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ABSTRACT

This document is a Congressional report about a proposed amendment to the Public Health Service Act to provide for a program to carry out research on the drug diethylstilbestrol (DES), to educate health professionals and the public on the drug, and to provide for certain longitudinal studies regarding DES. The amendment itself is presented in the document, followed by a discussion of the purpose and summary of the amendment and a brief report on the background and need for such legislation. These opening sections explain that DES was a drug prescribed to approximately five million pregnant women between 1941 and 1971 in the United States and that studies conducted during the 1970s have demonstrated that the drug damages the reproductive systems of the children of the women who were prescribed DES and may increase the risk of breast cancer in the women themselves. Other sections of the report describe hearings, committee considerations, oversight findings, and cost estimates. An inflationary impact statement is followed by a section-by-section analysis of the amendment and changes in the existing law that would be made by the bill. (NB)

102D CONGRESS
2d Session
HOUSE OF REPRESENTATIVES
REPORT
102-817



# DES EDUCATION AND RESEARCH AMENDMENTS OF 1992

AUGUST 10, 1992.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. DINGELL, from the Committee on Energy and Commerce, submitted the following

## REPORT

[To accompany H.R. 4178]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 4178) to amend the Public Health Service Act to provide for a program to carry out research on the drug known as diethylstilbestrol, to educate health professionals and the public on the drug, and to provide for certain longitudinal studies regarding individuals who have been exposed to the drug, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS



The amendment is as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

59-006

SECTION 1. SHORT TITLE.

This Act may be cited as the "DES Education and Research Amendments of 1992".

SEC. 2. ESTABLISHMENT OF PROGRAM REGARDING DES.

Part A of title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended by adding at the end the following new section:

"DES

"SEC. 403A. (a) The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as 'DES').

"(b) In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug, including the importance of identifying and treating individuals who have been exposed to the drug.

"(c) After consultation with the Office of Research on Women's Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:

"(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).

"(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.

"(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).

"(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.

"(d) For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or after January 1, 1938) administered to the biological mother of the individual.

"(e) In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 1996.".

## PURPOSE AND SUMMARY

The DES Education and Research Amendments of 1992 authorize a program for research and public education on the health effects of the drug diethylstilbestrol ("DES"). Between 1941 and 1971, DES was prescribed to approximately five million pregnant women in the United States. Studies conducted during the 1970's have demonstrated that the drug damages the reproductive systems of the sons and daughters of the women who were prescribed DES ("DES mothers"), including vaginal cancer in their daughters ("DES daughters").

There is also evidence that DES increases the risk of breast cancer in DES mothers, that it causes infertility and a number of serious pregnancy complications in their daughters, and that it causes infertility in their sons. Because DES injuries can cause premature labor in DES daughters, it can affect the health of the grandchildren of the women who took it.

H.R. 4178 requires the Director of the National Institutes of Health to establish a program for the dissemination of information

on DES to exposed individuals and the health professionals who will be responsible for treating them. The program would also support research, training and other efforts with respect to the diagnosis and treatment of conditions associated with exposure to DES.

The bill also provides that the Director shall conduct one or more longitudinal, epidemiological studies to provide information on long-term effects of DES and the relationship between DES and a number of diseases and disorders that are specified in the bill, as well as other diseases and disorders that may be discovered through research.

The bill authorizes appropriations of such sums as may be necessary for fiscal years 1993 through 1996 for carrying out the program.

## Background and Need for the Legislation

Between 1941 and 1971, approximately 5 million pregnant women were prescribed DES. Initially, DES was prescribed to women who had a history of miscarriage. Later it was prescribed for other complications of pregnancy. Ultimately, it was advertised and prescribed for any pregnant woman. One advertisement claimed that DES would make "bigger and stronger babies."

Today, drugs may not be marketed unless the Food and Drug Administration has first found that they are safe and effective. However, when DES was approved, the law required only that drugs be proven safe; the efficacy requirement was not added until 1962. As a result, DES was never proven effective for the purposes for which it was prescribed.

