Written Testimony
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Before the
Committee on Energy and Commerce, Subcommittee on Health
United States House of Representatives
"Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early"
May 12, 2010

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss with you the public health crisis of premature birth. On behalf of the 3 million volunteers and 1400 staff members of the March of Dimes, I want to thank Chairman Pallone, Ranking Member Shimkus, and all of the other Subcommittee Members who are interested in working on reducing the rates of preterm birth and infant mortality.

As you know, the March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to support research and services related to polio. Today, the Foundation works to improve the health of women, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education and advocacy. The March of Dimes is a unique partnership of scientists, clinicians, parents, members of the business community and other volunteers affiliated with 51 chapters and 213 divisions in every state, the District of Columbia and Puerto Rico. Additionally, in 1998, March of Dimes established its Global Programs to extend its mission overseas through partnerships with countries to deliver interventions directed at reducing birth defects and preterm birth.

Building upon our experience with population based initiatives, in 2003 the March of Dimes officially launched a National Prematurity Campaign to address the growing, costly and serious problem of infants who are born before 37 completed weeks gestation. Working with our partners in the private sector, the U.S. Congress and two Administrations, we are beginning to make tangible progress. In 2006, we worked with Representative Eshoo and many other members of this Subcommittee to gain enactment of the PREEMIE Act (P.L. 109-450). Among the results of the PREEMIE Act were the 2008 Surgeon General's Conference on Preterm Birth and expanded research activities at the Centers for Disease Control and Prevention (CDC).

The most notable accomplishment is a slight—3 percent—decline in the preterm birth rate from 2007 to 2008[1] (see Addendum A). But there is still much work to be done. We must build on progress to date and use both public and private efforts to accelerate this decrease in the rate of preterm birth. More than half a million will be born preterm this year and some 28,000 babies will die before they turn 1-year old.[2] The incidence of preterm birth represents a giant disconnect between our scientific knowledge and our capacity to meet basic and critical needs in maternal-

[1] Brady E. Hamilton, Joyce A. Martin and Stephanie J. Ventural."Births: Preliminary Data for 2008," *National Vital Statistics Reports* 58:16 (April 2010): 5.
[2] T.J. Mathews and Marian F. MacDorman. "Infant Mortality Statistics from the 2006 Period Linked Birth/Infant Death Data," *National Vital Statistics Reports* 58:17 (April 2010): 5.

child health. According to CDC, babies who died from preterm birth-related causes accounted for more than 36 percent of infant deaths in 2006.[3] For newborns, prematurity is the leading cause of death.

Causes

Decades of research funded by the National Institutes of Health, the March of Dimes and others have resulted in better care and outcomes for the sickest and smallest preterm babies, but primary prevention of prematurity remains elusive. We know that there are many factors that increase the risk of preterm birth. Perhaps the most important is smoking. Yet, in the United States today about one in five women of child bearing age smokes[4], and the incidence is far higher in many states. Alcohol, drug use, and chronic stress remain major risk factors for prematurity as well.

An additional factor contributing to the high preterm birth rate is the increasing problem of multiple births primarily due to assisted reproductive technologies and the use of fertility drugs. Fertility drugs are used to stimulate a woman's ovaries to increase the maturity and production of eggs. This causes a high percentage of multiple births. According to a study published in the American Journal of Epidemiology by authors from the Centers for Disease Control and Prevention (CDC) and the March of Dimes,[5] controlled ovarian hyperstimulation (COH) drugs account for four times more live births than assisted reproductive technologies (ART) such as in vitro fertilization. The study found that 4.6 percent of live births in 2005 resulted from fertility drug use – a figure four times higher than the 1.2 percent of births resulting from ART.

Approximately 88,000 babies born preterm annually are multiple births.[6] About 60 percent of twins, more than 90 percent of triplets, and virtually all quadruplets and higher-order multiples are born prematurely compared to 11 percent of singleton births. In addition to the increased risks associated with multiple birth, studies have also suggested that even infants born singly, but conceived with ART,[7] are at increased risk for preterm delivery than naturally-conceived single births. Present practices and voluntary professional guidelines have not been sufficient to date to limit this problem.

