

PREMATURITY AND INFANT MORTALITY: WHAT HAPPENS WHEN BABIES ARE BORN TOO EARLY?

HEARING
BEFORE THE
SUBCOMMITTEE ON HEALTH
OF THE
COMMITTEE ON ENERGY AND
COMMERCE
HOUSE OF REPRESENTATIVES
ONE HUNDRED ELEVENTH CONGRESS
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**PREMATURITY AND INFANT MORTALITY:
WHAT HAPPENS WHEN BABIES ARE BORN
TOO EARLY?**

WEDNESDAY, MAY 12, 2010

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 3:05 p.m., in Room 2123 of the Rayburn House Office Building, Hon. Frank Pallone, Jr. [Chairman of the Subcommittee] presiding.

Members present: Representatives Pallone, Green, Capps, Schakowsky, Barrow, Christensen, Castor, Murphy of Connecticut, Braley, Shimkus, Whitfield, Pitts, Murphy of Pennsylvania, Burgess, Blackburn and Gingrey.

Staff present: Ruth Katz, Chief Public Health Counsel; Sarah Despres, Counsel; Jack Ebeler, Senior Advisor on Health Policy; Robert Clark, Policy Advisor; Stephen Cha, Professional Staff Member; Alvin Banks, Special Assistant; Allison Corr, Special Assistant; Camille Sealy, Fellow; Ryan Long, Minority Chief Counsel, Health; and Aarti Shah, Minority Counsel, Health.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. The meeting of the Health Subcommittee is called to order, and today we are having a hearing on "Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early." I will recognize myself for an opening statement initially.

The consequences of premature births and infant mortality, both the causes and consequences, need to be examined because this is an important but complicated public health issue for which much is still unknown. According to the Centers for Disease Control and Prevention, each year more than a half-million babies in the United States, or one in every eight, are born prematurely. This statistic is up 20 percent from 1990 and we are just starting to see a decline. Despite the recent decrease, preterm birth remains a pressing health issue which deserves ample attention as it is the greatest risk factor for infant mortality and contributes to a host of acute and chronic conditions.

While much advanced research has been conducted and continues today, researchers are still trying to understand why preterm labor occurs. However, we do know that there is a set of

factors that put women at higher risk of having a premature baby. Some known factors include carrying more than one baby, having a previous preterm birth, high blood pressure and diabetes. In addition, we know that there are also external factors that occur either alone or in combination with other individual characteristics, and these include age, race, poverty, marital status, stress, environmental chemicals and many others. I am interested to hear from our witnesses today how these factors intertwine and what we can do moving forward to limit their effects.

While not directly linked to prematurity, I am particularly interested to hear today about the prevalence of stillbirths and sudden unexpected infant death, or SUID, within the infant mortality rate in the United States. Like preterm birth, stillbirth, there are some risk factors and causes such as maternal medical conditions, fetal factors, umbilical cord problems and placental abnormalities. However, despite these known risk factors, there is no known cause for as many as half of all stillbirths, leaving many parents without answers to the reasons for these deaths. No parent should have to endure the pain of losing a child, especially without knowing why that child was taken from them so soon.

And I have introduced a bill called the Stillbirth and SUID Prevention Education Awareness Act, which would improve data collection and education so we can better understand the cause of these deaths and help parents get the information and answers they want to prevent. The bill would also fund investigations to finally provide some answers by creating a national registry to help researchers understand the scope and impact of these tragedies. By understanding the causes of death, we can prevent these tragedies in the future, and we want every child to have the chance to grow up healthy.

In my opinion, infant mortality is a public health problem that needs the attention of the subcommittee, so I would like to thank all of our witnesses for being here today. I know other members have raised this. This is not a legislative hearing on my bill but an oversight hearing essentially to find more about these issues and to determine whether or not we should move forward with some legislation.

At this time I guess we will go to Mr. Whitfield. The gentleman from Kentucky is recognized.

OPENING STATEMENT OF HON. ED WHITFIELD, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF KENTUCKY

Mr. WHITFIELD. Well, Mr. Chairman, thank you very much, and I certainly want to thank the panel of witnesses for being here today on this very important subject.

As the chairman said, half a million babies are born preterm in the United States each year, and the Centers for Disease Controls states that preterm births are the greatest risk factor for infant mortality with over one-third of all infant deaths being attributed to preterm births, and according to the Institute of Medicine, there is no one cause of preterm birth, rather, there are socioeconomic, biological and environmental factors that all can lead to prematurity.

One area that I am particularly interested in and I think it is very important that we explore is the reporting methods used by different countries. I think it is important that we all have the same reporting standards so that we can really determine what the health statistics are as they relate to infant mortality. According to the CDC, in 2005, the latest year that the international ranking is available, the United States ranked 30th in the world in infant mortality behind most European countries, but there is not one consistent reporting standard for many of these countries and I do feel it is important that we establish a uniform standard.

I look forward to our witnesses today and the information that they will provide us, and I yield back the balance of my time.

Mr. PALLONE. Thank you, Mr. Whitfield.

Next is our vice chair, Ms. Capps, the gentlewoman from California.

OPENING STATEMENT OF HON. LOIS CAPPs, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mrs. CAPPs. Thank you, Chairman Pallone, for holding this extremely important hearing, to our witnesses for being here today, and to the fact that we have this bill being discussed. We have quite a few health professionals in the audience and we have a group on the Hill visiting of CARE, an international organization with very strong ties to this legislation as well.

Many people would just assume that the United States being as advanced as it is doesn't have significant infant mortality rates or that everyone has access to high-quality prenatal care, it is kind of a given, and that prevention of prematurity or other complications is not a serious situation. But the truth is, and that is why I am so thankful that we are having this hearing today, the United States lags far behind other industrialized nations in infant mortality rates, and I might add, maternal mortality rates as well.

So why is this happening in our country? First and foremost, we have a problem of access. Fortunately, we have now new health reform law which puts into place several measures that will improve the health of our mothers and of our infants. This will happen through eventually universal coverage, training of more health care providers, greater emphasis on prevention and wellness through grants and other incentives but there is always more than we can and should be doing to ensure safe pregnancies and safe babies.

For example, I was proud to join in the recent Capitol Hill launch of a new service called Text for Baby, and this is done with the Congressional Caucus for Women's Issues, and Text for Baby is a new, free mobile health information service designed to promote maternal and child health among underserved populations through simple text messaging, and I plan in my Congressional district to find a way to allow some of my constituents to see this program demonstrated, and I hope that we will see more programs like this to get funded through the new mandatory spending which are put in place for prevention and wellness.

The other important need is to better gather data and conduct further research so that we can develop a more coordinated and comprehensive strategy. I am proud to cosponsor two important pieces of legislation that do address infant health research and

education. One is the Birth Defects Prevention, Risk Reduction and Awareness Act, and this is sponsored by Rosa DeLauro, and then there is also your own bill, Mr. Chairman, SID prevention, Stillbirth and SUID Prevention Education and Awareness Act, sponsored by Chairman Frank Pallone. Having a healthy pregnancy and a healthy baby shouldn't be determined by the color of your skin, where you live or how much money you earn.

I am eager to hear from our witnesses today to see what steps we can take to reduce infant mortality and morbidity for all families in the United States. I pledge my continued support to make pregnancy and childbirth safe and healthy for all moms and their newborns, and I yield back.

Mr. PALLONE. I thank the gentlewoman.

The gentleman from Pennsylvania, Mr. Pitts.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. Thank you, Mr. Chairman.

As we will hear, prematurity is the number one risk factor in infant mortality, and preterm birth rate in the United States has been on the rise for the past few decades. Not only is the potential for mortality a risk for preterm infant but these babies could also face a wide range of health problems, some lifelong, such as breathing and respiratory problems, vision problems, increased susceptibility to infection and intellectual disabilities, to name a few.

While we do not know precisely why more babies are being born preterm, one thing we do know is that we need medical professionals to care for women and their babies throughout pregnancy, and this brings us to the issue of medical liability. One of our witnesses on the second panel, Dr. Hal Lawrence, is here representing the American College of Obstetricians and Gynecologists, or ACOG. ACOG's 2009 survey on professional liability sought to determine how medical liability legislation and medical liability insurance issues affect the practices of its members. Some of the survey's statistics and conclusions are astounding. This comes from the survey's executive summary: "Of the survey respondents who reported making changes to their obstetric practice because of insurance portability or availability or both, 19½ percent reported increasing the number of Cesarean deliveries. Additionally, 21.4 percent decreased the number of high-risk obstetric patients, 10.4 percent decreased the number of total deliveries and 6.5 percent stopped practicing obstetrics altogether." When survey respondents were asked about making changes to their obstetric practice as a result of the risk or fear of professional liability claims or litigation, here were the results: 30.2 percent decreased the number of high-risk obstetric patients, 29.1 percent reported increasing the number of Cesarean deliveries, an additional 13.9 percent decreased the number of total deliveries and 8 percent stopped practicing obstetrics altogether.

Over my years in Congress, I have heard from multiple OB/GYNs who due to medical liability climate could no longer afford to practice in Pennsylvania and were either retiring early, no longer delivering babies or moving their practices to nearby Dela-

ware. In just the city of Philadelphia and four surrounding counties in southeastern Pennsylvania, where I am from, 18 hospitals have closed their maternity wards since 1997, and a 19th will end obstetric services next month. Since 2001, southeastern Pennsylvania has lost 30 percent of its practicing obstetricians, and according to the chief of obstetrics at Hahnemann Hospital, Dr. Owen Montgomery, Lloyds of London calls southeastern Pennsylvania the worst liability market in the world.

Medical liability is a serious problem with direct consequences for patients, particularly for mothers and their unborn children, and in recently passed health care law, what did we do to ameliorate this situation? We funded state demonstration projects on medical liability. We have already had two large and quite successful demonstration projects on this issue. Their names are California and Texas. We don't need more studies. What we need is real reform, and in this case the new health care reform law does not deliver.

I yield back.

Mr. PALLONE. I thank the gentleman.

Next is the gentleman from Texas, Mr. Green.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman, for holding the hearing today on infant mortality.

According to the CDC, the United States ranks 28th among developed countries in infant mortality with 6.9 deaths per 1,000 live births. Among the leading causes of infant mortality in the United States, birth defects, preterm birth, low birth weight, sudden infant death syndrome and respiratory distress syndrome, preterm birth and low birth weight are the only factors that haven't declined. According to the March of Dimes, who we will hear from today, insurance plans for large employers paid an average of \$64,713 to cover the cost of inpatient and outpatient medical care and prescriptions for one preterm newborn and mother. That figure doesn't include the cost of potential re-hospitalization and long-term care and services. The Agency for Health Care and Research and Quality estimated in 2005 that on a national scale private insurance and Medicaid each paid about \$7.4 billion to cover preterm infants' inpatient hospital charges.

In Texas, Medicaid covers about half of all births annually. The Texas Health and Human Service Commission reports Texas Medicaid spent \$408 million in 2007 on hospital costs associated with preterm births. Texas and our district in particular still leads the Nation in percentage of uninsured residents. Texas also has the third highest rate of births to teen mothers nationally at 63.1 per 1,000. From 1990 to 2006, CDC National Center for Health Statistics showed the rate of preterm birth in Texas increased 22 percent from 11.2 percent of live births in 1990 to 13.7 percent in 2006. The State saw a slight decrease from 2006, a 1 percent decrease from 2006–2007. In Texas, 18.7 percent of live births to African American women are preterm compared to 12.7 percent for Anglo women, 13.3 percent for Hispanic women and 11.3 percent for Asian women.

One cause that has been pointed to as a potential cause of preterm birth is induced or cesarean births at 34 to 36 weeks due to a miscalculation in the gestational age of the baby. At the Tex Med Conference in 2009, the Texas Medical Association and House of Delegates adopted a recommendation to support the prevention of preterm births caused by delivering a baby early by physicians and others who attend at the delivery of infants. The recommendation presented by the TMA's committee on maternal and prenatal health grew out of the March of Dimes' concern that some premature births may occur without good medical justification such as request or convenience of the mother or because of incorrect calculation of the gestational age of the fetus. I am hoping the witnesses today will address this topic.

Again, I want to thank all our witnesses for being here and appreciate the time, Mr. Chairman.

Mr. PALLONE. Thank you, Mr. Green.

Our ranking member, Mr. Shimkus.

Mr. SHIMKUS. First of all, Mr. Chairman, thank you. I am going to ask unanimous consent that all opening statements are going to be submitted for the record. We have got competing hearings, and I am not sure everyone is going to be able to make it up.

Mr. PALLONE. Without objection, so ordered.

Mr. SHIMKUS. I also want to apologize for not being here punctually. The Appropriations Committee is dealing with some testimony. Kristin Fitzgerald, who testified before our committee, whose husband—

Mr. PALLONE. Well, I was told you were here before me.

Mr. SHIMKUS. I was, but then I left. So that is my apology.

The last thing. I want it on the record, we asked for someone to testify on the second panel, a Republican witness. They did not get their testimony in on time. I have been very hard on the Administration for not getting their testimony in on time so I asked the chairman to disinvite the Republican member of the second panel, which we ended up doing, and I think that is appropriate and I just want to take all the burden—

Mr. PALLONE. It is going to make it harder for me. I am going to have to make sure the Administration witnesses are on time now.

OPENING STATEMENT OF HON. JOHN SHIMKUS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. SHIMKUS. You have to lead by example. That is the key, Mr. Chairman.

Thank you, Mr. Chairman. Any time a child a born is special. Although preemie births make it challenging, I have been able, just like many members, to go through hospitals and see great facilities that are doing all they can to save the lives of premature babies. We have passed the PREEMIE Act a couple years ago, and so hence the analysis of data and the follow-up that is occurring here.

We do have issues with making sure—no one is going to dispute that we are not as good as we could be in this country. We want to make sure we are comparing apples to apples versus apples to oranges, and I do this in other committees. In Telecom, I hate it when we are compared to Liechtenstein on broadband access. So

we just make sure that when we want to compare apples to apples, we are doing—other countries may not consider a live birth what we consider a live birth, and so let us throw that out there and just get clear data so if we are going to do some comparisons, we are going to do some comparisons.

As always, I also want to make sure that as ranking member I continue to stay on record calling for additional hearings on the health care law. We just had a CBO report out this week. It says oh, we made a mistake, there is \$110 billion in additional costs. That is all part of that calculation that we were told that this was going to save money. So we know that those stats were not correct. We think it is time to start talking about this and we think it is time, especially on this issue, the Medicaid issue for the poor, as we add 18 million more people to the Medicaid rolls without funding, who gets left out? And I think the very people we are talking about today, the poor mothers with no care. Because what docs will do, in Illinois we are \$12.5 billion in debt. Medicaid is paying 30 cents on the dollar 280 days late. Thirty cents on the dollar, 280 days late. And the doctors who are servicing Medicaid patients, some are just writing it off and some are going to start limiting that access to care, and this is the issue that has also been raised by the Administration and Secretary Sebelius when she said we need more docs, we need more primary care physicians, and guess what? This health care law does nothing to address more providers. So we will continue the clarion call to say let us have some hearings on the law.

I am going to end with this. An individual who recently served in my staff left and went to Colorado and now has been working in the private sector. She sent me an e-mail, and as a direct result of the passage of this health care law, her insurance company folded. Her child, who had a preexisting condition, now has no coverage. As a direct result of this law, she cannot purchase insurance for her family because of a child with a preexisting condition. Now, folks, that is something we can fix. We can have a hearing today. We can draft legislative language tomorrow and we can move it to the floor next week. Why do we accept a gap in this period of time when we are allowing folks to not have coverage based on pre-existing conditions when we were promised that that would not be the case?

So Mr. Chairman, hopefully you will raise this issue to the full committee chairman. I know he is busy down in the Oversight and Investigation hearing. But we will continue to say I think it is time to start talking about the effects of this health care law, and I yield back my time.

Mr. PALLONE. Thank you.

The gentlewoman from Illinois, Ms. Schakowsky.

Ms. SCHAKOWSKY. Thank you.

First, at the request of our Energy and Commerce Committee colleague, Jay Inslee, I ask unanimous consent to enter into the record a statement from Seattle Children's Hospital.

[The information follows:]

Committee on Energy and Commerce
Subcommittee on Health

Hearing on May 12, 2010

“Prematurity and Infant Mortality:
What Happens When Babies are Born Too Early?”

Written Testimony Submitted by
Craig E. Rubens, MD, PhD
Executive Director of GAPPS, an initiative of Seattle Children’s

Prematurity impacts half a million families throughout our country every year, and is a leading cause of infant mortality. Babies born before 37 completed weeks of pregnancy have increased risks for infections, cerebral palsy, and respiratory, vision, hearing, and developmental problems. U.S. rates have risen by about a third since 1981 and significant racial and ethnic disparities persist.

A large discrepancy also exists between related costs and research: preterm birth is a leading U.S. health care expenditure (\$26B in 2005), yet perinatal health research ranks only 54th in NIH funding.

We commend the Chairman and Ranking Member for calling this hearing on prematurity. The first step in moving forward to reduce prematurity rates is awareness and open discussion. GAPPS recommends three essential actions that Congress could take now to address prematurity and the associated consequences and costs.

About GAPPS, an initiative of Seattle Children’s

Seattle Children’s hospital serves patients from four states: Washington, Alaska, Montana and Idaho. Between 40-49% of patients admitted to Seattle Children’s Neonatal Intensive Care Unit are born prematurely. Seattle Children’s identified prematurity as a research priority and, in 2007, launched the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS) to address these two devastating health problems. Prematurity and stillbirth share many common causes, and require interdisciplinary efforts to solve.

In February 2010, GAPPS published the *Global report on preterm birth & stillbirth: the foundation for innovative solutions and improved outcomes* with BioMedCentral Pregnancy and Childbirth (available at www.gapps.org/resources). This report provides a comprehensive assessment of what is known, what needs to be known and what can be done to improve pregnancy outcomes. It contains seven articles: (1) definitions, description of the burden and opportunities to improve data, (2) discovery science, (3) the effectiveness of interventions, (4) delivery of interventions, (5) advocacy barriers and opportunities, (6) ethical considerations, and (7) mobilizing resources to accelerate innovative solutions (Global Action Agenda).

The Global Action Agenda was developed by more than 200 stakeholders who attended the 2009 GAPPS International Conference on Prematurity and Stillbirth, which was co-convened with the Bill & Melinda Gates Foundation, March of Dimes, PATH, Save the

Children, UNICEF, and the World Health Organization. The Action Agenda is a comprehensive set of recommendations that include short-, intermediate- and long-term milestones, and success metrics. Most of the milestones are set to be achieved by 2015

Below are the key findings from the report and recommendations from the Action Agenda.

Commonly known causes of preterm birth

Causes or Pathway	Typical Gestational Age
Intrauterine infection Genital infection Systematic infection	Early preterm birth (24-32 weeks)
Excessive bleeding Early placental separation Autoimmune syndromes	Early or late preterm birth
Stress	Late preterm birth (32-26 weeks)
Multiple fetuses (such as twins) Excess amniotic fluid	Late preterm birth

Evidence-based interventions for preterm birth

Interventions are strategies to diagnose, treat, and prevent preterm birth and related maternal, newborn, and child health problems. There are only two interventions that have been shown to prevent preterm birth, and 11 to improve survival and care of preterm newborns in low-resource settings. We must balance the research paradigm to address upstream, basic science to better understand causes and prevent preterm birth.

Only 2 interventions exist to prevent preterm birth

- Smoking cessation
- Progesterone

11 interventions exist to improve survival of preterm newborns

- Prophylactic steroids in preterm labor
- Antibiotics for preterm labor with premature rupture of membranes
- Delayed cord clamping
- Vitamin K supplementation at delivery
- Community management of neonatal sepsis and pneumonia (where facility referral is unavailable)
- Resuscitation with room air
- Hospital-based kangaroo mother care
- Early breastfeeding
- Thermal care to prevent hypothermia
- Surfactant therapy for respiratory distress syndrome

- Application of continued distending pressure to the lungs for respiratory distress syndrome

What must be done to reduce prematurity and infant mortality?

We can save lives and reduce prematurity, but we urgently need more action and resources to better understand the causes of prematurity, and to guide development of cost-effective interventions. For the first time ever, experts have agreed to a comprehensive, evidence-based approach to solving this complex health problem.

In the Global Action Agenda that was developed by more than 200 stakeholders at the 2009 International Conference on Prematurity and Stillbirth, global health leaders outlined collaborative strategies to achieve four key goals:

- *Increase awareness and understanding of the magnitude of the problem*
Many policymakers are unaware of the magnitude of the health problems caused by preterm birth, and their relationships to maternal, child and adult health. Others have been aware of the problem, but have not known what to do.
- *Close the research gaps*
The biology of pregnancy and childbirth is poorly understood, as are the causes of preterm birth and stillbirth. Additionally, it is difficult to calculate the magnitude of the problem as there are no global standards for data collection.
- *Support the discovery, development and delivery of interventions*
More research is needed to determine which interventions are most effective. Effective interventions that are already available in low-resource settings should be promoted for scale-up. Effective interventions that are only available in high-income countries should be adapted and evaluated for effectiveness in low-resource settings.
- *Increase resources for research and implementation*
Significant funding, commitment and a coordinated effort are needed to reduce preterm births.