In 1971, Dr. Arthur Herbst published a study in the "New England Journal of Medicine" in which he reported an increased incidence in clear cell adenocarcinoma, a previously rare form of vaginal cancer, in young girls who had been exposed to DES in utero. It is believed that a DES daughter's increased risk of this cancer is about 1/1,000. Subsequent studies have found evidence that DES is associated with the following conditions: increased breast cancer in DES mothers; reproductive tract abnormalities in DES daughters (causing increased incidence of ectopic pregnancies and infertility); and genital abnormalities in DES sons. There is also evidence that DES may be linked to impairments of the autoimmune system.

The Department of Health and Human Services established a DES Task Force during the mid-1970's and supported research and limited educational initiatives. However, there has been little support for research or education since the early 1980's. An educational brochure that the Department once distributed has been out of print since 1983.

In April 1992, the Office of Research on Women's Health and three of the institutes of the National Institutes of Health sponsored a workshop on the long-term effects of exposure to DES. The conference included presentations on a broad range of issues, including findings from human and animal research on DES. Recommendations for further research and public education initiatives from the workshop will be published shortly. As a result of the conference, the Department of Health and Human Services has indicated that it supports increasing research on DES.

## HEARINGS

The Committee's Subcommittee on Health and the Environment has held hearings on research programs pertaining to women's health conducted by the National Institutes of Health. See for example hearings on H.R. 1532, H.R. 1161 and H.R. 1819 (April 15, 16, 1991). The Subcommittee did not hold hearings on H.R. 4178.

## COMMITTEE CONSIDERATION

On February 5, 1992, Ms. Slaughter and 17 other members introduced H.R. 4178.

On July 23, 1992, the Subcommittee on Health and Environment met in open session and ordered the bill (H.R. 4178) reported, as amended, by a voice vote, a quorum being present. On July 28, 1992, the Committee met in open session and ordered the bill (H.R. 4178, as amended) reported, without amendment, by voice vote, a quorum being present.

## COMMITTEE OVERSIGHT FINDINGS

In compliance with clause 2(l)(3)(A) of rule XI of the Rules of the House of Representatives, the Committee states that no oversight findings or recommendations have been made by the Committee's Subcommittee on Oversight and Investigations.

## COMMITTEE ON GOVERNMENT OPERATIONS

In compliance with clause 2(l)(3)(D) of rule IX of the Rules of the House of Representatives, the Committee states that no oversight findings have been submitted to the Committee by the Committee on Government Operations.

## COMMITTEE COST ESTIMATE

In compliance with clause 7(a) of Rules of the House of Representatives, the Committee states that the cost incurred in carrying out this legislation will be between $2 and $5 million per year for fiscal years 1993–1997.

## CONGRESSIONAL BUDGET OFFICE ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
*Washington, DC, August 5, 1992.*

Hon. JOHN D. DINGELL,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 4178, the DES Education and Research Amendments of 1992, as ordered reported by the House Committee on Energy and Commerce on July 28, 1992. Enactment of H.R. 4178 would not affect direct spending or receipts. Therefore, pay-as-you-go procedures would not apply to this bill.

If you wish further details on this estimate, we will be pleased to provide them.

Sincerely,

JAMES L. BLUM
(For Robert D. Reischauer, Director).

CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

1. Bill number: H.R. 4178.
2. Bill title: DES Education and Research Amendments of 1992.
3. Bill status: As ordered reported by the House Energy and Commerce Committee on July 28, 1992.
4. Bill purpose: To amend the Public Health Service Act to provide for a program to carry out research on the drug known as diethylstilbestrol, to educate health professionals and the public on the drug, and to provide for certain longitudinal studies regarding individuals who have been exposed to the drug.
5. Estimated cost to the Federal Government:

[By fiscal years, in millions of dollars]

| | 1993 | 1994 | 1995 | 1996 | 1997 |
|---|---|---|---|---|---|
| Estimated authorizations: | | | | | |
| Reseach | 4 | 4 | 4 | 4 | ..... |
| Education | 1 | 1 | 1 | 1 | ..... |
| Longitudinal study | 1 | 1 | 1 | 1 | ..... |
| Total estimated authorization | 5 | 5 | 5 | 6 | ..... |
| Estimated Outlays: | | | | | |
| Reseach | 2 | 3 | 4 | 4 | 2 |
| Education | (1) | (1) | 1 | 1 | (1) |
| Longitudinal study | (1) | 1 | 1 | 1 | 1 |
| Total estimated outlays | 2 | 5 | 5 | 5 | 3 |

[1] Less than $500,000.
Numbers may not add to totals because of rounding.

