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PREMATURITY RESEARCH EXPANSION AND EDUCATION FOR MOTHERS WHO DELIVER INFANTS EARLY ACT OR THE PREEMIE ACT

JULY 31, 2006.—Ordered to be printed

Mr. ENZI, from the Committee on Health, Education, Labor, and Pensions, submitted the following

R E P O R T

[To accompany S. 707]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 707) to reduce preterm labor and delivery and the risk of pregnancy-related deaths and complications due to pregnancy, and to reduce infant mortality caused by prematurity, having considered the same, reports favorably thereon with an amendment in the nature of a substitute and recommends that the bill (as amended) do pass.

CONTENTS

I. PURPOSE AND NEED FOR LEGISLATION

The purpose of the "Prematurity Research Expansion and Education for Mothers who deliver Infants Early" or "PREEMIE Act," is to reduce the rates of preterm labor and delivery; work toward an evidence based standard of care for pregnant women at risk of preterm labor, and for infants born preterm; and to reduce infant

mortality and disabilities caused by prematurity. In nearly half of cases, physicians and scientists cannot pinpoint a cause for preterm labor and delivery.

The rate of preterm birth constitutes a serious public health problem. In 2003, there were 499,008 preterm births in the United States, representing 1 in 8 babies born. The rate of preterm birth increased nearly 30 percent between 1983 and 2003 from 9.6 percent to 12.3 percent. Among racial/ethnic subgroups, preterm birth rates were highest among infants born to non-Hispanic black mothers, 17.8 percent.

Premature birth is the leading cause of infant mortality in the first year of life. For those who survive, approximately one quarter will face significant health problems, including cerebral palsy, mental retardation, blindness, respiratory problems, and other chronic conditions.

The human, societal and economic costs associated with prematurity are significant and increasing. According to the Institute of Medicine, the annual societal economic burden associated with preterm birth in the United States was at least $26.2 billion in 2005, or $51,600 per infant born preterm. Nearly two-thirds of the societal cost was accounted for by medical care services ($16.9 billion), with more than 85 percent of those medical care services delivered in infancy. Maternal delivery costs contributed another $1.9 billion. Early intervention services cost an estimated $611 million, whereas special education services associated with a higher prevalence of four disabling conditions, including cerebral palsy, mental retardation, vision impairment, and hearing loss among premature infants added $1.1 billion. Lost household and labor market productivity associated with those disabling conditions contributed $5.7 billion. A separate analysis by the March of Dimes found the direct health care costs to employers are $41,610 for a preterm birth compared to $2,830 for full term.

In order to meet the Healthy People 2010 objective of reducing the rate of preterm birth to 7.6 percent, an expanded and coordinated public-private research agenda is needed to best utilize the resources available as developed by the "PREEMIE Act."

II. SUMMARY

This legislation authorizes $91 million over 5 years to expand and coordinate Federal research and educational activities related to preterm birth. Of that amount, $1 million is designated for a Surgeon General's conference on preterm birth that will establish a public-private agenda to speed the development of prevention strategies for preterm labor and delivery.

First, the "PREEMIE Act" expands and coordinates prematurity related research at the National Institutes of Health and Centers for Disease Control and Prevention with the goal of best utilizing existing Federal funding and additional funding as a result of this bill; second, the bill authorizes demonstration projects to test promising prevention and treatment interventions; third, the legislation codifies an existing Interagency Coordinating Council on Prematurity and Low Birthweight to stimulate research and enhance coordination among all the agencies of the Department of Health and Human Services; and finally, it calls for a Surgeon General's conference on preterm birth to establish a public-private agenda

that will speed the development of prevention strategies for preterm labor and delivery.

III. History of Legislation and Votes in Committee

The Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act, referred to as the PREEMIE Act, was first introduced in the first session of the 108th Congress, S. 1726, and was referred to the Senate Committee on Health, Education, Labor, and Pensions. A hearing on the bill took place on May 13, 2004 before the Committee on Health, Education, Labor, and Pensions Subcommittee on Children and Families (now called the Subcommittee on Education and Early Childhood Development). No further action on S. 1726 was taken during the 108th Congress. A companion bill was introduced in the House during the first session of the 108th Congress, H.R. 3350. The bill was referred to the House Committee on Energy and Commerce, Subcommittee on Health with no further action taken on it during the 108th Congress. In the second session of the 108th Congress, the Senate unanimously passed a resolution, S. Res. 476, supporting the goals, activities, and ideals of National Prematurity Awareness Month during November 2004.

In the first session of the 109th Congress, the PREEMIE Act was introduced in the Senate on April 5, 2005 and referred to the Committee on Health, Education, Labor, and Pensions. On June 28, 2006, the Committee on Health, Education, Labor, and Pensions ordered the bill to be reported favorably with an amendment in the nature of a substitute co-sponsored by Senators Alexander, Dodd, Isakson, Kennedy, DeWine, Mikulski, Hatch, Bingaman, Murray, Reed, Clinton, Jeffords, Harkin and Enzi by unanimous consent. A companion bill was introduced in the House, H.R. 2861, on June 9, 2005 and referred to the House Committee on Energy and Commerce.