But in the last decade, with changing obstetric practices, we have recognized a new risk factor for preterm birth, iatrogenic prematurity caused by non-medically indicated early induction and cesarean delivery. A study published by the March of Dimes Perinatal Data Center found that 71 percent of all preterm births fall into the "late preterm" category, meaning 34-36 weeks gestation,[8] and that Cesarean sections account for nearly all (92 percent) of the increase in U.S.

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[3] T.J. Mathews and Marian F. MacDorman."Infant Mortality Statistics from the 2006 Period Linked Birth/Infant Death Data," *National Vital Statistics Reports* 58:17 (April 2010): 11.

[4] Centers for Disease Control and Prevention. 2008 Behavioral Risk Factor Surveillance System.

[5] Laura A. Schieve, Owen Devine, Coleen A. Boyle, Joann R. Petrini, and Lee Warner. "Estimation of the Contribution of Non–Assisted Reproductive Technology Ovulation Stimulation Fertility Treatments to US Singleton and Multiple Births," *American Journal of Epidemiology*, 1 December 2009; 170: 1396-1407

[6] National Center for Health Statistics, 2006 final natality data.

[7] Laura A. Schieve, Cynthia Ferre, Herbert B.Peterson, Maurizio Macaluso, Meredith A. Reynolds, and Victoria C. Wright. "Perinatal outcome among singleton infants conceived through assisted reproductive technology in the United States" *Obstetrics & Gynecology*: 103(6):1144-1153, June 2004.

[8] Davidoff MJ, Dias T, Damus K, Russell R, Bettegowda VR, Dolan S, Schwarz RH, Green NS, Petrini J. Changes in the gestational age distribution among U.S. singleton births: impact on rates of late preterm birth, 1992 to 2002. *Semin Perinatol* 2006;30(1):8-15.

singleton preterm births between 1996 and 2004.[9] The rise in elective inductions and cesarean deliveries before term is the result of a number of factors:

- Inaccurate gestational dating
- Changing culture of obstetrical practice—more interventionist
- Few evidence-based interventions after 34 weeks
- Mal-aligned incentives of health care insurance/delivery systems
- Litigious environment, defensive medicine
- Elective inductions/c-sections for convenience—both professional and patient

Consequences

For those babies born preterm that survive because of excellent care and intervention, early and fragile births are a major cause of devastating consequences such as a higher rate of birth defects, autism, learning disabilities, chronic health problems. In fact, about 25 percent of extremely preterm infants are significantly and negatively affected.[10]

More specifically, acute consequences of prematurity include:

- Respiratory Distress Syndrome
- Cardiovascular Function
- Fluid and Electrolyte Balance
- Jaundice
- Nutrition and Growth
- Infection
- Necrotizing Enterocolitis
- Intraventricular Hemorrhage and Periventricular Leukomalacia

While long-term ramifications include:

- Chronic Respiratory Problems
- Re-hospitalization
- Neurodevelopmental Problems
- Cerebral Palsy
- Cognitive Deficits
- Hearing and Vision Impairment
- Autistic Symptomatology

The complications of being born even four to six weeks premature are also significant, since one third of brain growth and development occurs in the last five weeks of pregnancy (see Addendum B). Late preterm infants, born just four to six weeks early, are more likely than term infants to have significant long-term deficits such as school learning problems, disabilities, and lower rates of college education and lower net salaries.[11,12]

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[9] Bettegowda VR, Dias T, Davidoff MJ, Damus K, Callaghan WM, Petrini JR. The relationship between cesarean delivery and gestational age among US singleton births. *Clin Perinatol* 2008;35(2):309-23.

[10] Nicholas S. Wood, Neil Marlow, Kate Costeloe, Alan T. Gibson, and Andrew R. Wilkinson. "Neurologic and developmental disability after extremely preterm birth," *New England Journal of Medicine* 2000;343:378-84.

[11] Steven Benjamin Morse, Hao Zheng, Yiwei Tang, and Jeffrey Roth. "Early School-Age Outcomes of Late Preterm Infants," *Pediatrics* Apr 2009; 123: e622 - e629.