Why we understand cancer better than pregnancy

Through a coordinated and focused research agenda led by the National Cancer Institute, scientists have made great strides in understanding and treating cancers. This has largely been accomplished through widespread collection and distribution of tumor specimens for research. Similarly, we need a coordinated and focused research effort to understand prematurity. As has been done for cancer, we need biobanks that collect maternal data linked to biological specimens (e.g., blood, urine, placental tissues) so that scientists can utilize the new tools of systems biology to understand normal and abnormal pregnancy outcomes. The tools to do this now exist and have led to exciting advances in cancer treatment and cures—but are barely being utilized for the study of prematurity.

What can congress do now?

Congress can invest in a national campaign to significantly reduce preterm births and infant mortalities in the United States. Three essential action items are outlined below.

1. Prioritize basic and translational science efforts on pregnancy, fetal development, and newborn health
2. Expand efforts to attract scientists to the fields of obstetrical and newborn research
3. Authorize a national campaign to develop national centers of excellence for the study of prematurity and infant mortality

One in eight babies is born too soon in the United States and, for the most part, we don't know why. We urgently need better data and tools, and more champions and resources.

We are grateful that the Committee on Energy and Commerce: Subcommittee on Health recognized the importance of prematurity in today's hearing. GAPPS is forging a collaborative effort toward achieving common goals to prevent preterm birth. We have a unique opportunity to move the prematurity agenda forward. We look forward to working with the Subcommittee to raise visibility for these critical issues in order to fuel investments, accelerate innovative research and interventions, and promote effective health policies that will improve maternal, newborn and child health.

Sincerely,



Craig E. Rubens
Executive Director
GAPPS, an initiative of Seattle Childrens

Mr. PALLONE. Without objection, so ordered.

**OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLI-
NOIS**

Ms. SCHAKOWSKY. Thank you.

The creation of the—oh, first let me say that fortunately the health care bill that we passed does allow for children with pre-existing conditions requires that they be eligible for health care and not be excluded.

The creation of the Millennium Development Goals has placed significant attention on maternal and infant mortality rates within the international community. The aim is to drastically reduce these rates by 2015, and we have made visible, albeit slow, progress toward these goals, but as we work with our international partners to reduce infant and maternal deaths in some of the most challenging places in the world, I am constantly reminded that we face a health disparities crisis right here at home. In fact, one out of eight U.S. babies is born prematurely.

Gwen Moore, our colleague and vice chair of the Congressional Caucus for Women's Issues, represents Milwaukee, Wisconsin, and she often talks about the absolutely abhorrent health disparities that are so evident in the infant and maternal mortality rates in her district. Thirty-three out of every 100,000 African American women died from pregnancy-related complications in 2006 compared to fewer than 10 among white women during that same period. There are studies showing that even when researchers control for socioeconomic factors, health risks like smoking or chronic disease and geographic locations, a poor white woman is more likely to have a healthy childbirth than a wealthy African American woman.

So most of our witnesses today have referenced this disparity and have pointed to reasons why these statistics might bear out the way that they do but what I am left with when looking at the collective testimony is that it doesn't seem that we really know why there is such a discrepancy in the rates of premature births, birth defects and infant mortality and maternal mortality across different populations. Is it an access to health care issue? Is it culture? Is it socioeconomic status or location or the number of children born to one mother? Why is it that African American women are 1-1/2 times more likely to deliver a preterm infant compared to a white woman? I hope we will get some of those answers today.

While I am concerned about the plateau that we seem to have hit in reducing infant mortality in this country in the 21st century, I do know that there is a lot of interest and a lot of collaboration aimed at bringing healthy pregnancies to healthy term. Congresswoman Capps mentioned a very interesting and innovative program, Text for Baby, which is a collaborative effort among the Department of Health and Human Services, White House Office on Science and Technology and seven major corporations, a public-private partnership to work with at-risk expecting moms. So you go to text baby, b-a-b-y or b-e-b-e, at 511411, and at-risk young women can receive text messages reminding them to schedule a

prenatal visit or get a flu shot or avoid drugs and alcohol, et cetera. One small step.

I look forward to hearing the testimony today and I yield back, and thank you, Mr. Chairman.

Mr. PALLONE. I thank the gentlewoman.

The gentleman from Pennsylvania, Mr. Murphy.

OPENING STATEMENT OF HON. TIM MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. MURPHY of Pennsylvania. Thank you, Mr. Chairman.

Years ago, before I ran for the State Senate, I practiced as a psychologist at Magee Women's Hospital in Pittsburgh and followed up infants in the newborn intensive care unit. There was a moment when I was seeing one of the babies there, very premature, very small, transparent skin, hooked up to all sorts of equipment, probably not much bigger than my hand, and another baby born addicted to crack cocaine, and I remember saying to the nurse, I have had enough of this, I can't put up with this anymore. She said well, are you going to run for office and change the system, and I said sure. So here I am. The system still has problems, and I want to point out how I hope the scope of this hearing actually expands so we can deal with these problems.

Some years ago when we looked at murder rates in this country as declining, people looked upon that as a reason either to give their community a pat on the back or a kick in the rear because their murder rates were either going up or down. One factor that was not computed into that was the access to paramedics and a critical-care hospital, which was making a difference in life and death and of course reducing rates of murder because some people didn't die. It is important that Congress at that time and this time does not misread statistics and we get accurate information on a number of things and that I suggest is not just mortality but long-term developmental outcome. It is extremely important. I hope this is something the witnesses can provide today with this.

We will take about a number of epidemiological issues and I hope we don't just caught up in which nation wins the contest of the lowest mortality rate because for me, that is not valid information at all. We need accurate information of what exactly happens. We need to know maternal factors, external factors. Is it income, education, family issues? Is it other factors such as maternal smoking, weight gain or loss, nutrition, drug use, age, trauma, complications during pregnancy, race? Are there medical issues we need to know about? Is it infection rates, prenatal care, access to level 3 nurseries, access to developmental intervention, levels of training of neonatologists, pediatricians, family physicians, schools, other educational institutions and statistical analysis to making sure that the definition of each one of these is the same between communities and between nations.

I might add this, that over the years of the children that I have seen born premature or very premature, it is interesting to me now as I go through in going back to visit communities and inevitably some parent will come up to me and introduce their child to me who I took care of and who is—when they were very, very young.

In many cases the child is successful, working, they introduce me to their own children. In addition to not making me feel so young when I see that happening, it also makes me very proud that when you surround people with good quality medical care and tertiary care, good NSU care, that is a very important factor.

I know the research I did on persistent pulmonary intervention in newborns, of all the factors we looked at, what was one of the most significant factors relating also to seizure disorders and infarcts and developmental outcome, had to do with where the child was cared for, how close they were to a level 3 nursery and not just the other medical care around. This is so extremely important. I want to make sure that any funding that Congress looks at or any change of policy directly addresses these issues. Rather than just saying let us throw money at this issue and make sure we have some there, let us make sure we are doing a critically good job, and I hope that the witnesses will provide this Congress with this information. We want to do it right but it is a matter of just doing more than comparing us to other nations.

With that, I yield back, Mr. Chairman.

Mr. PALLONE. Thank you.

The gentleman from Georgia, Mr. Barrow.

Mr. BARROW. I thank the Chair, but in the interest of the witnesses' time, I will waive an opening.

Mr. PALLONE. Thank you. The gentleman reserves.

The gentleman from Georgia, Mr. Gingrey.

OPENING STATEMENT OF HON. PHIL GINGREY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Mr. GINGREY. Mr. Chairman, thank you, and thank you for calling this hearing. Obviously as a physician member of the House, I am extremely interested in the subject, having practiced and delivered babies for 31 years.

You know, what concerns me most when I hear that CDC report going back to 2005 that ranks the United States 30th in the world in regard to infant mortality, which as we all know is the death of a child within the first year of life, and you start scratching your head and say well, how could that be when we spend two and a half times as much per capita on health care in this country, and clearly with all corrections that need to be done in making those comparisons, our prematurity rate and our infant mortality rate is too high and we should make every effort to do something about that, and I really look forward to both panels of witnesses today to help us understand how we can do that.

But when you compare our country to countries that count a death in the first 24 hours of life as a miscarriage essentially, that is not a fair comparison. Forty percent of premature infants in our country, many of them immature, born before 32 weeks, not just before 37 weeks, many of them are going to die in the first 24 hours of life, in fact 40 percent. So when some countries don't even count those as live births and others say well, you know—I think France does this—any child that is less than 500 grams is not considered a live birth or other countries that say any child that is less than 30 centimeters in length is not considered a live birth. We have got to as other colleagues have mentioned compare apples to

apples to get a true meaning and understanding, and I am not going to say these statistics were necessarily used to make a point that we need to have a universal health care system or single-payer system or pass the Senate bill 3590 that we did here just a month ago but let us use the right statistics. It is very important that we do that.

As we look at matters related to obstetric and pediatric care, I think we should not overlook the need to enact meaningful tort reform to help address a shortage of OB/GYN providers in markets all across the country. I believe that Republicans and Democrats together can work on this issue, one that I think most Americans support.

And Mr. Chairman, I want to make one last point. I realize my time is up. But I want to welcome Dr. Lawrence from the American College of OB/GYN, who is going to be on the second panel. Dr. Lawrence as a practicing OB/GYN for more than 30 years, I am interested in hearing more about your MOMS Initiative. It is my hope that efforts like yours might improve both maternal and infant health in our country, and I would like to find out ways that we can work together in this area.

Thank you, Mr. Chairman, and with that I will yield back.

Mr. PALLONE. Thank you, Mr. Gingrey.

Next is the gentleman from Connecticut, Mr. Murphy.

OPENING STATEMENT OF HON. CHRISTOPHER S. MURPHY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CONNECTICUT

Mr. MURPHY of Connecticut. Thank you, Mr. Chairman, for calling this hearing today.

I recently met with a constituent of mine, Arnold Goodman of Avon, Connecticut, whose wife died during childbirth, and he explained to me the causes of maternal mortality such as multiple Cesarean sections, increased age and obesity that are also risk factors for premature birth. He told me that the gaps in the research and the lack of uniform reporting that perpetuate both maternal mortality and premature birth and infant mortality still persist, so I am interested here today in learning more about the fact that maternal mortality and prematurity rates are on the rise, the connections between the two and what we can do on both of those issues, and just as Mr. Shimkus is, I am also interested in the issue of access to maternal and pediatric care for expectant mothers. I have no doubt that the health care reform bill that extends coverage to millions of women across this country is going to be able to link them up with the care that they have not had previous to today, but I also share Representative Shimkus's concern about the rates that are paid under the Medicaid program and would just remind this committee that at one time this Congress had in place a system by which the federal government oversaw both the rates for OB care and for pediatric care called the Born amendment. That amendment was stripped out of the law in 1997, and in the House version of the bill, we put back in that federal oversight over obstetric rates and pediatric rates, and I would be happy to work on a bipartisan basis to try to put back into place some of the lost oversight that the federal government has had to make sure that

States do the right thing when it comes to obstetric and pediatric rates. That issue of access to care is made much, much better by the health care bill but can be made even stronger with strong federal oversight over Medicaid rates.

I am thrilled that the panel is here. I am very eager to hear your testimony and again thankful for the opportunity to listen.

Mr. PALLONE. Thank you.

The gentlewoman from Tennessee, Mrs. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Mr. Chairman, and welcome to our witnesses. I want to thank you for the hearing.

In my district, Memphis, Tennessee, has one of the highest prematurity and infant mortality rates in the entire Nation, and it is a stat that impacts our neighborhoods, our State, and we know the impact it has here in our country. Too many mothers around the country just do not have, those young mothers don't have the information that they need and the educational resources that they need to keep their babies healthy. And DHS has stated that children of mothers who receive no prenatal care are three times more likely to be born at a low birth weight and five times more likely to die than those who are born to moms that get that necessary prenatal care.

And earlier this year, the Commercial Appeal, which is the Memphis newspaper, reported that premature birth and low birth weight are the biggest causes of those infant deaths in Memphis, Tennessee. So we are watching those numbers very closely. And since my days in the State Senate, this is an area where we have watched this very closely. Indeed, Congressman Cohen and I had legislation last year, had a resolution focused on our concern with this infant mortality rate. We have some great work that is being done in our State to address this. The Porterly Children's Hospital, the March of Dimes, University of Memphis and Memphis city schools all have programs, so we have got a partnership that we are doing in the public not-for-profit sector to help improve this rate. We have also got the UT Health Sciences Center that has a grant, a \$1.7 million grant that they are working to expand the Blues Project, hoping to reduce those rates, and we are focusing that on our TennCare eligible moms.

So welcome. We are pleased to have you with us today. We look forward to your testimony, and I look forward to working with you on this issue and I yield back, Mr. Chairman.

Mr. PALLONE. Thank you.

Next is the gentlewoman from Florida, Ms. Castor. I should mention that Ms. Castor has done quite a bit of work on this prematurity and infant mortality bill and also asked that we have a hearing on this subject.

OPENING STATEMENT OF HON. KATHY CASTOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Ms. CASTOR. Well, thank you, Chairman Pallone, very much for today's hearing so we can address infant prematurity and mortality

and some of my specific concerns about the rising rates of elective preterm Cesarean deliveries in the United States, and thank you for inviting Dr. Charles Mahan from the University of South Florida, the founder of the Lawton and Rhea Chiles Center for Healthy Mothers and Babies. I am honored that he is here today. I would also like to extend a special welcome to Dr. Fleischman, everyone at the March of Dimes and from the American College of Obstetricians and Gynecologists.

The overriding message for pregnant mothers and families and health providers in the United States has got to be taking babies fully to term, to that 39 weeks, 40 weeks unless there is an intervening medical reason. Researchers at the National Center for Health Statistics just reported this week that the high rate of premature births is the primary reason that the United States has a higher infant mortality rate than other industrialized nations. Preterm births are linked to neurodevelopmental disorders and developmental delays. Let us face it, brain development is the key to success for babies, when they are young and even into their adult years.

Many premature babies grow up healthy but sadly many do not. Some need lifelong constant care and have health problems throughout their lives. Although the National Center reported this week that preterm births have slightly declined in the United States, the rates are still way too high and the rates of preterm and low birth weight babies in my home State of Florida are much higher and of great concern. Even with all the great advances in science, technology, medicine, too many babies are born prematurely and there are disturbing racial disparities we must address. Nationally, the preterm birth rate is 12.3 percent. In my home State of Florida, it is nearly 14 percent. The March of Dimes gave Florida an F grade on its 2009 premature birth report card, so I am committed to working with you to bring that grade up.

And the Cesarean rate has risen across the country to 32 percent of all births as of 2008, and one factor in preterm births may be this rising rate of elective C-sections. In Florida, the C-section rate is even higher, accounting for roughly 38 percent of all childbirths, and they think that in Dade County, Miami, we are approaching 50 percent now where the World Health Organization said it really should be half of that. Elective C-sections prior to 39 weeks really put babies at risk, so we need to understand these troubling numbers. The data displaying the rise in C-sections is clear and speculation about the potential overuse of these surgeries is strong. The New York Times has featured several articles over the past 6 to 7 months reporting that late preterm births are the fastest growing subgroup of premature births. Cesareans have become the most common surgery in American hospitals, and ACOG has recognized that the surgery is overused, and the March of Dimes reports that C-sections accounted for 92 percent of all preterm births in the United States from 1996 to 2004.

So I would really like to hear from our witnesses about this. I think we need more data and research, so I am looking forward to your testimony and the input of my colleagues moving forward. Thank you.

Mr. PALLONE. Thank you.

The gentlewoman from the Virgin Islands, Ms. Christensen.
 Mrs. CHRISTENSEN. Thank you, Mr. Chair. In the interest of time, I am going to submit my statement for the record.
 [The information was unavailable at the time of printing.]
 Mr. PALLONE. And Mr. Braley, the gentleman from Iowa.

**OPENING STATEMENT OF HON. BRUCE L. BRALEY, A
 REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA**

Mr. BRALEY. Thank you, Mr. Chairman, for holding this hearing on premature and infant mortality. It is important that we examine the many risk factors and variables that relate to these tragedies.

In Iowa, five mothers who each lost a daughter to stillbirth or infant death got together in 2003 and founded Healthy Birthday, a nonprofit organization dedicated to preventing stillbirths and infant deaths through education, advocacy and parent support. This group of friends including State Representative Janet Peterson launched the Count the Kicks campaign in June of 2009, which is a public health and awareness effort to improve pregnancy outcomes. This campaign is supported by the March of Dimes Iowa chapter and seeks to reduce the number of preventable stillbirths by teaching expectant parents how to self-monitor their babies' movements and about the importance of tracking daily movements during the third trimester of pregnancy. Less than a year after the campaign's launch, 55 percent of OB/GYN clinics in Iowa and 56 percent of the birthing hospitals had begun using the program. Research has shown that this type of education and awareness is very effective.

A 2009 study conducted in Norway reported an overall decrease in stillbirth rate by one-third when patients were educated on monitoring fetal movements. If the United States achieved the same level of success, we could save more than 8,000 babies every year. With one out of every 150 pregnancies ending in stillbirth in the United States, it is hard to understand why this issue hasn't gotten more attention, but I believe that expanded awareness and education should be an integral part of efforts to reduce stillbirths.

I commend Chairman Pallone for introducing the Stillbirth and SUID Prevention, Education and Awareness Act. This bill will improve the health of children, enhance public health activities related to stillbirth and reduce the occurrence of infant death. I am proud to be a cosponsor of this bill and I encourage other members of the committee to support the bill, and I yield back the balance of my time.

Mr. PALLONE. Thank you, and I think that concludes our opening statements by the members of the subcommittee, so we will turn to our witnesses. I want to welcome you. Let me introduce our first panel. On my left is Dr. William Callaghan, who is the senior scientist for Maternal and Infant Health Branch, Division of Reproductive Health, the National Centers for Chronic Disease Prevention and Health Promotion of the Centers for Disease Control and Prevention. And then we have Dr. Catherine Spong, who is the branch chief for the National Institute of Child Health and Human Development of the National Institutes of Health. The drill is 5-minute opening statements, and they become part of the record and

then we may—well, you actually on your own discretion if you like can submit additional statements in writing afterwards, but if you would start, Dr. Callaghan. We appreciate your being here.

STATEMENTS OF WILLIAM CALLAGHAN, MD, MPH, SENIOR SCIENTIST, MATERNAL AND INFANT HEALTH BRANCH, DIVISION OF REPRODUCTIVE HEALTH, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION; AND CATHERINE SPONG, MD, BRANCH CHIEF, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, NATIONAL INSTITUTES OF HEALTH

STATEMENT OF WILLIAM CALLAGHAN

Dr. CALLAGHAN. Mr. Chairman, Mr. Shimkus and distinguished members of the subcommittee, thank you for the opportunity to participate in this hearing on preterm birth and infant mortality. I am Dr. William Callaghan, acting chief, Maternal and Infant Health Branch in the Division of Reproductive Health, the Centers for Disease Control and Prevention. I am also board certified in obstetrics and gynecology. Prior to making the transition to public health in 2001, I spent 14 years in private practice caring for thousands of women during their pregnancies. Today I will briefly outline the burden of disease in the United States due to preterm birth and summarize our current and continuing surveillance and research activities.

Preterm birth is defined as being born at less than 37 weeks, that is, at least 3 weeks before the predicted due date for the pregnancy. Today, more than half a million babies are born preterm each year in the United States. Although a CDC report released yesterday shows a very welcome and small decline in the preterm birth rate for 2007 and 2008 down to 12.3 percent, levels still remain higher than at any point in the 1980s and 1990s. Most of the increase prior to this recent decline was among late preterm births, and those are births from 34 to 36 weeks of gestation.

Preterm birth is an important risk for infant mortality. More than one-third of infant deaths can be directly attributed to preterm birth. Preterm birth and infant mortality are particularly critical issues in the African American community. African American women are one and a half times more likely to deliver a preterm infant compared to white women, and the infant mortality rate for black infants is more than twice that of white infants. We also need to think beyond infant mortality when we discuss prematurity. Preterm birth is the leading cause of disability in children. Moreover, in 2005 it was estimated the costs associated with preterm birth were \$26.2 billion.

At CDC, our work addresses preterm delivery through three basic mechanisms: surveillance, research and building public health capacity. Surveillance is the core of CDC's work. We monitor how many infants are born prematurely, analyze trends and define risk factors. There are several important surveillance systems that we use. The first is through collection of birth certificates and death certificates by the National Center for Health Statistics. The national statistics for prematurity rates are compiled from informa-

tion on birth certificates. When birth certificate information is linked to information on death certificates, we are able to look at the causes of death for those babies who died during their first year of life.