IV. Explanation of Bill and Committee Views

The bill has a variety of provisions, the explanation of and committee views on which follow below:

To reduce the rates of preterm birth, more research is needed on the underlying causes of preterm delivery, the development of treatments for the prevention of preterm birth, and treatments improving outcomes for infants born preterm. The committee believes that the expansion and coordination of preterm birth research within the National Institutes of Health and the Centers for Disease Control and Prevention is vital to achieving these outcomes. The committee strongly supports the work being done at the research networks at the National Institutes of Health. The bill establishes a multi-center clinical program that will authorize three networks that are currently in existence at the National Institutes of Health. This committee expects that initially the three existing networks will be the ones authorized, but the bill language provides the flexibility to adapt these Networks in the future as needed.

As part of the research expansion at the National Institutes of Health and the Centers for Disease Control and Prevention, the committee urges the Department of Health and Human Services to

consider the recommendations made by the 2006 Institute of Medicine Report "Preterm Birth: Causes, Consequences, and Prevention."

The bill requests epidemiological studies by the Centers for Disease Control and Prevention on the relationship between prematurity, birth defects, and developmental disabilities. The committee expects that these studies will be important in properly identifying the contribution of birth defects to the problem of preterm birth. In addition, these studies will help better understand the association between developmental disabilities and preterm birth.

This bill establishes systems for the collection of medical information, including electronic health records, to link with the Pregnancy Risk Assessment Monitoring System (PRAMS) in order to track pregnancy outcomes. This committee expects that any systems created or electronic health records accessed through these systems will utilize applicable interoperability standards as determined by the Secretary through a joint public and private sector process, including standards adopted by the Office of the National Coordinator for Health Information Technology.

The bill establishes a grant program to conduct demonstration projects to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death. Activities under this grant program may include providing books and videos to families that provide information about the neonatal intensive care unit experience, and providing direct services that provide emotional support within the neonatal intensive care unit setting. The committee expects these activities to be culturally competent.

In addition to prematurity research activities sponsored by academia and government sources, the committee recognizes that clinical, evidence-based research by specialists in the private sector has also contributed significantly to improved outcomes for mothers at risk of preterm delivery, and for premature babies. The result of these efforts is the ability to care for babies born as early as 24 weeks gestational age, and those weighing as little as 1 lb. The Department is encouraged to utilize the participation of private sector organizations, including physician groups, with demonstrated expertise in conducting research into the care of premature infants in Federal research activities designed to improve treatment for prematurity and outcomes for babies born prematurely, and to include such private sector expertise in the Surgeon General's Conference on Preterm Birth.

The grant programs established by this act will only be used to fund public or private non-profit entities.

The bill authorizes an already existing Interagency Coordinating Council on Prematurity and Low Birthweight. The committee believes the continuation of this Council will foster greater collaboration across the Department of Health and Human Services. The Council will also be required to annually report to Congress on Departmental activities related to preterm birth.

The bill requires the Surgeon General to convene a conference on preterm birth within 1 year of enactment. The conference will examine the current findings and reports issued by the Interagency

Coordinating Council and other key stakeholders and develop a public-private agenda to speed the reduction in preterm birth rates. The committee strongly believes that the public awareness and coordinated public private agenda resulting from a Surgeon General's conference will be key to achieving the purposes of this bill.

V. COST ESTIMATE AND UNFUNDED MANDATE STATEMENT

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, July 13, 2006.

Hon. MIKE ENZI,
Chairman, Committee on Health, Education, Labor, and Pensions, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 707, the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contact is Sarah Evans.

Sincerely,

DONALD B. MARRON,
Acting Director.

Enclosure.

S. 707—Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act

Summary: S. 707 would amend the Public Health Service Act to direct the Secretary of Health and Human Services (HHS) to intensify and coordinate research and surveillance activities relating to preterm labor and delivery and infant mortality, to conduct demonstration projects designed to improve the outcomes for premature babies, and to host a conference on preterm birth. Several of those activities would be implemented through the Director of the National Institutes of Health (NIH), the Director of the Centers for Disease Control and Prevention (CDC), and the Surgeon General. The bill also would require the Secretary of HHS to establish an Interagency Coordinating Council on Prematurity and Low Birthweight to oversee and coordinate those activities.

For the activities described above, S. 707 would authorize the appropriation of $19 million for fiscal year 2007 and $18 million a year for 2008 through 2011. CBO estimates that implementing the bill would cost $8 million in 2007 and $76 million over the 2007–2011 period, assuming the appropriation of the authorized amounts. Enacting S. 707 would have no effect on direct spending or revenues.