More specifically effects may include:

- Mortality
- Low Apgar scores (depression at birth)
- Respiratory distress, including respiratory failure
- NICU admission
- Hypoglycemia
- Feeding problems
- Temperature instability
- Apnea
- Hyperbilirubinemia (Jaundice)
- Sudden Infant Death (SIDS)
- Learning & behavior problems
- Hospital readmission

Costs

A report issued by the Institute of Medicine in 2006 found that the annual societal economic costs—medical, educational, and lost productivity—associated with preterm birth were at least $26.2 billion[13] (see Addendum C).

An analysis by Thomson Reuters for the March of Dimes found that in private plans offered by large employers, 2007 medical costs for healthy full-term babies from birth to their first birthday averaged $4500, of which more than $3,800 was paid by employers. For premature and/or low birthweight babies, the average cost was nearly $50,000, of which more than $46,000 was borne by the employer's health plan. Families' out of pocket expenses were substantial and significantly higher for premature/LBW infants. The analysis also found that, on average, premature infants spent more than 14 days in the hospital before their first birthday, compared to just over 2 days for healthy, full-term infants and that preterm babies averaged more than 21 outpatient medical visits compared to just 14 for full-term infants.[14]

When combined, infant and maternity costs for a premature infant were four times as high as those for an infant born without any complications, $64,713 and $15,047 respectively, with employer health plans paying over 90 percent of those costs. A separate analysis showed that maternity care costs for complicated deliveries, independent of the infant's status and costs, were also significantly higher than the costs for uncomplicated deliveries: $14,667 compared to $10,652[15] (see Addendum D).

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[12] Karolina Lindström, Birger Winbladh, Bengt Haglund, and Anders Hjern."Preterm Infants as Young Adults: A Swedish National Cohort Study," *Pediatrics*, Jul 2007; 120: 70 - 77.

[13] Institute of Medicine, *Preterm Birth: Causes, Consequences and Prevention* .(Washington, DC: National Academies Press, 2007), 398.

[14] Thomson Reuters. The Cost of Prematurity and Complicated Deliveries to U.S. Employers. Report prepared for the March of Dimes. October 29, 2008.

[15] IBID

In addition, Medicaid is a principal source of health insurance coverage for preterm infants. Approximately 48 percent of hospital stays for preterm infants were financed by Medicaid in 2007, with hospital costs for these babies averaging $45,900.[16]

March of Dimes Prematurity Campaign

In January of 2003, the March of Dimes launched its National Prematurity Campaign with the messages that prematurity is common, serious, and costly and having two goals:

(1) to reduce the rate of premature birth; and
(2) to raise awareness of the seriousness of prematurity in women of childbearing age and the general public.

The Campaign has been was extended to 2020 and now includes a global component. The March of Dimes released the first-ever white paper on international impact of prematurity in which it was reported that approximately 12.9 million babies are born preterm every year (9.6 percent) and an estimated 28 percent of the four million annual neonatal deaths worldwide are due to preterm birth.

March of Dimes Interventions

In the last seven years, the March of Dimes has developed a multi-pronged strategy to combat the incidence of prematurity which includes a robust portfolio of research, education and programs designed to unveil the causes, comfort families in need and address risk factors and racial disparities. The Foundation has awarded $18 million in grants through its Prematurity Research Initiative to improve understanding of the etiology of preterm birth by identifying genetic variations that play key roles in the timing of spontaneous term and preterm delivery, looking for genetic differences between African-American women who gave birth preterm and those who did not to gain understanding in ethnic disparities in preterm birth, developing a medical treatment that can delay or prevent preterm labor by studying the physical properties of the uterine muscle, and identifying obscure and elusive bacteria and other microbes that may cause preterm labor.

In direct support of families, the March of Dimes created the NICU Family Support® project. Currently operational in over 100 hospitals across the country, the program provides comfort and information to families, offers professional development to NICU staff and promotes family-centered care. An additional resource is found online at www.shareyourstory.org. This virtual community, along with the hospital sites, reaches more than 125,000 families each year.