CDC's second largest surveillance system on maternal and infant health is called PRAMS, the pregnancy risk assessment monitoring system. PRAMS is an ongoing state-specific surveillance system designed to identify and monitor maternal behaviors and experiences before, during and after pregnancy among women who had live births. PRAMS has served to expand the information capacity of 37 States and New York City and this unique surveillance system is now representative of approximately 75 percent of all births in the United States. CDC also provides resources to assist States in conducting surveillance of major birth defects, which are important causes of infant mortality.

In terms of research, we are working with partners to try to understand some of the biology among women who delivered preterm. These studies focus on the interactions among genes, other biologic markers, race and ethnicity, and social and economic exposures for women. We really don't know a lot about why late preterm births increased and drove the overall preterm birth rate during the last several decades. We are currently involved in a study to review hospital medical records in order to discover why and how late preterm births occur. In the area of capacity building, CDC has 23 federal staff assigned to State health departments providing technical support for epidemiological research, public health surveillance and State-based programs.

As we move forward, we will be investigating how the quality of surveillance information can be improved and how we can use it to inform programs and public health practice. A society measures what it values, and we will strive to improve the core public health function of surveillance. As new ideas emerge about the reasons for and predictors of preterm birth and about possible prevention interventions, we will continue to synthesize evidence and attempt to fill in knowledge gaps through research. We will continue to press forward with our work in the area of understanding late preterm birth as this group continues to comprise the largest proportion of preterm births. As we learn more about causes and prevention, we anticipate the result will be more healthy babies and healthy families.

Thank you for the opportunity to speak today, and I would be happy to answer questions.

[The prepared statement of Dr. Callaghan follows:]



**Testimony before the
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives**

**Prematurity and Infant Mortality: What Happens
When Babies Are Born Too Early?"**

*Statement of
William M. Callaghan, MD, MPH
Acting Chief, Maternal and Infant Health Branch
Division of Reproductive Health
National Center for Chronic Disease Prevention and Health
Promotion
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U.S. Department of Health and Human Services*



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For Release on Delivery
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Introduction

Mr. Chairman, Mr. Shimkus, and distinguished members of the Subcommittee, thank you for the opportunity to participate in this hearing. I am Dr. William Callaghan, Acting Chief of the Maternal and Infant Health Branch in the Division of Reproductive Health, Centers for Disease Control and Prevention (CDC), an agency of the Department of Health and Human Services (HHS). I am also board certified in obstetrics and gynecology and general preventive medicine. Prior to making the transition to public health in 2001, I spent 14 years caring for thousands of women during their pregnancies. I am pleased to be here today to participate in discussions of the challenges around the issues of preterm birth and infant mortality. It is difficult to speak about infant mortality without also speaking about preterm birth. However, as I hope to make clear, preterm birth carries risks over and above the risk of infant death and hence, it is one of the most important health issues facing women, children, and families in America today. I will briefly outline the burden of disease in the nation due to preterm birth and summarize current prevention and research activities and challenges. I will close with outlining plans for continuing activities as we work together to decrease the burden of preterm birth and infant mortality.

Background

Preterm birth is defined as being born at less than 37 weeks gestation, that is, at least three weeks before the predicted due date for the pregnancy. Throughout the 1990s and the early years of the 21st century, preterm births have steadily increased from just over 9 percent of all births in the early 1980s peaking at nearly 13 percent in 2006. Now, more than a half a million babies are born preterm each year in the United States.¹ Healthy People, a science-based, 10-year set of national objectives for promoting health and preventing disease, includes an objective to reduce pre-term births. The Healthy People 2010 Midcourse Review found that pre-term births between 32-36 weeks of gestation and less than 37 weeks of gestation moved away from their target improvement goals. The rate for pre-term births at less than 32 weeks of gestation did not change by the time of the Midcourse Review. The objective to reduce pre-term births will also be included in

Healthy People 2020 which will be launched in Fall 2010. Although a recent CDC report shows a welcome small decline in the preterm birth rate for 2007 and 2008, levels remain higher than at any point in the 1980s and 1990s. Most of this increase has been among late preterm births (34 - 36 weeks).² Many factors have likely contributed to the rise in the late preterm birth rate. One factor may be that the way pregnancy is managed has changed over this period, that is, there may be a lower threshold to induce labor or deliver by cesarean section at 34 - 36 weeks of gestation in recent times. While such intervention is often necessary for the health of both the mother and her infant, little is known about how case-by-case decisions regarding interventions are made.

Preterm birth is an important risk for mortality and short- and long-term disease and disability. Two-thirds of the approximately 28,000 infants who die each year are born preterm, although we cannot always say that being preterm was the direct cause of death. However, even when we use conservative assumptions from death certificate information, more than one-third of infant deaths can be directly attributed to preterm birth; more infants die as a direct result of being born too early than of any other cause.³ This preterm-associated risk is strongly related to how far into pregnancy the birth occurs. Those babies born at the early limits of living outside their mothers' wombs have a poor chance of surviving the first year, and these smallest and earliest babies, while accounting for only two percent of all births, bear the greatest mortality risk.⁴ Little progress has been made in reducing infant mortality in recent years and little progress has been made in reducing the fraction of births at the earliest gestations (less than 32 weeks gestation). Moreover, approximately eight percent of preterm births or about 40,000 preterm births also have a major birth defect.⁵ Until we can reduce the occurrence of preterm birth and major birth defects, it will be very difficult to see any dramatic reduction in the U.S. infant mortality rate.

The issue of preterm birth as it relates to infant mortality is at crisis proportions for African Americans. African-American women are one and one-half times more likely to deliver a preterm infant compared to white women; they are more than twice as likely to deliver a very preterm infant (less than 32 weeks gestation) compared to white

women.¹The infant mortality rate for black infants is more than twice that of white infants,² and the infant mortality rate due to major birth defects is approximately 40 percent higher in African Americans than in non-Hispanic white women.⁶

The death of an infant is a tragedy. Deaths are relatively easy to measure. Hence, we put a lot of emphasis on the outcome of infant mortality. However, while most infant deaths have at least an association with being born preterm, most preterm infants do not die. One reason for this is the great strides that have been made in the intensive care of these smallest of newborns. Another reason, not wholly unrelated, is that most preterm infants are born at the high end of the preterm gestational age range, i.e., late preterm. Although these infants have a higher infant mortality rate than term infants, deaths during the first year of life are much lower than those born earlier in pregnancy. Hence, we need to think beyond infant mortality when we discuss prematurity as a public health problem. Preterm birth is a leading cause of neurological disability, such as cerebral palsy and intellectual disabilities, in children. It can also result in blindness and chronic lung problems.⁷ We are only now beginning to understand the lifelong impact that being born too small and too early has on the individual and their families. Premature births exact a huge financial toll on our healthcare resources – in 2005 it was estimated that medical care, early intervention services, special education services and lost productivity associated with preterm birth cost \$26.2 billion.⁷ There is also an emotional toll. Taken together, it is clear that preterm delivery is a public health priority.

During my years as a practicing obstetrician, all too often my patients and I were faced with the unexpected situation of preterm delivery. Although women who have pre-existing medical conditions such as hypertension or who have pregnancies with impaired fetal growth are at risk for early delivery because of concerns for the health of the mother or fetus, it is difficult to predict the spontaneous occurrence of preterm labor. Women who had a preterm birth in the past are a notable exception. Weekly injections of 17-hydroxyprogesterone caproate (17-P) have been shown to reduce the risk of preterm birth among women who had a preterm birth in the past,⁸ and this treatment is important in this subgroup of women. The estimated reduction in the preterm birth rate from universal

usage of this medication in the United States has been estimated to be about two percent,⁷ and it is important that this treatment be used for women who had a prior preterm birth. However treatment alone with 17-P will not eliminate preterm births. Hence, we are left with unacceptably high rates of death and disability due to preterm birth. It is clear that solutions to the challenge of preterm delivery must come through better understanding of causes and applying that understanding to develop effective interventions.

Current Research and Challenges

Preterm birth is not a new challenge and it has not gone unaddressed. We must continue working toward the goal of predicting preterm birth and developing rational interventions to prevent it. At CDC, our work addresses preterm delivery by monitoring trends, sponsoring and conducting research and sponsoring programs, all of which attempt to address the social and biomedical factors that affect preterm risk. We achieve this through three basic mechanisms: surveillance, research, and capacity-building of states and communities.

Surveillance:

Surveillance is the core of CDC's work; we monitor how many infants are born prematurely, analyze trends, define risk factors, and target prevention programs, based on these data and analyses. Surveillance is our early warning system. It tells us if there is a new emerging health threat and if our programs are effective. There are several important surveillance systems that we use.

The first is through collection of birth certificates and death certificates by CDC's National Center for Health Statistics (NCHS). For prematurity, this is the backbone of health surveillance – all of the national statistics for prematurity rates are compiled from information on the birth certificate. We are also able to use birth certificate information to evaluate factors such as mother's education, tobacco use, race, and the infant's birthweight. It allows us to follow trends, risk factors, and identify variations in rates of preterm births at the state and county levels. When birth certificate information is linked to information on death certificates, we are able to look at causes of death for those

babies who died during their first year of life. Using data from this linked file, we were able to demonstrate the strong relationship between preterm birth and infant mortality. Each year, NCHS reports in detail on preterm birth rates across the country and on “preterm-related” infant mortality, and released new data on this earlier this week.

CDC has on-going projects to evaluate and improve the quality of the data from these new systems, but support to develop effective training for hospital personnel to thoroughly and accurately report gestational age and other vital statistics information is needed. CDC has also conceived a project to develop standards and pilot studies for the collection of selected vital records data such as gestational age via the use of the new electronic health records; we expect that this new approach will greatly enhance the timeliness and quality of gestational age data. The FY 2011 Budget requests additional resources to modernize vital records received from States and other jurisdictions to increase their timeliness and accuracy by implementing electronic birth registration, and phasing in electronic death registration through a 50-50 match. This will allow all states to have implemented EBRs or be in the process of developing by FY 2011. CDC’s second large surveillance system on maternal and infant health is called PRAMS – the Pregnancy Risk Assessment Monitoring System. PRAMS is an ongoing, state-specific, population-based surveillance system designed to identify and monitor selected maternal behaviors and experiences before, during, and after pregnancy. Through this system, we have been able to better understand issues such as prenatal care, folic acid to prevent birth defects, obesity, pregnancy weight gain, stressful life events, and physical abuse. For example, an analysis of PRAMS data showed that very low weight gain during pregnancy increases the risk of preterm birth, regardless of prepregnancy body mass index.¹⁰ PRAMS has served to expand the capacity of 37 states and New York City to define and address their health needs, and this unique surveillance system is now representative of approximately 75 percent of all births in the United States. It has provided vital information to program managers and decision-makers for development of policy and programs in maternal and infant health. For example, information from PRAMS is used in states as part of the criteria for distribution of Title V Maternal and Child Health block grants.

In addition, CDC provides resources to assist states in conducting surveillance of major birth defects, including the collection of data on the gestational age at delivery of infants with major birth defects. Data from the surveillance systems have allowed CDC to develop national prevalence estimates, study the association between preterm birth and major birth defects, and identify risk factors for birth defects including smoking in early pregnancy and pre-pregnancy obesity.

In addition to these large surveillance systems, CDC also uses more focused surveillance to address specific health issues. Under Congressional mandate, CDC collects and analyzes data from all clinics that use infertility treatment called ART or Assisted Reproductive Technology. We have identified how this technology is associated with elevated low birth weight and prematurity, but there is still much that we could learn through expanding this work. For example, linking ART surveillance data with birth and death files in states will provide a population-based database to examine maternal and infant health outcomes associated with this technology.¹¹ Although recent research has indicated that ART is not the primary driving force for preterm delivery in the U.S., it is important to continue to monitor its impact on preterm delivery. For example, we know that twins, triplets and higher order multiple births are at greater risk of delivering preterm, and ART surveillance data helps us understand how ART procedures contribute to increases in multiple births.

Research:

A complex array of factors interferes with healthy pregnancy outcomes and racial disparities. Decades of research at NIH suggests that treatment of infections may not be successful in preventing preterm delivery. Perhaps the body's inflammatory response to infection, and not the infection itself, is damaging to the pregnancy. There are damaging by-products of inflammation that spread throughout the body and result in increased risk of premature birth. We know that tobacco use and psychological stress from living in poor neighborhoods create the same damaging chemicals in the body as infection. The same inflammatory factors have been identified in heart disease.⁷ We are currently

working with partners to try to understand some of the biology associated with the inflammatory response among women who delivered early preterm. One focus of these investigations is to understand how variations in genes that govern the human inflammatory response might predispose to preterm birth, and how these variations interact with maternal race and ethnicity as well as social and economic exposures for the woman. Such lines of inquiry will likely generate more questions than answers, but they are questions that must be pursued if we are to make progress.

We know little about why late preterm births, births occurring between 34 and 36 weeks gestation, increased and drove the overall preterm birth rate during the last several decades. We are currently involved in a small study in metropolitan Atlanta to identify late preterm births and review the medical records of these women and infants in order to discover if it is feasible to expect that the answer as to why and how the birth occurred can be found in the medical records.

Public Health Capacity:

In the area of capacity-building, CDC has 23 federal staff assigned to state health departments, providing technical support for epidemiological research, public health surveillance, state-based programs, and one of the Indian Health Service's epidemiology centers.

Despite the complexities of preventing preterm delivery, there are ways we build public health capacity and act now. Tobacco use, for example, remains a significant preventable cause of low birth weight, preterm birth and of some major birth defects. CDC has responded by working with state health departments to assist with smoking cessation programs during pregnancy.

The Path Forward

We will continue to work with federal, state and academic partners to address the public health challenges of preterm birth and infant mortality. The information in vital statistics is the foundation for understanding where we are and measuring progress and we will be

investigating how the quality of that information can be improved and used to inform programs and public health practice. Along these lines, we will continue to enhance the capacity of states to use their vital statistics and PRAMS data for action. A society measures what it values, and we will strive to improve the core public health function of surveillance.

As new ideas emerge about the reasons for preterm birth, potential predictors and possible prevention interventions, we will continue to synthesize evidence and attempt to fill in knowledge gaps. Moreover, we will use our ability to convene partners in efforts to bring together the most recent thinking so that research and practice might be thoughtful and evidence-based. Although progress in improving preterm birth and infant mortality rates might not be as rapid as we would all hope, and racial disparities continue, bringing the best minds together to address these challenges is an important step forward.

We will continue to press forward with our work in the area of understanding late preterm birth, as this group continues comprise the largest proportion of preterm births. It is likely that this will involve new techniques such as qualitative research involving key informant interviews and focus groups to better understand how decisions are made regarding when and how delivery should occur.

Conclusion

Prevention of preterm birth is an important public health priority. Back in 1917, Dr. Grace Meigs who was in charge of the hygiene division for the Children's Bureau was tasked with investigating the reasons for high infant mortality rates. The findings of her investigation led her to conclude that the problem of infant mortality is inextricably tied to the health of women. We can say the same today, nearly a century later. As we learn more about causes and prevention, we hope the result will be more healthy babies and healthy families.

Thank you for the opportunity to speak to you about preterm birth. At this time, I would be happy to answer your questions.

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Mr. PALLONE. Thank you, Dr. Callaghan.
Dr. Spong.

STATEMENT OF CATHERINE SPONG

Dr. SPONG. On behalf of the Eunice Kennedy Shriver National Institute of Child Health and Human Development at the National Institutes of Health, I appreciate the opportunity to provide the committee with information about our research programs on preterm birth and infant mortality.

I am Dr. Catherine Spong, chief of the Pregnancy and Perinatology Branch at the NICHD. The NICHD mission is to ensure that every person is born healthy and wanted, that women suffer no adverse harmful effects from reproductive processes and that all children have the chance to achieve their full potential for healthy and productive lives free from disease or disability. As such, research on prematurity and its health outcomes falls squarely within the Institute's mission.

As we have heard from your opening statements and as Dr. Callaghan eloquently stated, preterm birth is a major public health problem. In 2001, preterm birth became the leading cause of death among newborns, and those who survive preterm birth account for one in five children with mental retardation, one of three children with vision impairment and almost half of all children with cerebral palsy. Late preterm infants appear to be at higher risk for sudden infant death syndrome and have higher rates of neurological and developmental morbidities during childhood. In adulthood, children born at low birth weight have an increased risk for cardiovascular disease such as heart attacks, strokes and hypertension and an increased risk for diabetes.

The NIH is committed to understanding the causes and to reducing the incidence of preterm birth, low birth weight and infant mortality and their consequences. The NICHD was the lead federal agency in planning and coordinating the surgeon general's conference on prematurity prevention held in June of 2008. As I will describe, NICHD preterm research efforts address these recommendations and range from basic work on the mechanisms of labor, genetics and proteomics to research regarding specific questions encountered in clinical practice and the long-term implications on the infant, mother and family.

While the NICHD supports the bulk of NIH research in this area, other institutes and centers also contribute to the overall NIH funding for infant mortality, low birth weight and prematurity research projects. This totaled \$278 million in fiscal year 2009 including ARRA funds, the last year for which we have complete data.

One of the most successful approaches for research related to prematurity are the NICHE research networks, which allow physicians and scientists across the country to coordinate their work and share data. The Maternal Fetal Medicine Units Network, composed of 14 sites across the country, conducts clinical studies to improve maternal, fetal and neonatal health. This network has a remarkable track record of conducting high-priority clinical trials with its findings incorporated into practice. The Neonatal Research Net-

work focuses on babies in neonatal intensive care units to improve their health and outcome.

The NICHD recently has funded a study on women in their first pregnancy, the Nulliparous Pregnancy Outcome Study. The best predictor of preterm birth, pregnancy outcome, is not available for these women yet they account for 40 percent of all deliveries each year. The aim of this large multicenter study is to identify markers early in pregnancy that will identify women at the highest risk for preterm birth, preeclampsia and stillbirth with the goal to ultimately develop interventions and therapies.

To understand the biologic mechanisms underlying spontaneous preterm births, the NICHD is supporting a wide range of research including intrauterine infection, bleeding and psychosocial stress. Another major emphasis is on preeclampsia as it is the primary reason for medically indicated preterm births. Research supported by NICHD has shown that this disease is associated with an abnormal development of the placenta. NICHD-supported research identified and highlighted the significant complications associated with late preterm births, those babies born between 34 and 37 weeks, that account for 70 percent of all preterm births, these supported practice guidelines affect changes in practice.

One aspect of research is to identify markers or predictors of preterm birth. A short cervical length is a predictive marker and was identified through NICHD research. In a blinded, multicenter observational study of women with a prior preterm birth, shortened cervical length in mid-pregnancy can predict early spontaneous preterm birth. This has led to screening for cervical length in women who are at risk for preterm delivery.

Ideally, the best outcome would be to prevent preterm birth in the first place. A major advance in prevention was made by the NICHD's Maternal Fetal Medicine Network studying women who have had a previous preterm delivery and therefore were at risk for a recurrent preterm birth. This trial compared progesterone to placebo, and progesterone treatment lowered the risk of preterm birth by one-third, the first successful preventative therapy to reduce the risk of recurrent preterm birth and improve neonatal outcomes. The impact of this treatment was evaluated in a 2005 study, which estimated that 10,000 preterm births could be prevented annually if all eligible pregnant women received progesterone. The American College of Obstetricians and Gynecologists has recommended the use of progesterone to prevent preterm birth for women with a prior spontaneous preterm birth.

In addition to studying preventative therapies, the MFMU Network studies interventions during pregnancy to prevent complications in preterm infants. Recently, the network identified a therapy, magnesium sulfate, or Epsom salts, which when administered to women who are at risk of delivering preterm, reduces the risk of cerebral palsy in surviving preterm infants by 45 percent.

The NICHD also supports research on how to manage and care for preterm infants. One example is nitric oxide, a compound that is used to treat infants with severe breathing problems, but the safety and efficacy for premature infants has had mixed results. To better understand the potential risks and benefits of inhaled nitric oxide therapy, the NIH will convene a consensus development con-

ference in October of this year to assess the available scientific evidence and form conclusions about its clinical use in preterm infants.

Both preterm infants and infant mortality have dramatic health disparities with higher overall rates in African American women. NICHD-supported researchers are attempting to identify the factors to explain these disparities, and in August of this year the NICHD will hold a scientific workshop focused on disparities in infant mortality, stillbirth and preterm birth.

Given the implications of preterm birth on long-term health and disease of the child and family and affecting over half a million pregnancies each year, preterm birth truly is a public health priority. Were we able to prevent preterm births, not only would infant mortality improve, we would actually improve the health of the Nation with less heart disease and diabetes in the children and healthier mothers and families. This is our goal.