The costs of this bill fall within budget function 550.

Basis of estimate: H.R. 4178 would authorize funding for the establishment of a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (DES). The bill authorizes appropriations of such sums as may be necessary for each of the final years 1993 through 1996 for these purposes.

H.R. 4178 authorizes funding for a research program regarding DES. According to the National Institutes of Health (NIH), $3.4 million was appropriated for DES research in fiscal year 1992. CBO estimated costs in fiscal years 1993 through 1996 by adjusting the fiscal year 1992 appropriation by projected inflation.

The bill authorizes funding for programs to educate health professionals and the public about DES. Based on information from the National Institutes of Health (NIH), CBO estimates that dissemination of health information on DES would cost approximately $500,000 in each of fiscal years 1993 through 1996.

H.R. 4178 also would authorize funding for one or more longitudinal studies regarding DES-related diseases or disorders. Based on

information from NIH, one longitudinal study would cost $1 million each year. Assuming that NIH conducts one longitudinal study, this provision would cost $1 million in each of fiscal years 1993 through 1996.

This estimate assumes that all authorizations are fully appropriated at the beginning of each fiscal year. Outlays are estimated using spendout rates computed by CBO on the basis of recent program data.

6. Pay-as-you-go considerations: The Budget Enforcement Act of 1990 sets up pay-as-you-go procedures for legislation affecting direct spending or receipts through 1997. None of the provisions of H.R. 4178 would affect direct spending or receipts. Therefore, this bill has no pay-as-you-go implications.

7. Estimated cost to State and local government: None.

8. Estimate comparison: None.

9. Previous CBO estimate: None.

10. Estimate prepared by: Connie Takata.

11. Estimate approved by: C.G. Nuckols, Assistant Director for Budget Analysis.

## Inflation Impact Statement

Pursuant to clause 2(l)(4) of rule XI of the Rules of the House of Representatives, the Committee states that it does not believe that the bill will have any impact on inflation.

## Section-by-Section Analysis

### SECTION 1. SHORT TITLE

Section 1 states that the short title of the bill is the "DES Education and Research Amendments of 1992."

### SECTION 2. ESTABLISHMENT OF PROGRAMS REGARDING DES

Section 2 would add a new section 403A(a) to the Public Health Service Act. Section 403A(a) states that the Director of the National Institutes of Health shall establish a program to conduct and support research and training, the dissemination of health information and other programs with respect to the diagnosis and treatment of conditions associated with exposure to DES.

Under section 403A(b), the Director, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public about the drug, including the importance of identifying and treating individuals who have been exposed to DES.

The educational program has three components. The first component involves the education of the public. Currently, many DES children are not aware of their exposure to DES or of the questions they should ask their mothers to determine whether they were exposed to the drug. Many women who were pregnant during the years that DES was prescribed have never obtained their medical records to determine whether they were prescribed DES.

Second, health professionals still need to be educated about what is currently known concerning the health effects associated with

DES, and the currently recommended medical treatment of DES-exposed individuals. There are many stories of misdiagnosis of cancer and other effects because the physician did not correctly determine that the patient had been exposed to DES. Under the bill, materials would be developed and distributed to hospitals, clinics and physicians' offices to educate doctors and nurses about the known and potential health risks and proper treatment for DES-exposed mothers, daughters and sons.

Third, educational materials would be available for distribution to the DES-exposed persons and their families to inform them about what is known about the effects of DES and about what medical care they should seek in order to minimize the risk of complications from the drug.