March of Dimes also provides professional educational opportunities for nurses and doctors, an informational Web site supplemented by social media, and a free workplace health promotion program for businesses called *Healthy Babies | Healthy Business*. This program offers education to women to better support healthy pregnancies and newborn care. To date, over 330 companies and organizations have signed on, making it available to some 20 million employees nationwide.

[16] Agency for Healthcare Research and Quality, 2009. March of Dimes HCUPnet tabulations using the 2007 Nationwide Inpatient sample. http://hcupnet.ahrq.gov (October 16, 2009).

The March of Dimes is also funding some innovative interventions including CenteringPregnancy®, a model of group prenatal care that combines assessment, health education, and social support. In 2009, the Foundation awarded $1.27 million in funding to 60 programs offered in 31 states at community health centers, hospitals and public health clinics. This group prenatal care program has contributed to a reduction in the number of c-sections (from 28 percent to 21 percent), preterm births (from 8.3 percent to 1.8 percent), and low-birthweight babies (from 8.3 percent to 2.65 percent). Centering pregnancy has also resulted in improved rates of breastfeeding initiation, psychosocial function, and patient satisfaction.

Three years ago, the March of Dimes launched, in collaboration with the State of Kentucky Department for Public Health and Johnson & Johnson, a project to address "preventable" preterm births in three target regions in Kentucky. The project focused on consumer awareness and education, health literacy in the context of prenatal care, community outreach, professional education, public health interventions, clinical interventions in the prenatal period, and quality improvement as well as safety strategies. Preliminary findings from the project show positive results in reducing preterm births and moderating cesarean sections.

In 2009, the March of Dimes convened a two day Symposium on Quality Improvement to Prevent Prematurity where 300 of the foremost experts developed recommendations for future research, policy development and professional action. The Symposium recommendations included: treating prematurity as a public health problem to which quality improvement strategies can be applied, considering medical, social and environmental contexts; improving national and state vital statistics data collection; developing more evidence-based interventions with a better science base; creating universal access to high quality health care throughout the life cycle; adopting a systems approach to sustain improvement; understanding medical culture and changing it where necessary by educating the public and professionals; and engaging employers and insurers in prevention efforts.

Examples of Other Effective Interventions

In recent years, the NICHD has made a major commitment to increasing our understanding of the factors that result in premature birth and to developing strategies to prolong pregnancy. One clinical trial reported a promising preventive intervention for recurrence of preterm birth that relies on a derivative of the hormone progesterone. The incidence of preterm labor and delivery among women who had a previous preterm birth was reduced by over 30 percent in subjects receiving weekly injections of the compound (17P) compared to the women who were given a placebo. A 2005 study to examine the potential impact of this new therapy found nearly 10,000 preterm births could have been prevented in 2002 if all pregnant women at high risk for a premature baby and eligible for weekly injections of a derivative of the hormone progesterone had received them.[17] This drug is currently awaiting approval by the Food and Drug Administration.

Preconception care also continues to improve birth outcomes by addressing the singular and combined factors that affect them – smoking, insufficient folic acid, alcohol consumption,

[17] Joann R. Petrini, William M. Callaghan, Mark Klebanoff, Nancy S. Green, Eve M. Lackritz, Jennifer L. Howse, Richard H. Schwarz, and Karla Damus., "Estimated Effect of 17 Alpha-Hydroxyprogesterone Caproate on Preterm Birth in the United States," *Obstetrics & Gynecology 105(2):*267-272, February 2005..

mental health issues, closely spaced births, genetic risks, obesity, and chronic medical conditions. The American College of Obstetricians and Gynecologists recommends that preconception care include a thorough and systematic identification of risks, the provision of education to fit the individual's need, and the initiation of desired interventions[18] to affect positive influences on a broad spectrum of outcomes including maternal health, preterm birth, birth defects, developmental disabilities, and infant mortality.