Again, thanks to the committee for your time and interest, and I am pleased to answer any questions that you may have.

[The prepared statement of Dr. Spong follows:]

	<p>Testimony before the Subcommittee on Health Committee on Energy and Commerce United States House of Representatives</p>
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**Prematurity and Infant Mortality: What
Happens When Babies Are Born Too
Early?**

*Statement of
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U.S. Department of Health and Human Services*



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On behalf of the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) at the National Institutes of Health, I appreciate the opportunity to provide the Committee with information about our research program on preterm birth and related issues. I am Dr. Catherine Spong, Chief of the Pregnancy and Perinatology Branch at the NICHD. The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence and well-being of all people through optimal rehabilitation. As such, research on prematurity and its health outcomes falls squarely within the institute's mission.

Background

Preterm delivery is a major public health problem. The preterm birth rate in the U.S. is over 12 percent of all live births, accounting for over half a million premature births each year (1). Over the last two decades, preterm birth rates have risen approximately 30 percent. Concomitant with the rise in preterm births is a rise in multiple gestations, due in a large part to the increased use of assisted reproductive technologies. The number of twin births doubled between 1980 and 2006. (1).

In 2001, preterm birth is the leading cause of death in newborns who die within the first month. (2). It is the leading cause of death among African-American infants and the second leading cause of all infant mortality. In those who survive, 8 percent of all preterm births also have a major birth defect, and 16 percent of very preterm births (less than 32 weeks gestation) have a major birth defect: preterm birth accounts for one of five children with mental retardation, one of three children with vision impairment and almost half of children with cerebral palsy. In adulthood, children born at a low birth weight have an increased risk for cardiovascular disease such as myocardial infarction, stroke and hypertension, and an increased risk for diabetes, and a possible increase in cancer risk (3). For the mother, delivering preterm increases her risk by nearly two-fold for a subsequent preterm delivery (4). In addition, there is a racial disparity in both the baseline and recurrence rates of preterm births. In 2004, preterm births occurred in 11.5 percent of Caucasian women and 17.9 percent of non-Hispanic black women. With one previous preterm birth, the recurrence rates of preterm births are 15-20 percent in Caucasian women, and 26 percent in black women. The additive risk associated with multiple prior preterm births is especially evident when early preterm births are considered. Women with one prior preterm delivery less than 35 weeks have a 16 percent recurrence risk, those with two early preterm deliveries have a 41 percent risk, and those with three prior preterm deliveries have a 67 percent risk of subsequent preterm birth before 35 weeks (5).

Of the over 540,000 preterm births in the United States each year, 70 percent are late preterm births (delivering between 34-36 weeks of gestation)(1). These infants account for about 40 percent of Neonatal Intensive Care Unit (NICU) admissions. Not only has the preterm birth rate increased in the U.S. from 9.1 percent (1981) to 12.3 percent (2008), but the rate of late preterm deliveries has also increased from 7.3 percent (1990) to 8.8 percent of all live births (2008). Data from 2008 indicate a slight decrease in the overall preterm birth rate, which primarily

reflects a decrease in late preterm births to 8.77 percent (1). These infants are at higher risk for sepsis, pneumonia, hypoglycemia, temperature instability, hyperbilirubinemia, kernicterus, feeding difficulties, white matter damage, seizures, and apnea, and for re-hospitalization after initial hospital discharge. Compared to their term counterparts, late preterm infants appear to be at a higher risk for Sudden Infant Death Syndrome (SIDS) and have higher rates of neurological and developmental morbidities during childhood.

The NIH is committed to understanding the causes of preterm birth and to reduce the incidence of preterm birth, low birth weight and infant mortality and their consequences. The NICHD was the lead federal agency in planning and coordinating the Surgeon General's Conference on the Prevention of Prematurity, held in June 2008 (6, 7). Federal agencies, nonprofit organizations, professional societies, and members of the public whose lives had been affected by preterm birth all participated in formulating an agenda to heighten the visibility of preterm birth and its consequences, and to provide guidance on top priority, cross-cutting efforts to speed the identification of the causes, risk factors, and treatment of preterm labor and delivery.

Preterm birth research supported by the NICHD ranges from basic work on genetics and genomics to research regarding specific questions encountered in clinical practice, including the mechanisms, prediction and prevention of preterm delivery, optimal management of preterm labor, optimal management of the preterm neonate and the long-term implications of preterm delivery on the infant, mother and family. The NICHD supports this work through the funding of investigator-initiated applications, specific solicitations for individual grants and networks, the identification of high priority topics, and the identification and highlighting of gaps through the use of conferences and workshops. In addition to funding a wide range of extramural research, the NICHD's intramural program includes a branch largely devoted to issues related to pregnancy, preterm birth and congenital anomalies. While the NICHD supports the bulk of NIH research in this area, other NIH institutes and centers also contribute to the overall NIH spending of \$278 million, including \$32 million in Recovery Act funds, for infant mortality/low birth weight/prematurity research projects in FY 2009, the last year for which we have complete data.

One of the most successful approaches for research related to prematurity is the NICHD's research networks, which allow physician scientists across the country to coordinate their work and share data. Currently, four networks focus on specific aspects of prematurity and its consequences. The first, the Maternal Fetal Medicine Units (MFMU) Network (<http://www.bsc.gwu.edu/mfinu>) conducts clinical studies to improve maternal, fetal and neonatal health emphasizing randomized-controlled trials. The aims of the Network are to reduce maternal, fetal and infant morbidity related to preterm birth, fetal growth abnormalities and maternal complications and to provide the rationale for evidence-based, cost-effective, obstetric practice. The MFMU Network is composed of 14 sites across the US and an independent data center. This network has a remarkable track record of conducting high priority clinical trials, with its findings incorporated into practice through professional societies. Work from this network includes the identification of preventative therapies for preterm birth in current practice that should be stopped as they have no impact on the preterm birth rate and on therapies that improve outcomes for preterm infants.

A second network, the Neonatal Research Network (like the MFMU, established in 1986), aims to improve the care and outcome of neonates, especially very low birthweight infants. It has led to several advances to improve the survival of infants, and additional work is addressing complications in the areas of infection, breathing problems, and neurodevelopmental outcomes. Currently the NRN is composed of 16 clinical centers and one data center.

Another network is the Genomic and Proteomic Network for Preterm Birth Research (GPN/PBR). Multiple factors may determine an individual woman's risk of preterm birth including her genetic makeup and the way(s) that her genes control the expression of substances such as proteins, hormones, and infection-fighting agents. To search the myriads of human genes and proteins for abnormalities that could help explain preterm birth, the NICHD's Genomic and Proteomic Network for Preterm Research (GPN/PBR) was introduced as a five-year initiative in 2006. Its main objective is to use wide-scale, high-output genomic and proteomic strategies to accelerate knowledge in the mechanisms responsible for premature birth. Approaches such as genome-wide scans and global serum protein profiling will be used to identify new biomarkers that increase the risk or are predictive of a preterm delivery and to delineate molecular mechanisms responsible for a preterm birth.

The NICHD has recently funded the Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-Be, which will address another important aspect of preterm birth. Women for whom the current pregnancy will lead to their first delivery (nulliparas) comprise about 40 percent of the approximately 4.3 million births in the United States each year. Because there is no information from previous pregnancy outcomes to guide assignment of risk or mitigating interventions, adverse pregnancy outcomes in nulliparas are especially unpredictable. Complications during the first pregnancy affect subsequent pregnancies. This Network will study the mechanisms and predictors of adverse pregnancy outcomes in nulliparous women. The aim of this large, multicenter cohort study is to identify markers early in pregnancy that will identify women at the highest risk for preterm birth, preeclampsia, fetal growth restriction, and stillbirth. Detailed epidemiologic data, intensive clinical research assessments and biologic samples will be collected. Recent advances in genomics, proteomics and epigenetics will be applied to elucidate the mechanisms of the interplay of genetic and environmental factors. Ideally, using the findings from this study, individualized interventions can be developed aimed at preventing adverse pregnancy outcomes. Grantees will share data with investigators outside the network, to accelerate the pace of preterm birth research.

Another highly useful method for consolidating currently available scientific data and informing practice are the NIH Consensus Development Conferences. In recent years, the NIH has focused twice on the role of Cesarean delivery on preterm birth. In 2006, the NIH held the first conference, "Cesarean Delivery on Maternal Request," which found that the incidence of cesarean delivery without medical or obstetric indication has increased in the U.S. Given the risks of complications that rise with each cesarean delivery, the conferees stated that cesarean delivery on maternal request should not be recommended for women desiring several children, and should not be performed without medical indication prior to 39 weeks gestation in order to maximize lung maturity. The NIH followed up this earlier conference with another held in March 2010, "Vaginal Birth after Cesarean." The panel convened for this recent conference found that, in

women who had undergone prior cesarean delivery, while both vaginal birth after cesarean delivery and subsequent cesarean delivery have important risks and benefits for both the pregnant woman and the fetus, given the available evidence, vaginal birth after cesarean is a reasonable option for many pregnant women. The panel emphasized that both the pregnant woman and her clinician should engage in a shared decisionmaking process. The conferees' statement from the first conference, can be found at: <http://consensus.nih.gov/2006/cesarean.htm>, and the statement from the March, 2010, conference, at <http://consensus.nih.gov/2010/vbac.htm>.

Understanding the mechanism

Approximately fifty percent of preterm births occur spontaneously following the premature onset of labor, 20 percent are medically-induced deliveries due to medical conditions endangering the mother and/or fetus, and 30 percent are associated with the preterm premature rupture of fetal membranes leading to either a spontaneously or medically- induced delivery. Consequently, the cause(s) for a preterm delivery is dependent on its categorical type.

Research supported by the NICHD has indicated that spontaneous preterm birth has a number of possible causes (8). These include intrauterine infection/inflammation, uterine bleeding, excessive uterine stretch, maternal psychosocial stress, and fetal physiological stress. Certain causes are more prominent during certain stages of pregnancy. For example, intrauterine infection is associated more often with an early (less than 34 weeks) than a late (34-36 weeks) spontaneous preterm delivery. The physiological processes underlying these causes are currently an area of intense study.

The main pregnancy complications leading to a medically-induced preterm delivery are preeclampsia, fetal distress, and fetal growth restriction. Notably, preeclampsia is a major focus of research supported by NICHD since it is the primary reason for a medically-indicated, preterm delivery, accounting for approximately 40 percent of all medically-induced preterm births. Preeclampsia is a pregnancy-specific, hypertensive disorder and occurs in about four percent of all live-birth pregnancies. Researchers supported by the NICHD have shown that this disease is associated with abnormal development of the placenta, which results in reduced blood flow between the mother and the fetus (9).

NICHD-funded researchers are exploring the use of drugs to manipulate certain protective enzymes to improve placental function. One enzyme being studied is a potent antioxidant defense protein called heme oxygenase-1 (HO-1), which has emerged in recent years as an important mediator of tissue protective and anti-inflammatory actions (10). It has been shown that HO-1 is crucial for keeping the human uterus in a relaxed state during pregnancy. A reduced level of placental HO-1 seems to be associated with a higher risk for preeclampsia. Therefore, the unique combination of tissue protective and smooth muscle relaxing properties of the enzyme HO-1 make it an interesting target for treatment of preeclampsia, and thus, possible prevention of many medically-indicated preterm births.

Research has indicated that preterm premature rupture of the fetal membranes (pPROM) has multiple causes. They include chronic inflammation and /or infection, repeated stretching,

maternal stress, and trauma. The likelihood of pPROM being the cause for a preterm delivery is higher for an early than a late preterm delivery; approximately 21 percent and 8 percent, respectively. The most common causes for pPROM, currently under investigation, appear to be chronic inflammation and/or infection.

Prediction of Preterm Birth

Fetal growth restriction is a risk factor for preterm birth. Labor and fetal growth involves a complex interplay of factors and signaling molecules within the maternal, placental, and fetal tissues. Recent advances have implicated placental corticotropin-releasing hormone (CRH) as one of the primary endocrine mediators of spontaneous labor and, possibly, of fetal development. NICHD-funded researchers have made substantial progress in a prospective study of women with a singleton pregnancy demonstrating that a single measurement of CRH at 33 weeks of pregnancy predicts fetal birth weight and identifies patients at high risk for preterm labor. These results, although not final, demonstrate that, in humans, placental CRH directly participates in the physiologic processes of parturition and fetal growth and maturation, as evidenced by the prospective relationship between elevated CRH levels and increased risk for preterm birth and fetal growth restriction.

Cervical length seems to be a predictor of spontaneous preterm birth. The NICHD's MFMU Network conducted a blinded, multicenter observational study of women with a prior preterm birth(11). The study showed that in high-risk women, shortened cervical length in the mid-trimester predicts early, but not later, spontaneous preterm birth. The results of this and other related studies of women at high-risk for preterm birth point to an association between cervical length and diminished cervical competence. Another NICHD-funded trial evaluated the use of cervical cerclage (a stitch around the cervix like a purse string) in high risk women with a short cervix and found in a subset that the cerclage significantly prevented preterm birth (12).

Home Uterine Activity Monitors (HUAM) have been widely prescribed for patients in the anticipation that detecting those patients who were having frequent uterine contractions would identify those patients who would deliver preterm. However, a team of researchers supported by the NICHD's MFMU Network found that portable monitors that detect contractions of the uterus do not appear to be useful for identifying women likely to deliver preterm(13). This work has demonstrated the failure of this new technology to attain a more precise diagnosis, and has stopped its ineffective and expensive use from spreading.

The NICHD also recently used part of its American Recovery and Reinvestment Act funding to support a grant to test a new, non-invasive technology device to study the physiological mechanism of uterine contractions through magnetic recordings. Insights from these recordings may provide innovative approaches toward suppression of preterm labor and induction of labor.

Prevention of Preterm Birth

A major advance in prevention of preterm birth was made in 2003 by a team of researchers supported by the NICHD's MFMU Network, who studied women who had had a previous

preterm delivery and therefore were considered at high risk for recurrent preterm delivery. This clinical trial compared weekly treatment by injection of a progesterone (17 alpha-hydroxyprogesterone caproate) with placebo in women at high risk for preterm birth(14). These treatments lowered the risk of a second preterm birth by one-third, the first successful treatment demonstrated to reduce the risk of recurrent preterm delivery and improve neonatal outcomes in a subset of high-risk women. The impact of this treatment was evaluated in a study published in 2005, which estimated that 10,000 preterm births could have been prevented annually if all eligible pregnant women had received it (a reduction of about two percent)(15). This preventative therapy has been translated into practice; the American College of Obstetricians and Gynecologists has recommended the use of progesterone to prevent preterm birth for women with prior spontaneous preterm birth(16). Since that time, the MFMU Network has evaluated other high risk groups, such as women with multiple gestations (twins and triplets), but thus far has found that progesterone is not beneficial in preventing preterm birth in those groups (17,18).

Research that disproves a current therapy or treatment can also provide valuable guidance to clinicians and their patients. Translational research in the 1990s found that the use of corticosteroids in pregnancies at risk of preterm birth improved the outcomes for infants born preterm, reducing the rates of breathing problems, bleeding into the brain, and problems with the intestines. However, the NICHD sponsored research that evaluated the use of repeated doses of corticosteroids, and found that they resulted in smaller birthweights and head circumferences (19). They also found a non-significant, but concerning increase in cerebral palsy in children who were exposed to four or more courses of corticosteroids (20). This study, along with an NIH Consensus Development Conference to pull together all available data, stopped the routine use of repeated courses of antenatal corticosteroids (21).

Vaginal infections have been associated in the scientific literature with preterm birth. Previous studies showed that antibiotic treatment of symptomatic bacterial vaginosis in women with a previous preterm birth reduced the risk of recurrence. Based on this evidence, many women – even those without symptoms of infection – were treated with antibiotics in an attempt to prevent preterm birth. However, a study supported by the NICHD’s MFMU Network found that the use of a course of antibiotics in asymptomatic women did not decrease the risk of spontaneous delivery and did not result in improved neonatal outcomes (22). Another trial showed that screening and antibiotic treatment of all women with another type of vaginal infection (*Trichomonas vaginalis*) not only did not prevent preterm birth, but actually increased preterm birth (23). These trials stopped the indiscriminate use of antibiotics in pregnancy.

Evidence from European studies suggests that the omega-3 fatty acids found in cold water oily fish may reduce the chances of preterm birth. The NICHD’s MFMU Network studied whether, in high risk women who are receiving weekly progesterone treatments, supplementation with two omega-3 fatty acids would result in an even greater reduction of preterm birth than progesterone alone. The trial found that omega-3 supplementation did not further reduce preterm birth, halting an ineffective intervention (24).

Antioxidants have been implicated in preeclampsia, a major cause of preterm birth. Although basic research suggested that antioxidants were beneficial, a trial evaluating supplementation

with Vitamin C and E did not prevent preeclampsia in 10,000 women in their first pregnancy, stopping the implementation of an ineffective therapy (25).

In addition to studying preventative therapies, the MFMU Network studies antenatal interventions to prevent complications in premature infants. Recently, the network identified another therapy, antenatal magnesium sulfate (Epsom salts) which, when administered to women at risk of delivering preterm, reduces the risk of cerebral palsy in surviving preterm infants by 45 percent (27). This finding was translated into clinical practice (28). Through the Network, the NIH also is supporting a new clinical trial to evaluate if antenatal corticosteroids will improve outcomes for women whose pregnancies are at risk for late preterm birth (34-36 weeks). Late preterm births account for 70 percent of preterm deliveries. The results of this trial may have substantial impact on the health of these infants.

In addition, the NICHD and the Society for Maternal Fetal Medicine will hold a workshop in February 2011 to synthesize the available information regarding conditions that result in medically indicated late preterm and early term births to determine the potential risks and benefits of continued pregnancy, the optimal gestational age for delivery (if optional), and to inform future research regarding these issues.

Caring for Preterm Newborns

Of the over 540,000 prematurely born infants in the US each year, more than five percent fail to grow appropriately in the womb due to placental insufficiency. Slow fetal growth, or fetal growth restriction (FGR), increases the risk of mortality and long-term neurological morbidity, including difficulties in infants' early learning. More than 70 percent of severe FGR infants develop learning disabilities and require special educational services. The NICHD is supporting research that will test the effectiveness of an intervention in the NICU for such infants, based on reducing overload on each baby's senses.

Extremely low birth weight (ELBW) infants are at increased risk for developmental and behavioral abnormalities. The NICHD Neonatal Research Network, in a large study of very small infants in 15 sites, collected detailed information on breast milk intake of extremely low birth weight infants as part of a large trial of glutamine supplementation. Infants given breast milk had an increase in several developmental scores, making efforts to enhance breast feeding and provision of breast milk to ELBW infants a high priority.

Nutrition and prevention of infection remain significant problems for this group of ELBW babies. Glutamine is one of the most abundant amino acids in breast milk and in blood, but is not included in standard solutions for intravenous nutrition. Glutamine showed significant promise in small human studies in adults for preventing infection and reducing death. Due to this finding, some intensive care nurseries had begun to supplement high-risk babies with glutamine. However, in the same Neonatal Research Network study, glutamine supplementation did not affect the rate of infection or the rate of death in the infants, providing sound information that glutamine supplementation for tiny babies should not be recommended at this time (29).

Nitric acid is a chemical compound that is sometimes used in its gaseous form to treat infants with severe breathing problems. Inhaled nitric oxide therapy was approved by the Food and Drug Administration in 2000 to treat term and near-term infants (born after the 33rd week of pregnancy) with respiratory failure. Since its approval, researchers have examined expanding the use of inhaled nitric oxide therapy to treat premature babies born at less than 34 weeks' gestation. Studies to evaluate its safety and efficacy for these infants have had mixed results(30, 31). To better understand the potential risks and benefits of inhaled nitric oxide therapy for premature infants, the NIH will convene a Consensus Development Conference on October 27-29, 2010, to assess the available scientific evidence and come to some conclusions about its use.

Infant Mortality

Infant mortality (6.7 deaths/1,000 live births), stillbirths (6.2/1,000 live births), major birth defects (30/1000 live births) and preterm births (128/1,000 live births) are major public health priorities in the U.S (32). All of these already high rates demonstrate dramatic health disparities based on race-ethnicity with higher overall rates in African American women. Despite numerous efforts, the disparities are persisting. Researchers are attempting to identify factors to explain the disparities, evaluating genetics, socio-economic status, accessibility to health care, maternal education, and stress and disease burden, among others. However, the complexity of the interactions among these factors has made the task more difficult.

In August, 2010, the NICHD will hold a scientific workshop focused on disparities in infant mortality, stillbirth, and preterm birth. The goals of this workshop are to identify the factors associated with such disparities and to determine their relative contributions and gaps in knowledge, and to design a plan for moving research forward in both the short and long term.

Again, thanks to the Committee for your time and interest in this critical public health topic. I am pleased to answer any questions you may have.