The bill contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA) and would impose no costs on state, local, or tribal governments.

Estimated Cost to the Federal Government: The estimated budgetary impact of S. 707 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2007	2008	2009	2010	2011
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated authorization level	19	18	18	18	18
Estimated outlays	8	15	17	18	18

Basis of estimate: S. 707 would authorize the appropriation of $19 million in 2007 and $18 million a year for 2008 through 2011 to fund research and activities designed to reduce the rates of preterm labor and delivery and to reduce infant mortality and disabilities associated with prematurity.

For this estimate, CBO assumes that S. 707 will be enacted near the start of fiscal year 2007 and that the authorized amounts will be appropriated for each year. Using historical patterns of spending for similar programs, CBO estimates that the costs of the bill would be $8 million in 2007 and $76 million over the 2007–2011 period.

The National Institute for Child Health and Human Development (NICHD) currently administers several maternal and child health research programs through its Pregnancy and Perinatology Branch. Among these are the Maternal-Fetal Medicine Unit, the Neonatal Research Network, and the Genomic and Proteomic Network for Premature Birth Research. According to officials at NICHD, approximately $22 million was spent on these programs in fiscal year 2005 through NICHD's broad authorization to conduct and support research with respect to gynecologic health, maternal health, and child health. S. 707 would specifically authorize funding through 2011 for the above research programs as well as other research programs at NIH that focus on preterm labor and delivery.

The CDC's National Center on Birth Defects and Developmental Disabilities currently administers many public health research and education programs targeted at the health of newborns. These activities include tracking the prevalence of birth defects, researching their causes, and educating providers and patients about the best techniques for avoiding birth defects. S. 707 would authorize funding for expanding research in such areas as it relates to preterm delivery and infant mortality. The bill would also require the Director of CDC to establish additional surveillance systems for monitoring maternal-infant clinical and biomedical information that could be linked with the Pregnancy Monitoring Risk Assessment System.

The bill would authorize the appropriation of $3 million for the additional maternal-infant surveillance systems for each of fiscal years 2007 through 2011. For the other research and activities at the NIH and the CDC, the bill would authorize the appropriation of $10 million for each of those fiscal years.

S. 707 also would authorize the appropriation of $5 million for each of fiscal years 2007 through 2011 for the Secretary of HHS to provide grants to public and nonprofit organizations for demonstration projects designed to improve the treatment and outcomes for premature babies.

The bill also would require the Secretary to establish an Interagency Coordinating Council on Prematurity and Low Birthweight. The Council would be composed of representatives of the agencies

of HHS and would oversee the coordination of activities authorized under this act. CBO expects that supporting the council would cost less than $200,000 a year, subject to the availability of appropriated funds.

S. 707 also would require the Surgeon General to convene a conference on preterm birth within one year of the enactment of the bill. The bill would authorize the appropriation of $1 million for this conference.

Intergovernmental and private-sector impact: S. 707 contains no intergovernmental or private-sector mandates as defined in UMRA and would impose no costs on state, local, or tribal governments.

Estimate prepared by: Federal costs: Sarah Evans and Tim Gronniger; impact on state, local, and tribal governments: Leo Lex; impact on the private sector: Jennifer Doleac.

Estimate approved by: Peter H. Fontaine, Deputy Assistant Director for Budget Analysis.

VI. Application of Law to the Legislative Branch

The committee has determined that there is no impact of this law on the Legislative Branch.

VII. Regulatory Impact Statement

In accordance with paragraph 11(b) of rule XXVI of the Standing Rules of the Senate, the committee has determined that there will be minimal increases in the regulatory burden imposed by this bill.

VIII. Section-by-Section Analysis

Section 1. Short title

"Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act of 2005".

Section 2. Purpose

The purpose of the bill is to reduce rates of preterm labor and delivery, to promote the use of evidence-based care for pregnant women at risk of preterm labor and for infants born preterm, and to reduce infant mortality and disabilities caused by prematurity.

Section 3. Expansion of Federal research related to preterm labor and delivery and the care, treatment, and outcomes of preterm and low birthweight infants

This section authorizes the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to expand, intensify and coordinate research related to prematurity. This section authorizes three existing networks at the NIH: the Maternal-Fetal Medicine Units Network, the Neonatal Research Units Network, and the Genomics and Proteomics Network for Premature Birth Research.

This section asks the CDC to conduct studies on the relationship between prematurity and birth defects and developmental disabilities. It asks the CDC to collect additional information such as maternal and infant clinical/medical information to link with their existing Pregnancy Risk Assessment Monitoring System (PRAMS) to track pregnancy outcomes and prevent preterm birth.

This section asks the Secretary of Health and Human Services to assess other relevant tools, systems, surveys, etc. to ensure that they include information related to some of the known risk factors of low birth weight and preterm birth.