There have been several effective interventions to decrease preterm birth through comprehensive quality improvement strategies. Intermountain Health system in Utah initiated prospective review of all elective inductions and c-sections prior to 39 weeks gestation that resulted in a dramatic decrease in early term and late preterm births, c-sections, NICU admissions, and length of stay for mother and baby.[19] At Parkland Hospital in Dallas, universal access to culturally sensitive comprehensive perinatal services over the past 15 years that includes high quality evidence based care with accountability and continuous quality improvement review processes has resulted in the lowest rates of preterm birth among African Americans and Indigent Hispanic populations in the U. S.[20]

Recommendations for the Subcommittee

As significant as we believe the March of Dimes Campaign and other private sector activities to be, success in reducing the incidence of preterm birth and infant mortality requires an ongoing commitment from the federal government as well. Today's recommendations from the March of Dimes focus on reauthorization of the PREEMIE Act (P.L. 109-450). In addition, but outside the scope of this hearing, there are a number of other issues, including improved access to health coverage and quality of care that are essential to families coping with the risk and reality of preterm birth.

In 2006, the Foundation was pleased to work Congress and the Administration to secure unanimous approval of the PREEMIE Act (P.L. 109-450). This initiative authorized funding to expand research, surveillance and a few targeted projects to investigate and prevent the causes of preterm birth. The authorization for these activities expires at the end of fiscal year 2011, but the need for support of these efforts continues. **Therefore, it is imperative that Congress reauthorize the PREEMIE Act to support expanded research, education and demonstration projects whose aim is to help reduce the rates of preterm labor and delivery.**

Enumerated below are our suggestions for the reauthorization bill and are drawn from the recommendations of the Surgeon General's Conference and the Institute of Medicine Report.

First, a recommendation included in the IOM report and reaffirmed by participants in the Surgeon General's Conference, calls upon the National Institutes of Health (NIH) to **establish trans-disciplinary research centers for prematurity**. The purpose of these Centers would be

[18] American College of Obstetricians and Gynecologists. Preconceptional Care: Technical Bulletin #205, 1995; and Primary and Preventive Care: Periodic Assessments, Committee Opinion #246, 2000.

[19] Bryan T. Oshiro, Erick Henry, Janie Wilson, D. Ware Branch, Michael W. Varner, and B.T. Oshiro. "Decreasing elective deliveries before 39 weeks of gestation in an integrated health care system," *Obstetrics and Gynecology 113(4)*:804-811, April 2009.

[20] Kenneth J. Leveno, Donald D. McIntire, Steven L. Bloom, Miriam R Sibley, and Ron J. Anderson. "Decreased preterm births in an Inner-City Public Hospital." *Obstetrics & Gynecology. 113(3):*578-584, March 2009

to enhance understanding of the etiology of preterm birth using a collaborative approach. Trans-disciplinary Centers integrate the expertise of a wide range of basic and social scientists as well as other professionals who work collaboratively to develop and use shared conceptual frameworks to synthesize and extend discipline-specific theories, concepts, and methods to create new approaches to address complex problems like prematurity. These centers would focus primarily on basic and translational research and would progress logically over time to include the need for interventional and clinical research. To accomplish their goal, the centers would benefit from close association or affiliation with other NIH-funded centers focused on clinical trials. Finally, the March of Dimes will be asking Members of the Appropriations Committee to provide new funding to plan and operate these centers.

To further the robust research agenda established by the **Centers for Disease Control and Prevention Division of Reproductive Health, the Foundation recommends reauthorizing and expanding on the preterm birth portfolio,** including: (1) understanding the clinical, biological, social, genetic and behavioral factors relating to prematurity; (2) improving national data to facilitate tracking the burden of preterm birth; (3) developing, implementing and evaluating novel methods for prevention to better understand the growing problem of late preterm birth; (4) causes of early preterm birth; (5) racial and ethnic disparities and effectiveness of community based interventions.