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Mr. PALLONE. Thank you, Dr. Spong.

What we do now is, we have questions from the members for 5 minutes or sometimes 8 if they didn't do an opening, and I am going to begin with myself.

I will ask initially Dr. Callaghan, in your testimony you discussed CDC's role in surveillance in terms of monitoring infants born prematurely, analyzing trends, defining risk factors and targeting prevention programs. I mentioned that I sponsored H.R. 3212, the Stillbirth and SUID Prevention, Education and Awareness Act, and I am particularly interested in the collection of critical data to determine the causes of stillbirth and sudden unexpected infant death. Can you tell me what the CDC is doing to understand the causes and risk factors associated with stillbirths, sudden unexpected infant death and sudden unexplained death in childhood, and are there ways to reduce those risks? And then secondly, how would better data collection help reduce and prevent these deaths in the future, if you could?

Dr. CALLAGHAN. The National Center for Health Statistics collects information on fetal deaths from fetal death certificates. Fetal death certificates are not birth certificates. A fetal death report is what it is called. So they are able to—those are collected by States, sent to NHS and NHS compiles those for the Nation. The quality of information on fetal death certificates is not always what we would hope it would be. These are filled out essentially in real time at the bedside in the hospital and sent in, and there is a fair amount of variability in how stringently people fill those out. There is also a fair amount of variability on how much each fetal death is investigated at the individual level. To do this correctly, there needs to be fetal autopsy, there needs to be fetal genetic studies. These aren't always done consistently and so the amount of information that is ultimately reported as to the cause of death can be variable, which leads us to your statement that in many cases we are left without a real good reason about why that happened. So efforts to improve the quality of fetal death reporting at each individual level at the time of each individual fetal death would be important in terms of improving our information.

There is also some pilot work that is being done at CDC at Atlanta in the National Center for Birth Defects and Developmental Disabilities. There is Atlanta Metropolitan Birth Defects Surveillance System and there is some pilot work being tagged onto that to try to see if fetal death registration can also be used with that same infrastructure. If that was successful, that could be expanded to other birth defect surveillance systems. Birth defect surveillance systems collect much more nuanced information, almost through survey.

Lastly, about sudden unexplained infant death, we have done a lot of work in this area, and we have learned that there is a difference between the sudden unexplained infant death and sudden infant death syndrome. Sudden infant death syndrome means there is no plausible explanation for the cause of death. It is truly unexplained. The more and more that people do death scene investigations on the ground, again, in and around the time of the infant death, the more and more people are finding that there actually may be explanations. The good thing about having an explanation,

it doesn't bring a lot of relief to the grief of parents, but if you have an explanation, now we have a chance of prevention. So we are in the process of establishing pilot registries for that.

Mr. PALLONE. Thank you.

I am going to try to summarize this next one for Dr. Spong. I think it is critically important that we do everything we can to ensure that we have the right research infrastructure and so I wanted to ask you three questions about the research network. First, how many women are usually in the clinical trials conducted by the network? I guess we are talking about the Maternal Fetal Medicine Unit Network. And is there a diverse population of women represented in the trials? Can you elaborate on use of 17P to prevent prematurity and would you discuss other interventions that have impacted patient care to date?

Dr. SPONG. Thank you, Mr. Chairman. The first question was the number of patients enrolled in clinical trials?

Mr. PALLONE. How many women are usually in them, yes, and is there a diverse population of women?

Dr. SPONG. So the number of patients enrolled in a given trial depends on what the trial is looking at and what the question is to be addressed, how big the effect needs to be, how rare the outcome is. We have had trials that have included few number of patients, for example, 200, 300, and we have recently completed a trial that included over 10,000 women. In addition, some of the observational studies have included, you know, many, many more women than that. The diversity of the population is assured when the network is openly and actively recomputed every 5 years. As part of that recompetition, as part of looking at who should be part of the network includes geographic diversity and diversity in the patient population.

Your question about 17 alpha hydroxyprogesterone caproate or progesterone for the use to prevent preterm birth, this was a landmark study as the first preventative therapy identified for women who had a prior preterm birth. As a clinician, I knew that one of the very common things that you would see with a patient who had come in for prenatal care who had had a prior preterm birth, we would say that you are at very high risk for another preterm birth but we had nothing to offer her. Now with the use of 17 alpha hydroxyprogesterone caproate, we have something that we can offer her that can reduce her risk of another preterm birth by about one-third. That progesterone is now being studied in other high-risk populations so women who have had a prior preterm birth or are at high risk, women who have multiple gestations are at high risk, and they have been studied, both women with twins and triplets, and it was found that progesterone did not reduce the rates of preterm birth in that population, and I think that is very important to know, that it is not a cure-all for all prematurity, it is for specific conditions and it is currently being evaluated in the setting of a shortened cervix in an asymptomatic woman.

There are a number of other studies that the network has undertaken that have impacted practice. One example is the use of antenatal corticosteroids which are given to women who are risk of delivering preterm with the understanding that it will improve outcome for the babies. It decreases their complications such as

breathing complications and bleeding complications. The network undertook a study looking at repeated doses of those steroids and found that in fact that was not beneficial, so it was a change in practice from repeating multiple doses of steroids.

Another example is one of magnesium sulfate being administered to women who are at risk for preterm birth where it significantly reduced the risk of cerebral palsy by about 45 percent. One of the unique factors from this network is that when these trials are published, their findings are then often incorporated into professional guidelines such as those by the American College of Obstetricians and Gynecologists making recommendations for how that should change and how that should be implemented into practice. I can give a number of other examples as well.

Mr. PALLONE. No, I think we better stop there because I made you go over. It is not your fault.

Mr. Shimkus.

Mr. SHIMKUS. Thank you, Mr. Chairman.

I want to throw this out there. In the health care law, either I am right that my constituent is denied the ability to purchase insurance on the sole reason of a preexisting condition of their child, or I am wrong, and I would ask someone on the majority side to help me have a hearing on this issue to see who is right. It is not a question. I am asking for a hearing. I have a case of a former staffer who cannot get insurance because of a preexisting condition of their child. My colleague from Illinois said that is not true, and I think this would be a good hearing to have on this issue of whether people right now under this health care law are being denied access because of preexisting condition. So I want to put that on the record. My colleague is not here from Illinois, who rejected my claim, but I throw that out as an issue.

I appreciate your testimony, and you say words I can't even pronounce, but I do have a question, Dr. Spong. The mission of the NICHD is to ensure that every person is born healthy and wanted, and I am curious of why you have the word "wanted" there. What does that mean and what does that mean for what you do? It is a curious word. Can you explain that?

Dr. SPONG. Thank you for your question. The question is why the NICHD mission includes the word "wanted," and I will be the first to admit that the mission was created before I started working at the National Institute of Child Health and Human Development so I do not have that information for you at this time, but I would be happy to get back to you in written testimony.

Mr. SHIMKUS. Yes, it is an interesting word. I mean, I don't know what it means. So if you could get back to me. Before we make conjectures and think things, I will just wait for a response because I just don't know what that means.

Let me follow up with this question. If individuals change their lifestyle, stop smoking and manage their weight, would that reduce the risk of prematurity, Dr. Spong?

Dr. SPONG. The risk factors that you stated were if they lost weight and if they stopped smoking, would that reduce preterm birth. Obesity itself—healthy lifestyles are good for pregnancy. Obesity itself has a mixed message on whether or not it actually causes preterm birth. There are studies that would suggest that

obesity is not in fact associated with preterm birth. That said, starting out with a healthy weight is optimal for pregnancy for a number of reasons regardless of preterm birth, so we would certainly encourage all women to start pregnancy at a healthy weight. Smoking itself is associated with low birth weight or smaller babies, and clearly is one major lifestyle change that people can make that can improve the health of their children and remove the risk of low birth weight.

Mr. SHIMKUS. Let me follow up, because Dr. Callaghan mentioned that infection itself may not be the cause of prematurity but rather the inflammation associated with the infection. Do you agree with that?

Dr. SPONG. The question regards to the role of infection versus inflammation on preterm birth, and preterm birth is a very complex condition, and I believe there are multiple pathways that can lead to a preterm birth. One is going to be an infectious pathway. Clearly, that can cause preterm birth but the inflammation itself in the absence of infection can also cause preterm birth.

Mr. SHIMKUS. And then are there contributing factors to increased inflammation that could be avoided through a change in lifestyle?

Dr. SPONG. That is an excellent condition. Those are areas that are currently getting teased out. It is likely that it is not a single factor that causes much of preterm birth but a constellation of events, so whether you have certain environmental factors, certain genetics, certain inflammatory markers and then certain lifestyle events that can ultimately result in a preterm birth.

Mr. SHIMKUS. And I want to thank you. I am going to end. Of course, on our side we have Dr. Gingrey and Dr. Burgess, who are both obstetricians, and I am waiting for their follow-up questioning as they are experts in the field, and I yield back my time. Thank you, Mr. Chairman.

Mr. PALLONE. Ms. Capps asked that we enter into the record this letter from Secretary of Health and Human Services to the Speaker and I guess to the Republican leadership, and it basically goes into the different provisions in the health care reform on adult and child coverage, preexisting conditions, early retirement, reinsurance, rescissions, Medicare Part B with a timeline.

Mr. SHIMKUS. That is correct. The point that Secretary Sebelius has said please, insurance companies continue to cover people, kids with preexisting conditions. The issue is they are not, and so I would suggest that we have a hearing on this, and—

Mr. PALLONE. I am not just reading it.

Mr. SHIMKUS. I am just—

Mr. PALLONE. You know what it is.

Mr. SHIMKUS. I am just—

Mr. PALLONE. Effective beginning—

Mrs. CAPPS. The date September 23rd is there.

Mr. PALLONE. And on March—

Mr. SHIMKUS. So right now people if they have no insurance, they cannot get coverage with preexisting conditions. That is the law.

Mrs. CAPPS. Because some insurance companies are operating to do it—

Mr. SHIMKUS. So you are not disputing the fact that my former staffer, this family cannot get health insurance right now?

Mrs. CAPPS. It isn't required yet.

Mr. SHIMKUS. It is not required. Thank you for——

Mrs. CAPPS. But it will be very soon.

Mr. PALLONE. But on March 29th it is required for children.

Mr. SHIMKUS. But it is now right now.

Mrs. CAPPS. September 23rd.

Mr. SHIMKUS. But it is not right now.

Mr. PALLONE. It says on March 29th——

Mr. SHIMKUS. So my point is, we could pass a law tomorrow to do this.

Mr. PALLONE. Well, Mr. Shimkus, first of all, does anybody have an objection to entering this into the record? I mean, the only thing it says on preexisting conditions, it says, "Effective for policies or plan year beginning on or after September 23rd be prohibited from excluding coverage of children."

Mr. SHIMKUS. If the chairman would yield, my point is, I am going to continue to raise issues that we ought to have hearings on this law, and this is just another example of people not having access to health insurance because of preexisting conditions, and this is something we can fix.

Mr. PALLONE. I don't think there is any question that the law is the September date, but you can look at it.

Mr. SHIMKUS. And we could bring a bill to the floor tomorrow and fix this. That is my point.

Mr. BURGESS. Mr. Chairman, if I could just stand in agreement with my colleague from Illinois. We handed an enormous task to the Department of Health and Human Services to create something out of whole cloth in this law that we passed hurriedly a couple months ago and really it is incumbent upon this committee to maintain the vigilance and oversight over HHS and CMS as they come up with these rules and regulations that are literally going to affect every American, not between today and Election Day but for the next three generations. So I hope you will consider Mr. Shimkus's request to hold the appropriate hearings at this level.

Mr. PALLONE. Let me just have that back.

Without objection, it is entered into the record.

The gentlewoman from California has the time.

[The information appears at the conclusion of the hearing.]

Mrs. CAPPS. Mr. Chairman, you may not wish to call on me after all of that, but thank you. This has been a good discussion. Back to the topic, but before I ask my question for Dr. Callaghan, I want to just acknowledge that there are many members of a non-governmental organization called CARE on Capitol Hill today because they are very interested not only in this hearing but in other topics having to do with preterm delivery and birth, and one of them is a constituent of mine so I want to welcome a particular group that was here. We had nurses earlier as well. And I appreciate the testimony that both of you have given us.

Dr. Callaghan, in your testimony you included some of the surveillance mechanisms that the CDC uses to monitor the pregnancy outcome and also infant health. Especially with issues such as the ones we are discussing today, I believe it is critical to have really

accurate and robust surveillance and data collection strategies. Now, you mentioned that only 37 States and New York City participate in what is called the PRAMS program and that the survey is representative is 75 percent of all births. It is too bad we can't have closer to 100 percent. What are some of the barriers to implementation of this participation in all States and for full representation so that we really have a much more robust data collection?

Dr. CALLAGHAN. The one thing I will say, and this is very pertinent to your state, is California has a very complementary system that does not participate in PRAMS. I could get the precise name of it. I think it is called MEWA.

Mrs. CAPPS. So we do something different but you can't use it in the national data collection?

Dr. CALLAGHAN. No, we cannot use that in the national data collection. That is parochial to California. It is a very good system.

Mrs. CAPPS. The California system is good but it doesn't help nationally?

Dr. CALLAGHAN. It doesn't help nationally.

Mrs. CAPPS. I see. So that in of the barriers then?

Dr. CALLAGHAN. It is a barrier because—

Mrs. CAPPS. And so maybe some kind of smart scientist can figure—a number cruncher can figure out how to coordinate it so it will be useful to California but also to the United States.

Dr. CALLAGHAN. Because then one of the other problems that is left with some of the other smaller States is the births are so small, and this is based on not a sampling of total births but on a sample of births and so some very small States, it becomes very difficult to get a sample that is representative.

Mrs. CAPPS. And you really want to have a large State like California and all of New York, not just New York City involved?

Dr. CALLAGHAN. Right.

Mrs. CAPPS. That is useful. Thank you very much. It gives me something to think about with my own State.

Here is another question. I am very excited to hear of the move to modernize vital records systems. Maybe this is one arena where we need to do this. But there seems to be more room for data collection. Can you tell us more about what is currently being collected on electronic records in light of the many factors? Maybe we are not even asking enough questions when we do data collection. In light of the many factors associate with premature birth and infant mortality and morbidity, what other data would be helpful to collect? Especially with the kind of technology we have to collect and sort data.

Dr. CALLAGHAN. You are asking what other information could we collect on birth certificates?

Mrs. CAPPS. Are we lacking—

Dr. CALLAGHAN. We collect a lot of information on birth certificates. We collect a lot of information about maternal conditions during pregnancy. We collect information about problems that occurred during labor and delivery. But one of the things that we have seen over and over again when we go back and do validation of that information is that it doesn't do very well most of the time.

Mrs. CAPPS. So there is room for improvement?

Dr. CALLAGHAN. There is room for improvement at the level of data collection, and data collection occurs individually at individual hospital level.

Mrs. CAPPS. So there might be some legislation that would be useful to you to help with the CDC to do a better—to be more equipped to do a better data collection?

Dr. CALLAGHAN. I have always said that if there is anything that I could do in career in public health is to improve vital statistics because we have an infrastructure in place.

Mrs. CAPPS. Mr. Chairman, I am going to suggest, or just suggest it to my fellow committee members that this is an area that would seem to be the low-hanging fruit, if you will, for some of the challenges that we face in this area, that if we can put some bright heads together to figure out a better way to collect data and use it in a proper way, that would be very useful.

I am going to try one more question because I have 17 seconds. Dr. Spang, I appreciated your testimony as well. You know, there are so many factors associated with preterm birth, the health status of the mother, you know, issues like diabetes, obesity, deficiencies of certain nutrients and so forth, high blood pressure. Can you just say in a couple of seconds more about the importance of preconception health? This is such a huge issue that starts really prebirth with the one-day mother, doesn't it?

Dr. SPONG. Yes, preconception care is clearly important. Women who start pregnancy healthy tend to have healthier pregnancies. That said, I cannot point to research or data as to what exactly needs to go into that preconception care that will actually ultimately result in improved outcomes. But we do know that women who have a healthy lifestyle, who are an appropriate weight, who don't have habits such as smoking or alcohol exposure tend to have healthier pregnancies.

Mr. PALLONE. Thank you.

The gentleman from Pennsylvania, Mr. Pitts.

Mr. PITTS. Thank you, Mr. Chairman. First, I would like to ask unanimous consent to enter into the record a couple of articles and a list of studies that have found that women with prior induced abortions are at increased risk for premature birth and low birth weight.

Mr. PALLONE. I am going to take a look at them but I don't see a problem.

Mr. PITTS. The articles are by the American Association of OB/GYNs.

Mr. PALLONE. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. Thank you, Mr. Chairman.

Dr. Callaghan, you mentioned that the CDC had worked with States to assist with smoking cessation programs during pregnancy. Have any States used their master settlement agreement funds to implement smoking cessation programs targeted at pregnant women?

Dr. CALLAGHAN. I really don't have the information at hand to answer that question. I would be happy to do that and get that information to you.

Mr. PITTS. All right. You mentioned that African American women are more than, I think you said twice more likely than white women to have preterm birth, one and a half times more likely to have preterm birth, twice as likely to have very preterm infants. Why is that the case?

Dr. CALLAGHAN. That is one of the holy grails. Understanding that is probably one of the holy grails in all of perinatal health and perinatal medicine. These are disparities that we have seen over and over and over again. They are pernicious. When we adjust for almost anything that we can think of, if we adjust for socioeconomic status, we adjust for education levels, it doesn't go away. In fact, as was mentioned previously in this hearing, these gaps are even greater when we look at the difference between the most well-off African American women and the most well-off white women, the gap is even greater. As Dr. Spong mentioned, the paths to preterm birth are likely very, very complex. This has been likened to this other group of diseases that we call common complex diseases like cardiovascular disease where at the end of the day there is a preterm birth but there are a lot of different ways to get there.

Our current kind of working hypotheses around these, that there are genetic factors, that are environmental exposures, environmental in most holistic ways such as stress, poverty, all of which are interacting to result in whatever happens that goes into spontaneous preterm birth. If we knew the answer to that question and if we could fix that problem, our preterm birth and our infant mortality rate would be dramatically decreased in the United States.

Mr. PITTS. And in 2006, Congress passed the PREEMIE Act authored by Mr. Upton in the House, and one provision of the legislation called on HHS to award grants to public and private nonprofit entities to conduct demonstration projects for the purpose of improving the provision of information on prematurity to help professionals and the public and improving the treatment and outcomes for babies born preterm, and the grants were to support programs to test and evaluate screening for and treatment of infections, counseling on optimal weight and good nutrition, smoking cessation, education, counseling, stress management, appropriate prenatal care. How many grants have been awarded under this program and what have been the results of these demonstration projects so far?

Dr. CALLAGHAN. We began receiving appropriations for the PREEMIE Act in 2009, and we have continued to do work in preterm birth as I outlined with regard to looking at late preterm birth, with looking with factors associated with the interactions that we are looking at in California, looking at in Michigan, the interactions between preterm birth, race, genetic factors and biologic markers. There are people at CDC that are working in authorization and appropriations and I would be happy again to have them get back in touch with you, but as the scientific liaison for the branch that I work in, that is information I am just not familiar with.

Mr. PITTS. OK.

Dr. Spong, I don't have much time. You mentioned genomic research in the field of prematurity. Can you further expand about

what we have learned about prematurity from genomic perspectives?

Dr. SPONG. There have been a number of smaller studies looking at specific genes or specific alterations in genes to try to identify why one group might be at higher risk of delivering preterm, and they have identified certain changes in alleles or changes in genes. However, we realize that really that is not going to answer the question, looking at small groups of people one gene at a time or one alteration in a gene at a time. Because of that, the NICHD undertook launching a network on genomics and proteomics of preterm birth to try to really do a genome widescreen and really evaluate what are the changes in the genomics and proteomics associate with spontaneous preterm birth and indicated preterm birth, and that network is ongoing and over the next couple of years I expect we will have some findings from it.

Mr. PITTS. Thank you. My time is expired.

Mr. PALLONE. Thank you, Mr. Pitts.

I guess we are going to the gentlewoman from Florida, Ms. Castor.

Ms. CASTOR. Thank you very much for your testimony.

Dr. Callaghan, correct me if I am wrong, but I believe there is no conclusive evidence that links rising C-section rates to prematurity numbers or data that displays that increases in C-sections are the reason that prematurity rates went up from 1996 to 2007. However, the speculation is strong. The March of Dimes reported that from 1996 to 2006, C-sections accounted for 92 percent of all preterm births in the United States. Can you please discuss the type of studies that must be conducted to get to the bottom of this and what steps are currently underway?