Under section 403A(c), the Director, after consultation with the Office of Research on Women's Health and through the appropriate national research institutes, shall conduct one or more longitudinal studies to determine the incidence of diseases and disorders in DES-exposed individuals and the relationship of DES to those diseases and disorders. The bill highlights the following diseases and disorders as subject for study:

Breast cancer, gynecological cancers and impairments of the immune system, including autoimmune disease in DES mothers;

Clear cell cancer (including recurrences), the long-term health effects of such cancer and the effects of treatments for such cancer, impairments of the reproductive and autoimmune systems in DES daughters; and

Impairments of the reproductive and autoimmune systems in DES sons.

Section 403A(d) contains a definition of exposure to DES in utero.

Section 403A(e) authorizes such sums as may be necessary for fiscal years 1993, 1994, 1995 and 1996 for carrying out section 403A. Subsection (e) also explicitly states that the Director may use any other appropriated funds that are authorized by another provision of law to carry out section 403A.

## Agency Views

On July 28, 1992, the Committee received the following letter from Department of Health and Human Services Secretary Dr. Louis Sullivan stating that the Department does not object to favorable consideration of H.R. 4178.

Secretary of Health and Human Services,
*Washington, DC, July 28, 1992.*

Hon. John Dingell,
*Chairman, Committee on Energy and Commerce,*
*House of Representatives, Washington, DC.*

Dear Mr. Chairman: The purpose of this letter is to present our views on H.R. 4178, as reported by the Subcommittee on Health and the Environment, which would authorize research programs on the long-term effects of diethylstilbestrol (DES). The Administration does not object to this legislation.

Between 1941 and 1971, DES was prescribed for some pregnant women to reduce their risk of miscarriage. The drug, however, has been linked to cancers and other reproductive difficulties in the daughters, and genitourinary abnormalities in the sons, of mothers exposed to the drug. H.R. 4178 would authorize such sums as necessary over three years for professional and public education concerning, and longitudinal studies of individuals exposed to DES.

We strongly support initiatives aimed at furthering our knowledge about the long-term effects of DES, and we therefore do not object to the bill's favorable consideration. The National Institutes of Health (NIH) is currently reviewing its DES research portfolio, and recommendations for further research from an April 1992 workshop sponsored by NIH will be published shortly. The agency will continue to increase its efforts in this research area, and will work with other public and private organizations to develop a comprehensive strategy for this program.

We are advised by the Office of Management and Budget that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

LOUIS W. SULLIVAN, M.D.

## CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (new matter is printed in italic):

### SECTION 403 OF THE PUBLIC HEALTH SERVICE ACT

*DES*

*Sec. 403A. (a) The Director of NIH shall establish a program for the conduct and support of research and training, the dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to the drug diethylstilbestrol (in this section referred to as "DES").*

*(b) In carrying out subsection (a), the Director of NIH, after consultation with nonprofit private entities representing individuals who have been exposed to DES, shall conduct or support programs to educate health professionals and the public on the drug, including the importance of identifying and treating individuals who have been exposed to the drug.*

*(c) After consultation with the Office of Research on Women's Health, the Director of NIH, acting through the appropriate national research institutes, shall in carrying out subsection (a) conduct or support one or more longitudinal studies to determine the incidence of the following diseases or disorders in the indicated populations and the relationship of DES to the diseases or disorders:*

*(1) In the case of women to whom (on or after January 1, 1938) DES was administered while the women were pregnant, the incidence of all diseases and disorders (including breast cancer, gynecological cancers, and impairments of the immune system, including autoimmune disease).*

*(2) In the case of women exposed to DES in utero, the incidence of clear cell cancer (including recurrences), the long-term health effects of such cancer, and the effects of treatments for such cancer.*

*(3) In the case of men and women exposed to DES in utero, the incidence of all diseases and disorders (including impairments of the reproductive and autoimmune systems).*

*(4) In the case of children of men or women exposed to DES in utero, the incidence of all diseases and disorders.*

*(d) For purposes of this section, an individual shall be considered to have been exposed to DES in utero if, during the pregnancy that resulted in the birth of such individual, DES was (on or after January 1, 1938) administered to the biological mother of the individual.*

*(e) In addition to any other authorization of appropriations available for the purpose of carrying out this section, there are authorized to be appropriated for such purpose such sums as may be necessary for each of the fiscal years 1993 through 1996.*

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