To stimulate more consistent collaboration among HHS agencies and to better target resources to support promising research activities conducted under the auspices of various federal agencies, the 2006 PREEMIE Act called for the **establishment of the Interagency Coordinating Council (ICC) on Prematurity and Low Birthweight.** Unfortunately, four years later, the ICC has yet to be formally established. Moreover, the charter for the Secretary's Advisory Committee on Infant Mortality expired in 2007. We encourage Members of this Subcommittee to formally **authorize the Secretary's Advisory Committee on Infant Mortality, with specific reference to an ICC that has the authority to solicit advice and recommendations from non-governmental organizations with expertise and an interest in prematurity.** Activities for the Committee should include:

- Development of a consensus research plan on prematurity for HHS
- Regular reporting to the HHS Secretary and appropriate committees of Congress on current HHS activities relating to infant mortality, prematurity and low birth weight

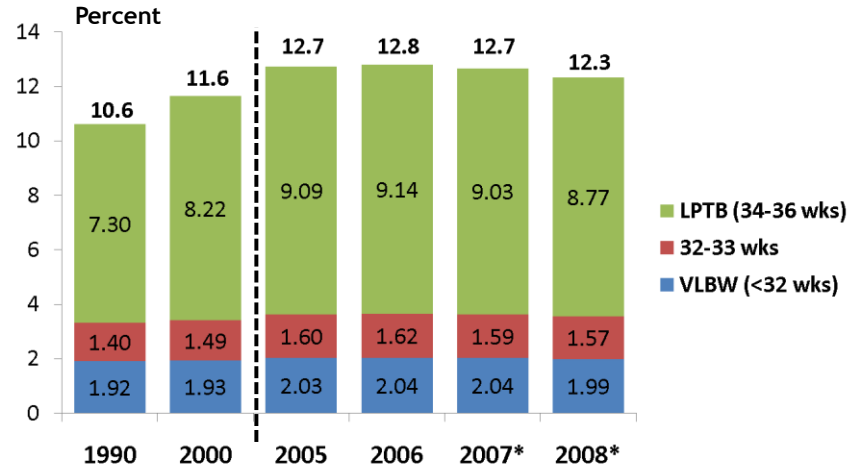
Additionally, the Foundation recommends that the **Health Resources and Services Administration be authorized to award demonstration project grants for the purpose of improving the dissemination of information on prematurity to health professionals and other health care providers and to the public.**

March of Dimes volunteers and staff look forward to working with Members of this Committee as well as with the Administration and our Prematurity Campaign Partners—the American College of Obstetrics and Gynecology, the American Academy of Pediatrics, and the Association of Women's Health, Obstetric and Neonatal Nurses—to accelerate the nation's efforts to solve this very serious problem. We hope you will agree to work with us to draft and obtain swift enactment of legislation reauthorizing and expanding upon the progress made as a result of the 2006 PREEMIE Act.

ADDENDUM

A) Preterm birth rates by gestational age-National Center for Health Statistics

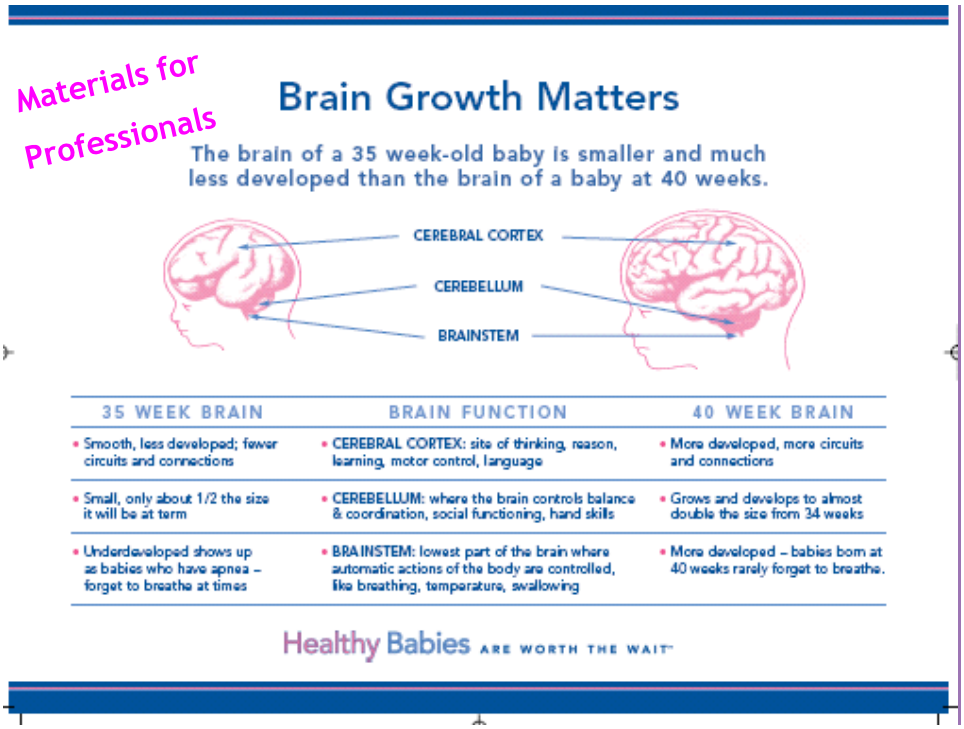
Preterm Birth Rates by Gestational Age
U. S., 1990, 2000, 2005, 2006, 2007*, 2008*



