection of children participating in research and its findings reported to Congress by April 17,

The Office for Human Research Protections (OHRP) had primary responsibility, in the Department, for conducting the review and preparing the report for Congress. The staff of OHRP took into consideration comments provided by experts in the field, as well as experience acquired during compliance oversight investigations of research involving children in developing findings and recommendations.

Several recommendations are contained in the report including, that the current regulations under Subpart D not be modified at this time. Other recommendations suggest that the Department provide detailed guidance to address a number of complex issues inherent in both the conduct of research involving children and the interpretation of the provisions of the regulations under Subpart D. The report also recommends that the DHHS National Human Research Protections Advisory Committee provide input in the development of such guidance.

**CONCERNS:** None (Congress anticipates receiving the report by May 18th)

**RECOMMENDATION:** That the Secretary sign the transmittal letters transmitting the Report to Congress

**CONTACT PERSON:** Irene Stith-Coleman  
(202) 260-1587  
istitheco@osophs.dhhs.gov

*I think this  
stays on  
plain paper.* *Doris*  
*O/K to final*  
*T yne*

OPDIV/STAFF/ DIV: OS/WHCCAMP

DATE: August 24, 2001

### SUMMARY STATEMENT

SUBJECT: Interim Progress Report on Complementary and Alternative Medicine Policy

PURPOSE: Secretary Signature

SUMMARY: Executive Order 13147 established in the DHHS on March 7, 2000 the White House Commission on Complementary and Alternative Medicine Policy. The Commission was directed to provide a report, through the Secretary, to the President on legislative and administrative recommendations for assuring that public policy maximizes the benefits to Americans of complementary and alternative medicine. The Commission is scheduled to terminate on March 7, 2002, unless extended by the President prior to this date.

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*logistical / administrative*

The Final Report will provide detailed recommendations regarding the four topics identified in the Executive Order. The Commission will continue to solicit and consider the advice received from the public after presenting this interim report on the Commission's website.

CONCERNS:

None.

RECOMMENDATION:

That the Secretary sign the transmittal letter transmitting the Interim Progress Report to the Congress.

CONTACT PERSON:

Stephen C. Groft, Pharm.D.  
Executive Director  
301-435-6199  
SG18B@nih.gov

OS  
Stationary

**DATE:** August 27, 2001

**TO:** The Secretary  
Through: DS \_\_\_\_\_  
COS \_\_\_\_\_  
ES \_\_\_\_\_

**FROM:** Executive Director  
White House Commission on Complementary  
and Alternative Medicine Policy, OS, DHHS

**SUBJECT:** Interim Progress Report to Congress

#### BACKGROUND

Attached is the Interim Progress Report of the White House Commission on Complementary and Alternative Medicine Policy requested by former Secretary Shalala at the swearing-in ceremony held on July 13, 2000. Because of delays in establishing the Commission and the broad scope of activities required by Executive Order 13147, Secretary Shalala, Senator Tom Harkin, and Senator Barbara Mikulski requested an interim report be submitted highlighting the issues identified and discussed during public testimony and received at the seven issue-specific meetings and four Town Hall meetings during the past year.

#### HIGHLIGHTS

The Commission elected to provide in its interim report a brief overview of its activities and progress to date as it develops recommendations that address the four major topic areas outlined in the President's Executive Order. This report provides no formal recommendations. However, the final report from the Commission, to be submitted prior to March 7, 2002, will make administrative and legislative policy recommendations promoting the public's health and safety when using Complementary and Alternative Medicine (CAM) practices and products. The Final Report will also provide strategies to increase the availability of useful information about the safety and efficacy of CAM practices and products.

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Page 2 - The Secretary

If you have any questions on the contents of the report or on future activities of the Commission, I can be reached on 301-435-6199.

RECOMMENDATIONS

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Stephen C. Groft, Pharm.D

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Tab B - Letter to the Speaker of the House

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Tab E - Interim Progress Report, White House Commission on Complementary  
and Alternative Medicine Policy

DECISION:

Approved \_\_\_\_\_

Disapproved \_\_\_\_\_

Date \_\_\_\_\_