Dr. CALLAGHAN. First of all, because I was a coauthor on that paper, it is really 92 percent of the increase in preterm births and not the total preterm birth rate. Still, that is a very compelling number. The issue about this really hinges around the word "cause." During this time, 1996 through now in fact, Cesarean sections have been rising for all comers and pregnancy no matter what the gestational age, perhaps more particularly in the late preterm births but it is going up. I think that the issue around cause, and maybe we need to look at this a little bit differently, is not so much as a Cesarean section that is caused but might we expand that a little bit more to say is it intervention because there are other decisions that are being made around delivery. And I think that is what we need to get at, what kinds of decisions are being made. There are always two steps in this process. The first step on a clinical basis is the physician and the patient together in the best circumstances make a decision that delivery should occur. So that is the first thing that happens is should delivery occur. Next question is how delivery should occur. So I think that first step, should an intervention take place, is what we really need to get at. One of the things that we are doing right now is, we have a pilot study in three metropolitan Atlanta hospitals. We are going to identify through vital records a group of infants that were born between 34 and 36 weeks, go to the medical records and see if it is even possible by looking through the medical records to find a reason why the birth occurred. We are also planning on doing some

key informant interviews in those hospitals, physicians, nursing staff, et cetera, to try to get some more qualitative information about what might be influencing those decisions because I think what we really need to do is get at these processes, and this is hard stuff because this isn't just numbers, it is really getting around qualitative information about what process goes on when decisions are made to deliver prior to term and then how delivery should take place.

Ms. CASTOR. You know, ACOG and the March of Dimes have probably the best recommendations on protocols for health providers. It sounds like the study in Atlanta, something along those lines so you support something like that on a broader basis as well. Yes?

Dr. CALLAGHAN. Yes.

Ms. CASTOR. Thank you very much.

Mr. PALLONE. Thank you.

The gentleman from Texas, Mr. Burgess.

Mr. BURGESS. Well, I am actually glad that subject Ms. Castor brought up, that you are having that discussion. In 2006 when we reauthorized the National Institute of Health, there was report language in the bill dealing with the concept of doing a Cesarean suction study. Dr. Ken Leveno down at Parkland where I trained had been concerned that there was a movement toward elective Cesarean section. In my professional lifetime, I saw rates go from 12 percent during my residency to probably 25 percent when I concluded active practice in 2003 and now I suspect they are even higher still. Dr. Leveno's concern was, we may reach a point where simply the indication for Cesarean section is patient demand, and we really ought to have the data before we reach that point because once we are there, it then becomes very hard to walk back from patient demand on something along those lines. So where are we with that? Are we looking into the concept of Cesarean section rates and elective Cesarean sections are the rates of late prematurity which are a result of some iatrogenic influences either with Cesarean section or planned induction of labor? Do you have data on those issues?

Dr. CALLAGHAN. Yes, that is exactly what we are trying to get at now with these studies. There is also another study that I am involved in peripherally through wearing my CDC hat in Florida that is trying to look at that exact issue. There are no national data on Cesarean section on demand.

Mr. BURGESS. Again, it was Dr. Leveno's concern that we ought to get that data before it becomes an established norm. I would never be able to go back and randomly assign people to groups. I mean, you know that. It becomes almost an impossible study to construct, so we ought to be prospective about our look at that.

Dr. CALLAGHAN. And that would probably to do that on a national basis to include all deliveries in the United States would likely demand really changing our birth reporting forms to have that as a check box, if you will, or questions on that regarding the indications for Cesarean delivery. To the degree that could be done, I would be in wholehearted support. I don't know logistically if that is going to happen very quickly.

Mr. BURGESS. Yes, it is expensive to do that type of study. Honestly, it may be something that we need to look at in a prospective fashion.

I represent a part of north Texas, the east side of Fort Worth. Fort Worth is where the west begins, but I have the east side. That is where the east levels out. We have some infant mortality rates in some of my zip codes that are some of the highest in the country, and if you look at African American women and the infant mortality rates for African American populations in those zip codes, it is astoundingly high, and yet on the other side of the Trinity River in Dallas, their mortality rates are much more benign and you don't see the ratio of disparities. Both counties are large. Both have significant urban populations. Both have a county hospital. The difference between the two is the availability and the access to what might be referred to as a community clinic or federally qualified health center. And I have labored for that since 2005 when I began representing that part of Fort Worth, to get a federally qualified health center there. We did not quite a year so, so it will be a while before we see if it makes a difference, but it really drove home to me that access may be a problem, and that is something we need to pay attention to, but arguably there is equal access in Dallas and Tarrant counties because of the availability of a county facility even for someone who lacks the ability to pay, and these are tax-supported institutions. But utilization was hugely different between Dallas and Tarrant County, and I think I attribute part of that to the fact that the availability, the doctors weren't where the people were, and that has been one of the difficulties that I have sought to outcome. Do you guys have any experience with looking at things like that?

Dr. CALLAGHAN. We don't have a lot of experience with looking at that particular thing although I think you are probably referring to your home base, the Parkland experience and the report that they have about reducing preterm birth and infant mortality and it is an intriguing model where it is almost doing prenatal care as I read that almost as community outreach.

Mr. BURGESS. And interestingly, back in the 1950s, Dr. Prichard, looking at a map of Dallas and putting a pin in the map, a very low-tech activity but a pin in the map every time an out-of-hospital birth occurred, and that's where he set up the clinic after he got a cluster of pins, and we as residents would rotate through those clinics back in the 1970s. So they have a longstanding robust outpatient clinic department that is well accepted in the community because it has been there now for almost 50 years. Again, on the other side of the Trinity, we don't have—that is not an established part of what people think about. When they think of John Peter Smith, it is because it is the county hospital, not because there is a community clinic that feeds into that. I just think, you know, we talk about how we spend money, we have got to spend money wisely, I just think that is one of the areas where we perhaps missed an opportunity in this health care bill that we did. Well, we missed a lot of opportunities, but an opportunity we missed in this health care law was recognized in that.

Thank you, Mr. Chairman. You have been indulgent. I will yield back the balance of my time.

Mr. PALLONE. Thank you.

The gentlewoman from the Virgin Islands, Ms. Christensen.

Mrs. CHRISTENSEN. Thank you, Mr. Chairman. I would like to ask unanimous consent to insert into the record written testimony from Dr. Paula Braveman, professor of family and community medicine at University of California San Francisco.

Mr. PALLONE. What is it that you are giving me again?

Mrs. CHRISTENSEN. Written testimony that I would like to insert into the record of today's hearing.

Mr. PALLONE. Oh, OK, from—

Mrs. CHRISTENSEN. Dr. Paula Braveman.

[The information appears at the conclusion of the hearing.]

Mr. PALLONE. Without objection, so ordered.

Mrs. CHRISTENSEN. Thank you. And just for the record, and I know this is not NIH but it is really CDC, but I see no reason why the territories' infant mortality, low birth weight and preterm deliveries are not reported on because we have that data, and I am proud to say that our infant mortality in the Virgin Islands last quarter was 7.56, and I can say I am proud because I know where we came from to get to 7.56, and that is in a largely African American and Puerto Rican community.

Mr. SHIMKUS. Would the gentlelady yield for one second? I think it would be good for the Administration, because she has raised this a couple times that they better be prepared to report on the territories when they come to this committee. We are glad to have her on the committee.

Mrs. CHRISTENSEN. Thank you.

Dr. CALLAGHAN. I will be happy to take that back to National Center for Health Statistics.

Mrs. CHRISTENSEN. Thank you. And thank you, both of you, for raising the issue of the disparities in African Americans that I didn't have to do my opening statement.

Dr. Callaghan, what is puzzling and has been known for a while is that even in African American women who are well off, well educated, live in supportive surroundings, there is still a higher low birth weight baby. They still have higher rates of low weight babies. Is there research being done to determine why this is and are you coming up with—this is sort of following up on the other question, but this is low birth weight babies, not preterm necessarily, not necessarily infant mortality.

Dr. CALLAGHAN. I came to CDC in 2001. Even prior to me coming there, there has been a long history of CDC bringing people together to look at this problem. A lot of the work in what is the social context of pregnancy in African American women and what is the context of African American women in the United States and looking at the long-term effects of institutionalized discrimination and institutionalized race and how does that chronic stress, which is very difficult to measure, there is not a blood test for it, but we know from some qualitative work that that stress exists and we also know that chronic stress plays itself out biologically. There is no question about it. Stress is a biologic phenomenon. There are pathways between what is going on in our brains and our brains are connected to everything, and there has been the hypothesis that some of these stress hormones actually regulate what has

been euphemistically called the placental clock, and that there may be messages coming down that it is time to be born that are not in the best interest of the woman or the baby but that is what is going on. That being said, when we start drawing these pathways, there are so many lines feeding back on to one another that they are almost not even lines anymore, they are this line going up, this line going down and all of a sudden the line becomes a plane.

The more important thing perhaps might be not so much the recognition that stress plays a part but then in the next step so what do we do about this, how can we ameliorate the effects of chronic stress, almost a bigger problem than trying to understand that stress affects our biology. We have done—

Mrs. CHRISTENSEN. Are you actually testing women in any way to see what their level of stress is? You are talking about people who are working in great jobs, have a decent education, and I mean, everybody has stress.

Dr. CALLAGHAN. Right, and in fact, when we look at least epidemiologically, we see that women who like in PRAMS, for example, they ask a lot of question about individual stress and individual stress is much worse when you sort of overlay their neighborhood context, for example, people who live in poor neighborhoods have a more profound response to stress, at least as it relates to preterm, than women who don't. I would like also Dr. Spang to weigh in because NIH is doing a lot of that fundamental work as well.

Mrs. CHRISTENSEN. And before you answer, though, let me just get my second question which is to you, Dr. Spang, and we are glad to hear about the August conference that you are having. In your answer, could you also tell me if the trials with magnesium sulfate, progesterone or treatment of bacterial vaginosis, if those trials are—the people in those trials, are they diverse enough to be able to tell the impact on African American and Latino or American Indian?

Dr. SPONG. I thank you for both of your questions. I am going to take the second question first. The diversity of the patient population in the network is required by the open recompetition every 5 years that the sites are geographically diverse and the population is geographically diverse. And I think one of the best examples is that progesterone was found to be equally beneficial in both African American women and non-African American women, which is so important given the disparities associated, so yes, we do strive for that and we are achieving that at least at this point.

I would like to bring to your attention one study that the NICHD currently has underway called the community child health research network, which is focused specifically on the question you are asking about the African American community disparities in preterm birth as well as infant mortality, and the goal of this network is to involve the community itself along with the academic sites to develop the interventions to try to see if we can understand the disparities when measuring these markers of stress and to try to see if we identify potential interventions.

Mrs. CHRISTENSEN. Thank you. Thank for your answers, and Mr. Chairman, thank you. I yield back the balance of the time I have left.

Mr. PALLONE. I think that completes the questions for this panel. Thank you very much. It was helpful in terms of what we are trying to achieve and we appreciate it. We may send you additional questions from some of the members within the next 10 days to answer in writing as well. But thanks.

I will ask the next panel to come forward. Let me introduce the three of you. First on my left is Dr. Alan R. Fleischman, who is senior vice president and medical director of the March of Dimes Foundation. And next to him is Dr. Charles S. Mahan, who is dean and professor emeritus of the USF College of Public Health, the Lawton and Rhea Chiles Center for Healthy Mothers and Babies. Thank you for being here. And finally, Dr. Hal Lawrence, who is vice president for practice activities of the American College of Obstetricians and Gynecologists. Thank you, Dr. Lawrence.

As you know, we ask you each to speak for about 5 minutes and then later if you want to submit additional materials in writing, you can.

We will start with Dr. Fleischman.

STATEMENTS OF ALAN R. FLEISCHMAN, MD, SENIOR VICE PRESIDENT AND MEDICAL DIRECTOR, MARCH OF DIMES FOUNDATION; CHARLES S. MAHAN, MD, FACOG, DEAN AND PROFESSOR EMERITUS, USF COLLEGE OF PUBLIC HEALTH, LAWTON AND RHEA CHILES CENTER FOR HEALTHY MOTHERS AND BABIES; AND HAL LAWRENCE, MD, VICE PRESIDENT, PRACTICE ACTIVITIES, AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

STATEMENT OF ALAN FLEISCHMAN

Dr. FLEISCHMAN. Thank you, Chairman Pallone, Ranking Shimkus and members of the subcommittee. On behalf of the 3 million volunteers and 1,400 staff members of the March of Dimes, I want to thank the committee for your interest in the public health crisis of premature birth.

As you know, the March of Dimes is a national voluntary health organization founded in 1938 by President Franklin Delano Roosevelt to prevent polio. Today, the foundation works to improve the health of mothers, infants and children by preventing birth defects, premature birth and infant mortality through research, community services, education and advocacy.

After 3 decades of continual increases in the rate of prematurity, the March of Dimes is heartened by the news that the rate of preterm birth has finally leveled off and has begun to decline. But now is not the time to rest on our laurels. The life-threatening and lifelong consequences of prematurity as well as its extraordinary costs in dollars can still be felt by more than half a million babies and their families and each year in the United States some 28,000 babies die before the first year of life due to preterm birth. Prematurity is also the number one cause of neonatal death and is the major contributor to infant mortality. It is responsible for lifelong disabilities.

We have also learned that the complications of being born late preterm, just four to six weeks premature at 34 to 36 weeks' gestation are also significant since one-third of brain growth and devel-

opment occurs in the last 5 weeks of pregnancy. Infants born just 4 to 6 weeks early are more likely than term infants to have significant long-term deficits such as school learning problems, disabilities and lower rate of college education and lower net incomes.

In addition to the severe consequences, the costs of prematurity are immense. The Institute of Medicine estimated the annual societal economic costs associated with preterm birth are at least \$26 billion a year. Approximately half, or 48 percent, of hospital stays for preterm infants are financed by Medicaid. In 2007, hospital costs for these babies averaged \$45,900 each.

In recent years, we have seen several effective interventions to decrease preterm birth through comprehensive quality improvement strategies. The Intermountain Health System in Utah initiated prospective review of all elective inductions and C-sections and were extremely successful with dramatic decreases in early deliveries. Parkland Hospital in Dallas universal access to culturally sensitive comprehensive perinatal services over the past 15 to 20 years including high-quality, evidence-based care with accountability and continuous quality improvement has resulted in the lowest rates of preterm birth among African Americans and indigent Hispanics in the United States.

For the March of Dimes, the Cesarean section question is simple. Every baby should be delivered at the right time for the right reason. We applaud the guidelines and efforts of the American College of Obstetricians and Gynecologists. Adherence to their current guidelines and holding hospitals and clinicians accountable to these standards of care through quality and safety initiatives in hospitals can make a major difference in the rate of preterm birth and is needed in every hospital in the United States.

So we are beginning to see some progress, but to sustain and to be truly successful in reducing the incidence of preterm birth and infant mortality, we require the continuing commitment of the federal government. That is why the March of Dimes is seeking reauthorization of the 2006 PREEMIE Act to support expanded research, education and demonstration projects. My written testimony provides more specific recommendations, but let me be clear: First, further research is essential into the fundamental causes of prematurity, and as the Institute of Medicine report and the surgeon general's conference recommended, transdisciplinary research centers for prematurity funded by the National Institutes of Health with new dollars allocated for these activities will integrate a wide range of disciplines and study this complex problem. Second, we need to reauthorize and expand preterm activities at the CDC Division of Reproductive Health to improve national vital statistics and increase community-based intervention programs, to impact on perinatal health disparities, and third, we need to reestablish the federal interagency coordinating council on prematurity and low birth weight to coordinate federal efforts and keep Congress apprised of progress on the issue of prematurity prevention.

Finally, we hope that one of the outcomes of this hearing is that 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 PREEMIE Act, and I am sure that each of you in the room join of all at the March of Dimes who look forward to

the day when every baby will be born healthy and stay healthy.
Thank you very much.
[The prepared statement of Dr. Fleischman follows:]

Written Testimony
Alan R. Fleischman, M.D.
Senior Vice President and Medical Director, March of Dimes Foundation
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 2008¹ (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 smokes⁴, 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.

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}

⁹ Bettgowda 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 billion¹³ (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 \$10,652¹⁵ (see Addendum D).

¹² Karolina Lindström, Birger Winblad, Bengt Haglund, and Anders Hjerm. "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 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 interventions¹⁸ 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

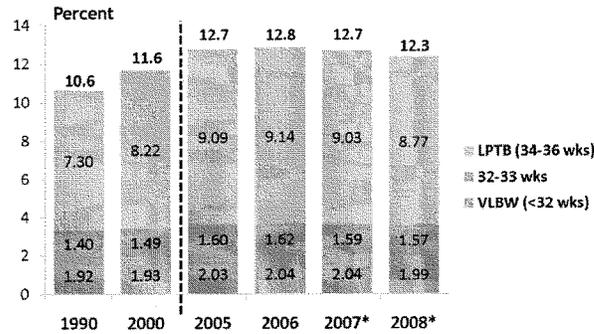
Additionally, the Foundation recommends that the **Health Resources and Services Administration be authorized to award demonstration project grants for the purpose of improving the dissemination of information on prematurity to health professionals and other health care providers and to the public**.

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***



*preliminary
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

Materials for Professionals

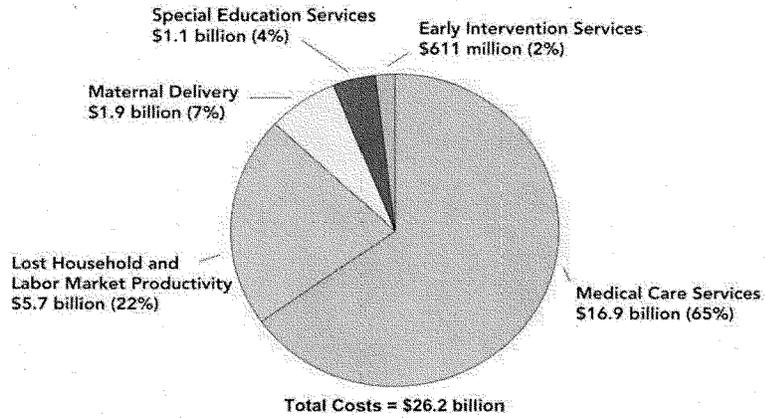
Brain Growth Matters

The brain of a 35 week-old baby is smaller and much less developed than the brain of a baby at 40 weeks.

36 WEEK BRAIN	BRAIN FUNCTION	40 WEEK BRAIN
<ul style="list-style-type: none"> • Smoother, less developed, fewer circuits and connections • Small, only about 1/2 the size it will be at term • Underdeveloped shows up as babies who have apnea - forget to breathe at times 	<ul style="list-style-type: none"> • CEREBRAL CORTEX: site of thinking, reason, learning, motor control, language • CEREBELLUM: where the brain controls balance & coordination, social functioning, hand skills • BRAINSTEM: lower part of the brain where automatic actions of the body are controlled, like breathing, temperature, swallowing 	<ul style="list-style-type: none"> • More developed, more circuits and connections • Grows and develops to almost double the size from 34 weeks • More developed - babies born at 40 weeks rarely forget to breathe.

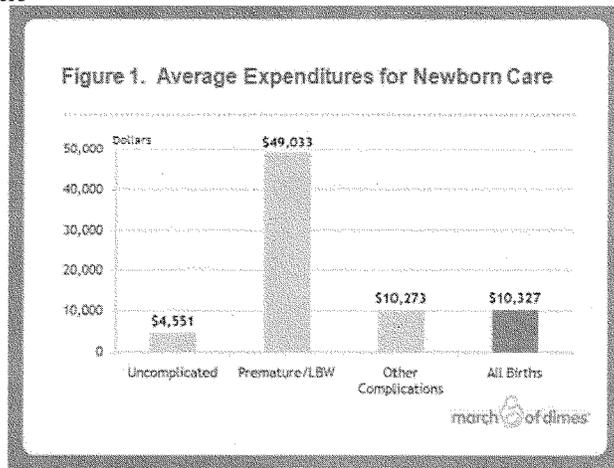
Healthy Babies ARE WORTH THE WAIT

C) Annual Societal Costs Associated with Preterm Birth Institute of Medicine
Annual Societal Economic Costs Associated with Preterm Birth, US, 2005



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



Ms. CASTOR. [Presiding] Thank you, Dr. Fleischman.
Dr. Mahan.

STATEMENT OF CHARLES S. MAHAN

Dr. MAHAN. Madam Chair and members of the committee, I finished my OB/GYN residency 45 years ago, and practiced for the first 20 years, and then morphed into public health and directed the State health department in Florida for 8 years before becoming dean.

I have been asked to speak to two areas by the committee. One was disparities, and the other is some public health steps that we could take immediately and in the fairly short term to start turning this around. A lot of people have also spoken to the disparities. The biggest problems are in African Americans. In Florida, we have the most black births of any State in the union, and our black-white infant death ratio has gone from 1.9 to 1 to 2.6 to 1, and last year we woke up our Hillsboro County and Tampa and found that it was four times the white rate. I have put some statistics there about maternal mortality again which black women suffer much more heavily than white women, and that has already been mentioned.