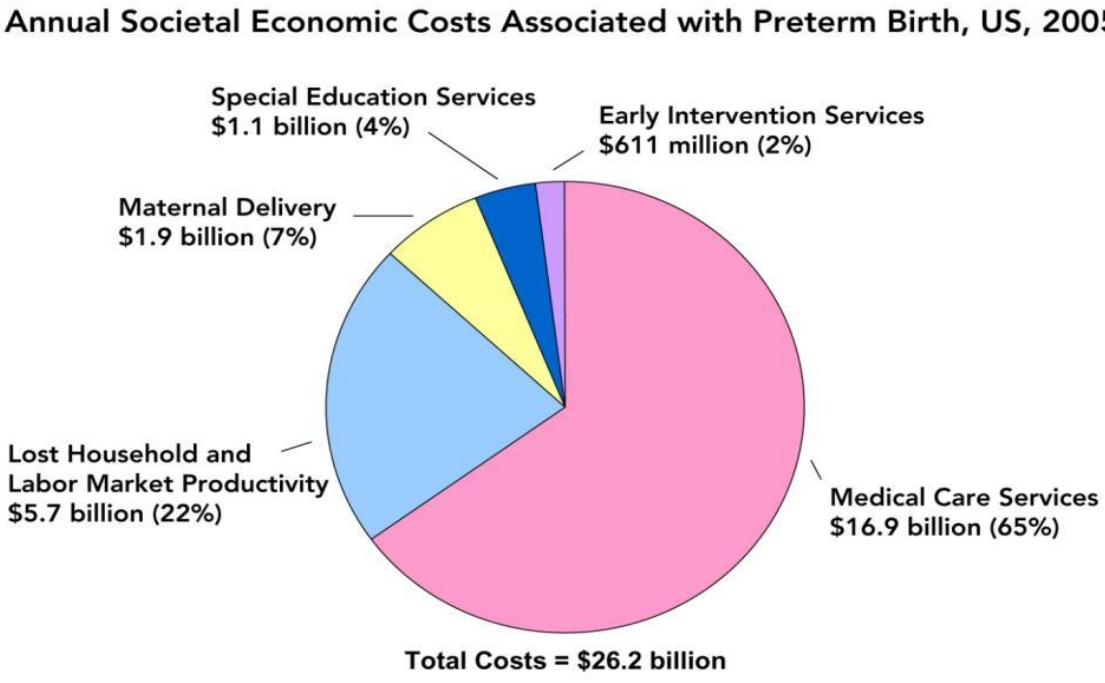
*premlinary

Source: National Vital Statistics Reports Vol. 58, Number 16 April 2010.

B) Late Preterm Birth and Effects on Brain Development March of Dimes Educational Materials



C) Annual Societal Costs Associated with Preterm Birth Institute of Medicine



Preterm is less than 37 completed weeks gestation.
Source: Institute of Medicine. 2006. Preterm Birth: Causes, Consequences, and Prevention. National Academy Press, Washington, D.C. Published and unpublished analyses.
Prepared by the March of Dimes Perinatal Data Center, 2006.

D) The Cost of Prematurity and Complicated Deliveries to U.S. Employers Thompson Reuters