This section authorizes a total of $13 million for each of fiscal years 2007 through 2011, of which $3 million each year is authorized to carry out the requirements under the Pregnancy Risk Assessment Monitoring Survey (PRAMS).

Section 4. Public and health care provider education and support service grants

This section authorizes the awarding of grants to public or private non-profit entities for demonstration projects to improve the provision of information on prematurity to health care providers and the public to improve the treatment and outcomes for babies born prematurely. It is one grant program that can be used to fund programs to test and evaluate strategies to provide information and education to health care providers and the public related to prematurity; to improve treatments and outcomes for babies born prematurely; and to respond to the informational needs of families during the stay of a preterm infant in a neonatal intensive care unit, during the transition of the infant home, and in the event of a newborn death.

This section authorizes $5 million for each of fiscal years 2007 through 2011.

Section 5. Interagency Coordinating Council on Prematurity and Low Birthweight

This section authorizes the existing Interagency Coordinating Council on Prematurity and Low Birthweight at the Department of Health and Human Services. The Council is to include (and does include now) representatives of the Department of Health and Human Services agencies that conduct prematurity-related activities. The Council is to report annually to the Secretary of Health and Human Services and Congress on current activities related to prematurity. The Council is to oversee the coordination of the implementation of this act.

Section 6. Surgeon General's Conference on Preterm Birth

This section requires the Secretary of Health and Human Services, acting through the Surgeon General, to hold a conference on preterm birth within 1 year of enactment of this act. With the goal of increasing awareness of preterm birth, the conference will review findings and reports issued by the Interagency Coordinating Council, key stakeholders, and any other relevant entity. The conference will establish an agenda for activities in both public and private sectors that will speed the identification of, and treatments for, the causes of preterm labor and delivery. The agenda will be reported to Congress.

This section authorizes $1 million.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing

law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

IN GENERAL

SEC. 301. (a) * * *

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(d) * * *

(e) the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand, intensify, and coordinate the activities of the Centers for Disease Control and Prevention with respect to preterm labor and delivery and infant mortality.

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SEC. [399O] *399P* GRANTS TO FOSTER PUBLIC HEALTH RESPONSES TO DOMESTIC VIOLENCE, DATING VIOLENCE, SEXUAL ASSAULT, AND STALKING.

(A) AUTHORITY TO AWARD GRANTS.—* * *

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SEC. 399Q. PUBLIC AND HEALTH CARE PROVIDER EDUCATION AND SUPPORT SERVICES.

(a) IN GENERAL.—The Secretary, directly or through the awarding of grants to public or private nonprofit entities, may conduct demonstration projects to improve the provision of information on prematurity to health professionals and other health care providers and the public and to improve the treatment and outcomes for babies born preterm.

(b) ACTIVITIES.—Activities to be carried out under the demonstration project under subsection (a) may include the establishment of programs—

(1) to test and evaluate various strategies to provide information and education to health professionals, other health care providers, and the public concerning—

(A) the signs of preterm labor, updated as new research results become available;

(B) the screening for and the treating of infections;

(C) counseling on optimal weight and good nutrition, including folic acid;

(D) smoking cessation education and counseling;

(E) stress management; and

(F) appropriate prenatal care;

(2) to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of

preterm labor or other serious complications and for infants born preterm and at a low birthweight; and

(3) to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death.

(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $5,000,000 for each of fiscal years 2007 through 2011.

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TITLE IV—NATIONAL RESEARCH INSTITUTES

PART A—NATIONAL INSTITUTES OF HEALTH

ORGANIZATION OF THE NATIONAL INSTITUTES OF HEALTH

SEC. 401. * * *

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

APPOINTMENT AND AUTHORITY OF THE DIRECTORS OF THE NATIONAL RESEARCH INSTITUTES

SEC. 405. * * *

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SEC. 409J. EXPANSION AND COORDINATION OF RESEARCH RELATING TO PRETERM LABOR AND DELIVERY AND INFANT MORTALITY.

(a) IN GENERAL.—The Secretary, acting through the Director of NIH, shall expand, intensify, and coordinate the activities of the National Institutes of Health with respect to research on the causes of preterm labor and delivery, infant mortality, and improving the care and treatment of preterm and low birthweight infants.

(b) AUTHORIZATION OF RESEARCH NETWORKS.—There shall be established within the National Institutes of Health a multi-center clinical program (that shall be initially established utilizing existing networks) designed to—

(1) investigate problems in clinical obstetrics, particularly those related to prevention of low birth weight, prematurity, and medical problems of pregnancy.

(2) improve the care and outcomes of neonates, especially very-low-birth weight infants; and

(3) enhance the understanding of DNA and proteins as they relate to the underlying processes that lead to preterm birth to aid in formulating more effective interventions to prevent preterm birth.

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