As far as the causes of infant mortality, there is a chart on my testimony that shows sort of a flow chart that shows how these things develop, and as Dr. Callaghan pointed out, there is a very complex problem. You have root causes of which health and health care are only two, and stress has been mentioned, economics, education, family support, crime. All of these are things that can lead to a problematic outcome of pregnancy. And the two biggest factors that enter into preterm birth are social issues and maternal health when the mother enters pregnancy. By people smarter than I am, it has been predicted that if we corrected and every African American woman got into great health and great health care without addressing those other issues, we may be able to nibble away at 30 percent of this problem. But other countries that have passed us in this area have dealt with the education, the jobs and the other things that are important leading into this issue.

Now, depending on where you live, this isn't just a problem in the black community. I am on the board of the Frontier Nursing Service in Kentucky, and in Appalachia, which is mostly white, we have terrible pregnancy outcomes there also. We have different root causes. Twenty-five percent of our patients at the Frontier Nursing Service are addicted to prescription drugs, and there is very little treatment available and many providers will not accept people that are addicted into their practice.

The other issues that have been studied by Dr. Michael Lu at UCLA and Flita Mass Jackson in Atlanta Morehouse are that black women are victims of what is called weathering, and that is that if you are a black mother that has a low birth weight baby, your low birth weight daughter is more likely to also produce a low birth weight baby and then they predict it may take three or four generations of being upper income to actually shed this weathering system which they think is mostly due to stress. And adding to that, black women have the highest rates of Cesarean of any group in the country.

Now, the second part I was asked is, what public health interventions could we do to reduce prematurity. Well, one thing you could do right now is pick up the phone, call CMS and tell Medicaid to stop paying for elective inductions and Cesareans at any stage of pregnancy, and I don't even agree with ACOG's recommendation of 39 weeks, and we agree that that may be arbitrary, but there is probably no reason a normal woman should ever be induced no matter where she is. The second thing is that in our studies in Florida, we find that women that are agreeing to this, and national studies show that generally when elective things are done, the doctor recommends it, the patient generally does not bring up the subject. In fact, national studies show that less than one-half of 1 percent of patients do. But they are quick to go along with what the doctor recommends. So we have designed some informed consent that is true informed consent showing that elective procedures such as elective Cesarean are hazardous to the health of the mother and the baby. They are not equivalent to having a vaginal birth. And again, these are in low-risk women. And those are part of the attachments you will get. Unfortunately, you don't have them right now.

Vaginal birth after Cesarean has essentially disappeared even though studies show that having a repeat Cesarean is slightly more dangerous to the mother and the baby than having a vaginal birth, so I would propose a new scale of payment for Medicaid that would be something like \$2,000 for a VBAC, \$1,500 for a vaginal birth and \$1,000 for a C-section, which takes less time and effort. Those are immediate steps that could be taken. In the short term, I would say in about a year, we can encourage the development of new pregnancy provider models. Most other countries have a midwife- and doula-based system for primary care for normal women and pregnancy. That can even be used for people that have high-risk problems comanaged with an obstetrician. Although I would recommend, and this is just coming from me, that we stop producing generalist OB/GYNs because as ACOG has pointed out, the young folks coming out today don't want to work on nights and weekends, and turn it over to midwives backed up by an increased number of maternal fetal medicine specialists working with groups of midwives, which is a model that I have worked in in Gainesville over the years. It is a wonderful lifestyle and way to work.

I also put in here pay midwives the same amount as obstetricians get paid for taking care of normal people, but it was pointed out to me that that is already in the new health care bill, so forget that one.

I would encourage the movement to group prenatal care that both ACOG and other groups have recommended instead of individual prenatal care, especially for low-income women, so that they can do some community support of each other.

Ms. CASTOR. Dr. Mahan, can you bring it to a close and we will move on?

Dr. MAHAN. Pardon?

Ms. CASTOR. Can you bring to a—

Dr. MAHAN. Yes. I think develop quality standards, provide pre-conception, interconception care, and then I have an extensive ses-

sion on the cost savings that this could have, which would be to the tune of about \$50 billion.

[The prepared statement of Dr. Mahan follows:]

Testimony

of

Charles S. Mahan, MD, FACOG

DISPARITIES:

The most serious disparities in pregnancy outcomes in the U.S. occur in African-Americans.

Black babies in the U.S. have always been twice as likely to die before their first birthday as white babies but in the last decade these figures have gotten far worse in many states. (Appendix A) In Florida the black/white infant death ratio has gone from 1.9/1.0 in 1970 to 2.6/1.0 in 2005. Last year in Hillsborough County (Tampa) the black infant death rate was 4x that of whites.

Maternal mortality among black women is a serious concern also:

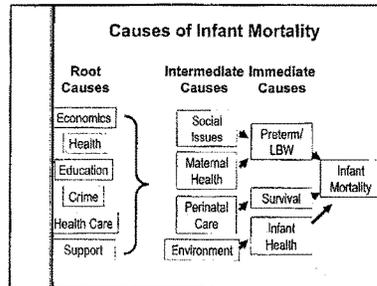
Maternal Mortality – U.S.

<u>1996</u>	<u>2006</u>
Total: 8/100,000	13.3/100,000
Black 20/100,000	33/100,000
White 6/100,000	9.5/100,000

(U.S. goal for 2010 = 4.3/100,000)

Florida has the highest number of black babies born in the U.S. at 56,904 in 2006. (Appendix B)

Many factors enter into causing infant deaths as depicted in the chart below:



Problems with root causes are often more severe in poor black communities in the U.S. However poor white women are often impacted by a different set of root causes, for instance, whites in Appalachia have huge issues with prescription drug abuse with 25% of our pregnant women cared for by the Frontier Nursing Service in Kentucky addicted to oxycodone or similar drugs. The resources to deal with addiction in pregnancy are scarce all over the U.S. and many obstetricians refuse to care for substance abusing pregnant women.

More recent studies of the difficult issue of black infant mortality in the U.S. point to an intergenerational effect – black mothers who themselves were prematurely born are more likely to have premature babies. This effect, called “weathering” by obstetrician Michael Liu at UCLA, seems to defy health care intervention, being so deep-seated in social problems as root causes. Because of this, if the U.S. somehow manages to perfect the delivery of health and health care to black families, it is estimated that, at most, that would impact 30% of the prematurity problem. Adding elective cesareans to the mix (black women in the U.S. have had the highest cesarean rates of any group for over 10 years) only compounds the problem. (Appendix C)

PUBLIC HEALTH INTERVENTIONS TO REDUCE PREMATURITYIMMEDIATE STEPS:

1. Medicaid – stop paying for elective inductions and elective cesareans at any stage of pregnancy – even 39 weeks and above.
2. INFORMED CONSENT – Insist that true informed consent be given to pregnant patients at the beginning of the third trimester to be read and discussed at least 8 weeks before the due date. These should especially highlight the dangers of elective induction and cesarean to the baby. (Appendix D1, D2)
3. Vaginal Birth After Cesarean (VBAC): Put tiered financial incentives for providers in insurance programs to encourage VBAC since babies are healthier after VBAC than repeat cesarean. (Appendix E)

Proposed scale:	VBAC – \$2,000
	Vaginal birth – \$1,500
	C-section - \$1,000

SHORT TERM (1 YEAR):

4. Encourage new pregnancy provider models:
 - Midwives and doulas do basic primary care on all pregnant women and co-manage high risk women with maternal-fetal medicine specialists. (Appendix F, G, H)
 - Pay midwives full amount paid to obstetricians for managing normal pregnancy. (Equal pay for equal work.)
 - Encourage change to group prenatal care (from individual visits).
 - Stop funding the training of generalist OB/GYN's and invest in the training of maternal-fetal medicine specialists to back up groups of midwives.
 - Move away from hospital birth to out-of-hospital birth centers except for high-risk women. (Appendix I, J)
5. Quality Standards:
MCH Bureau (HRSA), AHRQ, CMS and CDC work with MOD and provider organizations (ACOG, ACNM, AAP, APHA, etc.) to outline quality standards for perinatal care and encourage states to use them to build their own state perinatal quality improvement initiatives. (Ohio, California, North Carolina and Florida have already begun this process.) This should include a list of procedures Medicaid will pay for (medical or OB high risk) and those they will not pay for (elective procedures). (Appendix K, L)
6. Preconception and Interconception Care:
Building on the excellent work of the CDC and MOD the past four years, Medicaid and private insurance companies should develop a panel of pre-pregnancy

interventions (diabetes & HIV testing, folic acid Rx, etc.) that providers can use to be sure the woman and her family are ready for a pregnancy and then advertise so that pre-pregnancy visits become as routine as prenatal care itself.

In the interconception period all women should receive a pregnancy spacing method of their choice and the provider should be paid a fair price for this service. (Not happening now in some states' Medicaid waivers.) Women with chronic diseases (diabetes, hypertension) should be followed closely between pregnancies and not just dropped by insurance after the post-partum visit as they are now in many parts of the country.

7. COST SAVINGS:

Pregnancy is the number one diagnosis for hospital admissions in the U.S. and cesarean is the number one operation performed.

Maternal and newborn charges – U.S.

2005 - \$79B

2006 - \$86B

More than \$2.5B was spent on unnecessary cesareans. Eliminating elective inductions and cesareans would also save hundreds of millions of dollars in unnecessary NICU admissions but untold amounts in the long term expenses of late preterm birth (special education, etc.) due to lack of brain development. (Appendix M, N, O, P)

Conclusion:

Elective induction and cesarean and the resulting late preterm births are serious public health problems in the U.S. – and quickly preventable. (Appendix PP)

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Addendum: DeClercq numbers analysis (appendices Q →FF)

Ms. CASTOR. Thank you very much.
Dr. Lawrence.

STATEMENT OF HAL LAWRENCE

Dr. LAWRENCE. Thank you, Representative Castor and Chairman Pallone and the distinguished members of the subcommittee. My name is Dr. Hal Lawrence and I am an obstetrician/gynecologist and ACOG's vice president of practice activities. I am here today representing 53,000 physicians and partners in women's health care.

Preterm birth is one of the most complicated and difficult issues in obstetrics. As a Nation, we still don't know very much about the risk factors, the causes or prevention of preterm labor. We do know that preterm labor is the most common cause of hospitalization before birth, that there is a link between preterm birth and infant mortality, that the rate of preterm births is a growing public health problem that cuts across social, racial, ethnic and economic groups and that our Nation must do better.

ACOG firmly believes that we can make a difference and we are committed to leading the change and we are very clear that deliveries before 39 weeks' gestation should only occur when an accepted medical maternal or fetal indication for delivery exists. We have been intimately involved in a number of efforts over the years to improve research and practice guidelines to reduce the rate of premature births in America.

ACOG is the nationally recognized source for clinical guidelines and medical information that help shape maternity care based on evidence-based peer-reviewed science and some expert opinion. These include practical information on late preterm births, management of preterm labor, assessment of risk factors for preterm birth, use of progesterone to reduce preterm birth and obesity in pregnancy. But where research has not been conducted, clinical guidelines have to wait. Preterm birth can occur in any pregnancy and our current clinical tools cannot determine a woman's risk except for women, as you have already heard, who have had previous preterm births, the only clear risk factor. Even so, the ability to predict whether a woman is at risk of preterm delivery has value only if an intervention is available to reduce or eliminate that risk, and right now we have very few effective interventions. Better research can be translated into more complete clinical guidelines and better care.

ACOG has been intimately involved in a number of other efforts to advance our knowledge in this area including the 2006 Institute of Medicine report on preterm birth, the surgeon general's 2008 conference on the prevention of preterm birth, and the 2009 Symposium on Quality Improvement to Prevent Prematurity that we did with the March of Dimes. These efforts identified gaps in clinical knowledge and research, many of which ACOG in our MOMS Initiative, and that stands for Making Obstetrics and Maternity Safer, called on Congress to support, and those include NIH research to reduce preterm births and the focus on obesity, CDC's surveillance and research to assist State maternity mortality reviews, modernized State birth and death record systems, and improve the safe motherhood program, the HRSA fetal and infant

mortality review, which brings together local OB/GYNs and health departments to reduce infant mortality rates and improve the maternal child health block grant, comparative effectiveness research into preterm birth interventions and efficacy, disparities research, testing the obstetric medical home to address the unique issues of pregnancy and supporting quality improvement measures.

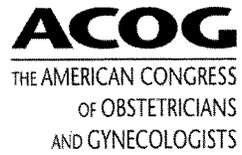
It is also impossible not to also mention the link medical liability and the practice of obstetrics performing deliveries. In the world of childbirth, a perfect pregnancy can turn disastrous in a heartbeat, and through no fault or malpractice of the obstetrician/gynecologist. Vaginal births after Cesarean sections, VBACs, can seem perfectly normal until something goes wrong. At that moment, one and sometimes two lives can be on the line and seconds count. It is often in these scenarios that OB/GYNs get sued and result in very large awards regardless of the physician's care. The risk is really that great. ACOG recommends exploring medical liability alternatives including early offer programs, health care courts, alternative dispute resolution and birth injury compensation funds, and I would like to thank Representatives Pitts and Gingrey for your attention to this important issue in your earlier comments.

I would also like to thank Representative Burgess, who plans to introduce a bipartisan piece of legislation extremely relevant to today's hearing. His legislation will provide for research on birth defects and breast feeding to help educate women on ways to reduce the risk to their babies and have healthy pregnancies. Once introduced, I urge the subcommittee to quickly take up this legislation.

I would also like to thank Chairman Pallone. ACOG has been fortunate to be able to work with his staff and thank him for his focus on stillbirth and sudden infant death, and we look forward to offering support as that legislation goes forward.

Again, I would like to thank you for this opportunity to provide this statement. A written statement of my comments has been supplied, and we applaud your commitment and leadership on this issue. We look forward to working closely with you and the subcommittee. Thank you.

[The prepared statement of Dr. Lawrence follows:]



Testimony of

Dr. Hal C. Lawrence, III, M.D., F.A.C.O.G.

Vice President, Practice Activities

American Congress of Obstetricians and Gynecologists

Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early?

Before the House Committee on Energy and Commerce

Subcommittee on Health

Thank you, Chairman Pallone, for holding today's important hearing and inviting testimony from the American Congress of Obstetricians and Gynecologists (ACOG). My name is Dr. Hal Lawrence. I am an obstetrician-gynecologist and ACOG's Vice President of Practice Activities. I am here today representing 53,000 physicians and partners in women's health care and it is my pleasure to offer this statement to the House Committee on Energy and Commerce, Subcommittee on Health on the issues of prematurity and infant mortality.

With the passage of health reform, this is a very good time to examine what more we can do to reduce prematurity and infant mortality rates in the U.S. We look forward to working closely with you, Mr. Chairman, and Members of the Subcommittee on a variety of measures to get us to that goal.

Preterm birth is the leading cause of neonatal mortality in the United States, and accounts for approximately 35% of all U.S. health care spending for infants and 10% for children. According to preliminary 2008 NCHS data, over half a million babies were born preterm representing 12.3% of all live births occur before term in the United States. About two-thirds of all infant deaths are among preterm infants. Slightly more than one-third of which are officially designated preterm-related, i.e., there is sufficient information recorded to ascribe being born preterm as the fundamental contributor to death.

Preterm birth is one of the most complicated and difficult issues in obstetrics. As a Nation, we still don't know very much about the causes of preterm labor. We do know, though, that the rate of preterm births in the United States is a growing public health problem that cuts across social, racial, ethnic, and economic groups. We know that preterm labor is the most common cause of antenatal (before birth) hospitalization. And we know that there is a link between preterm birth and infant mortality.

Unique among all health events, infant death is always viewed as a measure of a community's social and economic well-being, as well as its health. It is also a measure of the organization and capability of a community's health services and community resources. Often infant deaths leave families and communities with few answers, asking: "Can anything be done to prevent this in the future?"

ACOG firmly believes that the answer is a resounding yes, we can make a difference in the future. ACOG will continue its long history of leadership and collaboration with other stakeholders to make this happen.

This year, ACOG President Dr. Gerald F. Joseph, Jr. launched the Making Obstetrics and Maternity Safer (MOMS) Initiative, a multi-pronged campaign to improve maternal and infant outcomes by filling the glaring gaps in research and understanding. ACOG's clinical guidelines that help shape maternity care in America are based on evidenced-based, peer-reviewed science and expert opinion. Our guidelines are limited, though, to clinical areas that have been well-researched. Where the research has not been conducted, clinical guidelines have to wait. **Congress has a unique opportunity to fund research that will provide the underpinnings for our guidance for practicing ob-gyns and other maternity care providers.**

PRETERM BIRTH

In most pregnancies, labor starts between 37 and 42 weeks gestation. Labor before 37 weeks gestation is considered preterm. According to preliminary 2008 data from the National Center for Health Statistics (NCHS), approximately 12.3% of babies born in the United States are born preterm and these preterm births account for most newborn deaths.

Growth and development in the last part of pregnancy are vital to the baby's health. In fact, the earlier a baby is born, the greater the chance he or she will have health problems. Babies born preterm tend to grow more slowly than babies born at term, and often have problems with their eyes, ears, breathing, and nervous system; and experience learning and behavioral problems.

While preterm labor can occur in any pregnancy without warning, we know that some women are at greater risk. Obese women, women who have little or no prenatal care and those who have had preterm labor before are at increased risk. So are women for whom too much amniotic fluid is in the sac that surrounds the baby. Problems with the placenta or birth defects also increase the risk. Certain health factors may be linked to an increased risk for preterm birth, including short cervical length or maternal developmental abnormalities, which are structural abnormalities of the uterus. However, for many women preterm labor occurs without a known cause.

There are medical reasons why the baby is better off being born, even if it is early, including maternal infection, high blood pressure, bleeding, or signs that the fetus is having problems. Sometimes preterm labor may be too far along to be stopped. Preterm babies may need to be cared for in a neonatal intensive care unit (NICU) for weeks or even months.

Women at risk for preterm labor can help reduce their risks by refraining from smoking or abusing drugs. Assuring safe environments to protect women from intimate partner violence is also important. Healthy habits also help ensure healthy pregnancies, including eating healthy food, not skipping meals, and following the doctor's advice.

ACOG'S CLINICAL GUIDELINES

ACOG is the nationally recognized source for developing clinical guidelines and communicating technical and scientific information for our specialty of women's health and obstetrics and gynecology. In a recent membership survey, ACOG found that nearly 98% of respondents were aware of ACOG guidelines, and 96% of respondents reported that they had used those guidelines over the previous five years. Sixty-one percent responded that an ACOG publication or guideline changed their practice within the last two years. ACOG Practice Bulletins were ranked first by ACOG Fellows, followed by ACOG Committee Opinions, as the sources used most often to stay informed about advances in research, practice trends, and ethics in obstetrics and gynecology.

ACOG issues guidelines and recommendations for obstetric-gynecologic practice in four primary vehicles: Committee Opinions, Practice Bulletins, Guidelines, books and reports. We develop our recommendations and guidelines through a rigorous peer review and approval process, utilizing standing committees or special task forces composed of experts in the field that

continually examine and update existing guidelines for clinical practice based on the most up-to-date scientific and medical literature, as well as expert opinion where data are lacking. Representatives from many related specialty societies, voluntary organizations, and federal agencies also serve on our committees and work groups.

ACOG has a number of Committee Opinions and Practice Bulletins addressing premature births, bulleted and summarized here.

- Late-Preterm Births

Late-preterm births, defined as deliveries after 34 and before 37 weeks, make up 71% of all preterm births. Late-preterm infants are at higher risk of developing medical complications, resulting in higher rates of infant mortality, morbidity before initial hospital discharge, and hospital readmission in the first months of life. Late-preterm infants are 4 times more likely than term infants to have at least 1 medical condition and 3.5 times more likely to have 2 or more conditions. The neonatal mortality rate (deaths among infants 0–27 days chronologic age) for late-preterm infants is much higher than the rate for term infants.

ACOG is very clear that deliveries before 39 weeks gestation should occur only when an accepted medical maternal or fetal indication for delivery exists.

- Management of Preterm Labor

It is important to recognize that preterm labor is not the only mechanism leading to preterm birth; numerous preterm births are preceded by rupture of membranes or other medical problems. In fact, 80% of women with presumptive preterm labor do not progress to preterm delivery.

A physician's ability to determine the risk of preterm delivery with clinical accuracy is seriously hampered by the large variations in symptoms of preterm labor and the inability of our current clinical tools to precisely determine a woman's risk. In earlier days, when a patient had symptoms of preterm delivery, her doctor was likely to handle this uncertainty by recommending an abundance of caution, including reduced maternal activity and administering fluids with the aim of stopping the uterine activity. Many of these early interventions have proven to be ineffective.

- Assessment of Risk Factors for Preterm Birth

The functional changes that trigger preterm labor are largely unknown but may include decidual hemorrhage (abruption), mechanical factors (uterine overdistention or cervical incompetence), and hormonal changes, perhaps mediated by fetal or maternal stress.

Risk factors for preterm birth include demographic characteristics, behavioral factors, and aspects of obstetric history. Despite the identification of a number of risk factors, attempts to determine the risk of preterm delivery based on historic and epidemiologic risk scoring systems have been unable to reliably identify women who will give birth preterm. **The ability to predict**

whether a woman is at risk of preterm delivery has value only if an intervention is available that is likely to improve the outcome.

- Obesity in Pregnancy

The prevalence of obesity in the United States has increased dramatically over the past 20 years to the point where, today, one third of adult women are obese. During pregnancy, obese women are at increased risk for several adverse outcomes, including complications related to anesthesia and necessary surgical procedures. Multiple studies have shown that maternal obesity and excessive weight gain during pregnancy are associated with large-for-gestational-age infants who are at increased risk for childhood obesity.

Studies consistently report higher rates of preeclampsia, gestational diabetes, and cesarean delivery for failure to progress in obese women. **Some studies have reported a greater rate of premature delivery for obese women.** Operative and postoperative complications include increased rates of excessive blood loss, operative time greater than 2 hours, wound infection, and endometritis. Surgery in obese women poses anesthetic challenges, such as difficult epidural and spinal placement requiring multiple attempts and intraoperative respiratory events from failed or difficult intubation. Sleep apnea may further complicate anesthetic management and postoperative care for these women.

Obese women who require cesarean delivery are more likely to have an increased incidence of wound breakdowns and infections. Because of the increased likelihood of complicated and emergency cesarean delivery, extremely obese women may require additional blood products, a special operating table, and extra personnel in the delivery room. The success rate of attempted vaginal birth after cesarean delivery is very low in extremely obese women.

- Use of Progesterone to Reduce Preterm Birth

Progesterone is one strategy to reduce pre-term birth. **However, based on current knowledge, it is important to offer progesterone for pregnancy prolongation to only women with a documented history of a previous spontaneous birth at less than 37 weeks of gestation.**

Progesterone supplementation for the prevention of recurrent preterm birth should be offered to women who are carrying only one fetus, not multiples, and who have had a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes. Current evidence does not support the routine use of progesterone in women with multiple gestations. Progesterone supplementation may be considered for women with an identified very short cervical length (less than 15 mm) but who have no other symptoms.

ACOG's Committee on Obstetric Practice and the Society for Maternal Fetal Medicine believe that further studies are needed to determine if progesterone therapy can be designed to help prevent preterm delivery in other ways, including optimal preparation, dosage, and route of administration.

CLINICAL and RESEARCH GAPS IN KNOWLEDGE IDENTIFIED

ACOG supported and was intricately involved in the two most recent major initiatives to examine the issue of preterm birth; the Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention and the Surgeon General's Conference on the Prevention of Preterm Birth

Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention

The Institute of Medicine's (IOM) 2006 Report, Preterm Birth – Causes, Consequences, and Prevention identifies a number of gaps in clinical knowledge. Upon review of the literature assessing the causes and consequences of preterm birth, the diagnosis and treatment of women at risk for preterm labor, and treatments for infants born preterm, the IOM proposed a research agenda for investigating the problem of preterm birth that is intended to help focus and direct research efforts.

The priority areas developed for research include the need to:

- Improve national data, including standardization of birth certificate reporting as advocated by ACOG;
- Study the economic outcomes for infants born preterm;
- Improve the methods of identifying and treating women at risk for preterm labor;
- Study the acute and the long-term outcomes for infants born preterm;
- Study infertility treatments and institute guidelines to reduce the number of multiple gestations;
- Improve the quality of care for women at risk for preterm labor and infants born preterm;
- Investigate the impact of the health care delivery system on preterm birth;
- Investigate the etiologies of preterm birth;
- Study the multiple psychosocial, behavioral, and environmental risk factors associated with preterm birth simultaneously; and
- Investigate racial-ethnic and socioeconomic disparities in the rates of preterm birth.

Surgeon General's Conference on the Prevention of Preterm Birth

To address the serious and seemingly intractable problem of preterm birth, the Surgeon General's 2008 Conference on the Prevention of Preterm Birth convened many of the country's experts from the public and private sectors of research, public health, and health care delivery to discuss preventive strategies.

With the support and participation of ACOG, the Conference adopted the following recommendations:

- Biomedical Research - A better understanding of the basic mechanisms underlying its etiology must be established, including the role of such factors as infection, inflammation, abnormal implantation and placentation, and gene-environment interactions.
- Epidemiological Research - Epidemiologic research must address the heterogeneity of preterm birth and identify methods to characterize preterm births according to underlying causes.

- Psychosocial and Behavioral Considerations - Research on the effects of race, racism, and social injustice for African Americans must be a priority as they bear the highest burden of prematurity.
- Professional Education and Training - The education and training of professionals on preterm birth should be comprehensive, targeted to the discipline, incorporate the social determinants of health, and provide skills enabling them to educate the public and patients.
- Public Communication and Outreach - Several potential audiences should be made aware of the most recent research findings on preterm birth, including women of reproductive age and their families, health care providers, medical/health institutions, and both government and nongovernment policymakers.
- Quality of Care and Health Services – The care and treatment of women before and during pregnancy should be equitable, individualized, and consistent across populations. Health care systems and practitioners should implement practices that are known to be effective and should collect data about the quality of patient care and services provided.

Specific Knowledge Gaps Identified by ACOG

In consideration of the broad recommendations from IOM, the Surgeon General's Report, and the apparent knowledge gaps evidenced in ACOG's clinical material, below are important specific gaps that could be addressed with additional research investments.

- Improved assessment tools are needed to address the large variations in symptoms of preterm labor and the inability of routine clinical tools to precisely determine a woman's risk;
- Evidenced-based research on interventions to delay or prevent preterm delivery;
- Comparison studies of the effectiveness of different drugs used to prevent or slow preterm labor and birth;
- Studies to evaluate the optimal preparation, dosage, route of administration, and other indications for the use of progesterone to prevent preterm delivery;
- Studies on the association of multiple gestations, i.e. twins, to the risk of preterm delivery;
- Studies on bacterial infections that have been associated with preterm labor to better understand if their effect and nature of association;
- Research and interventions to address the increased risk for poor outcomes in obese women; and
- Research into the disproportionately higher rate of preterm birth among African American women that cannot be accounted for by known risk factors.

ACOG'S MAKING OBSTETRICS AND MATERNITY SAFER (MOMS) INITIATIVE

Due the magnitude of the problem, it is essential that we address the issue in a comprehensive manner. We must make well-informed and targeted investments to help lower the rate of prematurity, and remember that the health of every baby starts with the health of its mother. For this reason, ACOG developed our MOMS Initiative, a legislative proposal to improve maternal and infant health outcomes through:

- Maternal/infant health research at the NIH to reduce the prevalence of premature births and to focus on obesity research, treatment, and prevention;

- Maternal/infant health research and surveillance at the CDC to assist states in setting up maternal mortality reviews; modernize state birth and death records systems to the 2003-recommended guidelines; and improve the Safe Motherhood Program to better understand maternal deaths;
- Maternal/infant health programs at HRSA to continue the Fetal and Infant Mortality Review (FIMR) which brings together local ob-gyns and health departments to solve a community's problems related to infant mortality; and improve the Maternal Child Health Block grant, the only federal program that exclusively focus on improving the health of mothers and children;
- Comparative effectiveness research into interventions for preterm birth;
- Disparities research into maternal outcomes, preterm birth and pregnancy-related depression;
- The development, testing and implementation of quality improvement measures and initiatives;
- The testing of an obstetric medical home model.

- Maternal Mortality Reviews

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. CDC should fund states to implement maternal mortality reviews that would allow them to conduct regular reviews of all maternal deaths within the state to identify causes, factors in the communities, and strategies to address the issues. Maternal mortality reviews are now conducted in only 15 to 20 states. Combined with adoption of the recommended birth and death certificates in all states and territories, CDC could collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity.

- Electronic Birth and Death Records

Currently, only 75 percent of states and territories use the standardized 2003 birth certificates and 65 percent have adopted the 2003 death certificate. The National Vital Statistics System (NVSS) needs federal support to help states and territories implement the 2003 birth certificate and modernizing their infrastructure to collect these data electronically to expand the scope and quality of data collected on a national basis. NVSS will need \$3 million to phase in the 2003 death certificate and electronic death records in all states and territories. CDC should work with the Centers for Medicare and Medicaid Services and the Office of the National Coordinator to pilot test the integration of electronic birth and death records and electronic medical records.

- National Fetal Infant Mortality Review

Since 1990, the Maternal Child Health Bureau has worked in cooperative agreement with ACOG to run the National Fetal Infant Mortality Review (NFIMR) program. NFIMR provides training and assistance to enhance cooperative partnerships among local community health professionals, public health officers, community advocates and consumers to reduce infant mortality. The goal

is to improve local services and resources for women, infants and families, to remove barriers to care, and to ensure culturally appropriate, family friendly services.

These efforts are crucial to understanding and addressing infant health disparities in communities at highest risk and are a component of many existing Healthy Start Initiatives. A rigorous national evaluation of FIMR conducted by Johns Hopkins University concluded that FIMR is an effective perinatal initiative. The Bureau should continue to use Healthy Start funds to support the NFIMR project and encourage all Healthy Start Programs to implement FIMR.

- Obesity Research, Treatment and Prevention

Obese pregnant women are at increased risk for poor maternal and neonatal outcomes. Additional research and interventions are needed to address the increased risk for poor outcomes in obese women receiving infertility treatment, the increased incidence of birth defects and stillbirths in obese pregnant women, ways to optimize outcomes for obese women who become pregnant after bariatric surgery, and their babies' increased risk of childhood obesity.

- Comparative Effectiveness Research into Preterm Birth and Pregnancy-Related Depression

Support for AHRQ's comparative effectiveness research initiatives is needed in order to better understand the range of interventions for preterm labor, such as different drugs and preventive tools in diverse patient populations. Research evaluating the efficacy of perinatal/postpartum screening tools and whether they can impact the outcome of pregnancy and perinatal depression is also needed.

- Health Disparities Research in Women

Women of racial and ethnic minorities face higher rates of diseases including obesity, cancer, diabetes, heart disease, and HIV/AIDS. There is also a disproportionately higher rate of preterm births among African American women that cannot be accounted for by known risk factors. HHS should conduct research into the causes of health disparities and develop and evaluate interventions to address these causes. Also, the continued and expanded collection of data capturing racial and ethnic information is essential in understanding and eliminating disparities.

- Safe Motherhood/Infant Health

Late-preterm births make up 71% of all preterm births. Funding should be directed to CDC to improve national data systems to track preterm birth rates and expand research that focuses on the causes and prevention of preterm births.

- Preterm Birth Research

According to preliminary NCHS data, over half a million babies were born preterm in 2008, representing 12.3% of live births. NICHD needs increased funding to expand its support of preterm birth research. Congress should help explore the feasibility of establishing integrated

research centers at NIH as recommended by the Institute of Medicine and the Surgeon General's Conference on the Prevention of Preterm Birth. Specifically, NICHD needs additional financial support for planning activities related to the establishment of Transdisciplinary Research Centers for Prematurity.

- Quality Improvement Measures and Initiatives

ACOG urges Congress and the Administration to support these efforts and assist in the dissemination and voluntary adoption of quality measures in both the Medicare and Medicaid programs. ACOG is currently engaged through the PCPI in development of maternity care quality measures. The PCPI process is the gold standard for national development, testing, and maintenance of scientific evidence-based clinical performance measures at the physician/clinician/group level, balanced with stakeholder engagement, public comment, and transparency and spearheaded by clinician ownership, accountability and professionalism. We look forward to maintaining and improving current measures, developing new clinical measures in other facets of obstetrical and gynecologic care and expanding national data collection and aggregation initiatives on all aspects of women's health care through both voluntary data registry participation for physicians and facilities and mandatory certification and accreditation programs like American Board of Obstetrics and Gynecology Maintenance of Certification and The Joint Commission.

- Obstetric Medical Home Model

The testing of a women's medical home, with particular attention to maternity care, is an important opportunity to facilitate the improvement of health outcomes in the United States and reduce duplicate and inappropriate utilization of services. Medical homes are rooted in the principle that care coordination, increasing health care access, patient-provider communication, and collaborative care are fundamental to improving patients' health. This delivery model has the potential to address the unique issues that arise during pregnancy and may be able to address troubling health disparities in certain populations of pregnant women. CMS should test a model in the Medicaid program, which finances approximately 42% of the nation's births.

OTHER ISSUES OF IMPORTANCE

Elective Inductions

In more than 22% of all pregnant women in the U.S. labor is induced, and the overall labor induction rate has more than doubled since 1990 to 225 per 1,000 live births in 2006. The goal of induction of labor is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Induction has merit when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy. The benefits of labor induction must always be weighed against the potential maternal and fetal risks associated with this procedure.

ACOG stipulates that unless a medical indication exists, labor induction or a scheduled elective delivery should not be done before 39 weeks of pregnancy. Indications for induction of labor are not absolute, but should take into account maternal and fetal conditions, gestational

age, cervical status, and other factors. Following are examples of maternal or fetal conditions that may be indications for induction of labor:

- Abruptio placentae;
- Isoimmunization, i.e. Rh disease;
- Chorioamnionitis;
- Fetal demise;
- Gestational hypertension;
- Preeclampsia, eclampsia;
- Premature rupture of membranes;
- Postterm pregnancy;
- Maternal medical conditions (eg, diabetes mellitus, renal disease, chronic pulmonary disease, or chronic hypertension); and
- Fetal compromise (eg, severe fetal growth restriction or a deficiency in amniotic fluid.)

Labor also may be induced if the patient is at risk for very rapid labor, if she lives an unsafe long distance from the hospital, or if she has serious mental health indications. Even in these circumstances, at least one of the established gestational age criteria should be met or fetal lung maturity should be established. A mature fetal lung test result before 39 weeks of gestation, in the absence of appropriate clinical circumstances, is not an indication for delivery.

The individual patient and clinical situation must always be considered in determining when induction of labor is indicated.

Maternal Caesarean Delivery Request

Cesarean delivery on maternal request is defined as a primary cesarean delivery requested by the patient in the absence of any medical or obstetric indication. ACOG is clear that **cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity**. Cesarean delivery on maternal request should not be motivated by the unavailability of effective pain management.

Cesarean delivery on maternal request is not recommended for women desiring several children, given that the risks of placenta previa, abnormal placental adherence, and the need for hysterectomy increase with each cesarean delivery. Other risks include a longer maternal hospital stay, an increased risk of respiratory problems for the baby, and greater complications in subsequent pregnancies, including uterine rupture and placental implantation problems.

Literature on elective cesarean delivery without labor shows that the risk of respiratory morbidity, including transient rapid breathing of the newborn, respiratory distress syndrome, and persistent pulmonary hypertension, is higher for elective cesarean delivery compared with vaginal delivery when delivery is earlier than 39–40 weeks of gestation. Because of these potential complications, cesarean delivery on maternal request should not be performed before gestational age of 39 weeks has been accurately determined unless there is documentation of lung maturity.

Babies can benefit, too, by medically indicated planned cesarean delivery. Benefits can include lower fetal mortality; lower newborn infection rate; reduced risk of intracranial hemorrhage diagnosis, neonatal asphyxia, and encephalopathy; and fewer birth injuries.

Further research is needed to get direct evidence for better counseling for women in the future. This includes surveys on cesarean delivery on maternal request, modification of birth certificates and Current Procedural Terminology coding to facilitate tracking, prospective cohort studies, database studies, and studies of modifiable risk factors for cesarean delivery on maternal request versus planned vaginal delivery. Short-term and long-term maternal and neonatal outcomes as well as cost need further study.

ACOG's Task Force on Cesarean Delivery Rates

In 1995, ACOG held a focus session to determine ways to reduce cesarean delivery rates. This focus session led to the appointment in 1997 of ACOG's Task Force on Cesarean Delivery Rates, which was convened to assess the factors that contribute to the cesarean delivery rate in the United States, review ways to reduce these rates, and develop guidance material for our members and other concerned institutions.

The Task Force was charged with assisting institutions and individual practitioners assess and, if appropriate, reduce their cesarean delivery rates. The Task Force developed the report entitled the *Evaluation of Cesarean Delivery*.

The factors that have contributed to the increased cesarean delivery rate in the United States over the last 25 years are not completely understood. The report showed a wide variation in cesarean delivery rates between practitioners, hospitals, and geographic regions of the United States, and between patient characteristics including payer type, socioeconomic status, ethnicity, and education. Aspects of physician practice, including solo versus group practice, employment status, in-house coverage, and education, also appear to be associated with variations in cesarean delivery rates.

From this research, it appears that the most dramatic increase in primary cesarean delivery rates was found in patients in their first pregnancy, with normal term single fetuses and with vertex presentations. It was not apparent, though, that higher cesarean delivery rates in these lower-risk patients result in improved outcomes. Accordingly, it would seem appropriate to focus on these patients when evaluating strategies for lowering the primary cesarean delivery rate.

Although cesarean delivery rate analysis may help obstetric institutions and practitioners adjust their practice patterns, cesarean delivery rates alone are not an indicator of quality. All practitioners have some patients in their practices who are at increased risk for needing to be delivered by cesarean, regardless of management practices. Therefore, unadjusted cesarean delivery rates cannot be used to assess the quality or appropriateness of individual institutions or obstetric practitioners. Cesarean delivery rates must be adjusted for case mix to have any value.

The following variables should be examined when cesarean deliveries are performed:

- Cervical dilatation was less than 4 cm;
- In the presence of intact membranes;
- Without appropriate use of oxytocin;
- After the patient has received an epidural when cervical dilatation was less than 4 c;
- After the patient has undergone elective induction of labor at less than 41 weeks of gestation;
- Without trial of labor for suspected macrosomia in nondiabetic women;
- For failed induction of labor for suspected macrosomia in nondiabetic women;
- For the sole indication of twin gestation; and
- For the indication of term fetuses with breech presentations, without offering external cephalic version.

Medical Liability

When addressing the issue of delivery rates, it is impossible to not also mention the medical liability problem that disproportionately targets obstetricians. Our Nation provides exceptional medical education, training some of the world's finest obstetricians and gynecologists. Yet, 90% of ACOG Fellows report they have been sued at least once. On average, ob-gyns are sued 2.7 times during their careers, and nearly 63% have made changes to their practice during the last three years because of the high risk of liability claims. 35% have either decreased the number of high-risk obstetric patients treated or have ceased providing obstetric care altogether; 29.1% reported increasing the number of cesarean deliveries; and 25.9% indicated they stopped performing or offering VBACs due to professional liability concerns.

In the world of childbirth, a "perfect" pregnancy can turn disastrous in a heartbeat, and through no fault or malpractice of the ob-gyn. Vaginal births after c-sections can seem perfectly normal until something goes wrong. At that moment, one and maybe two lives can be on the line and seconds count. It's often in these scenarios that ob-gyns get sued and result in very large awards, regardless of the physician's care. The risk is really that great.

A recent study conducted by staff from the Harvard School of Public Health and the Harvard Medical School for the Medicare Payment Advisory Commission showed caps on non-economic damages to be predictive of lower rates of cesarean delivery. Additionally, one study found that states with pretrial screening panels had significantly lower rates of cesarean delivery and higher rates of vaginal birth after cesarean delivery. Finally, another study of obstetrical practice found that joint-and-several liability reform led to decreased use of cesarean delivery and induction or stimulation of labor.

ACOG has for many years advocated reform of our broken medical liability system, including caps on non-economic damages, and other reforms like those found in Texas and California. We will continue to fight for those reforms on behalf of our specialty and our members. At the same time, we strongly support alternatives, including sorry works programs and health courts, that can help reduce the need for defensive medicine and improve patient safety.

ACOG highly recommends exploring ways to reduce rates of caesarean delivery through state and federal experimentation on medical liability reform. We urge Congress to assist states foster **meaningful** alternatives to current medical tort litigation that improve patient safety and quality

of care, provide fair and prompt compensation for medically-related injuries, restore fairness and reliability to the medical justice system, and reduce defensive medicine. These alternatives can include early offer programs, healthcare courts, voluntary alternative dispute resolution, and birth injury compensation funds.

RECOMMENDATIONS

ACOG's MOMS Initiative

ACOG strongly urges Congress to implement the MOMS Initiative to develop and apply evidence-based interventions, and improve maternal and infant health outcomes through funding research to:

- Reduce the prevalence of premature births;
- Focus on obesity research, treatment, and prevention.
- Assist states in setting up maternal mortality reviews;
- Modernize state birth and death records systems to the 2003-recommended guidelines;
- Improve the Safe Motherhood Program to better study pregnancy-related deaths.
- Continue the Fetal and Infant Mortality Review (FIMR);
- Improve the Maternal Child Health Block grant;
- Carry-out comparative effectiveness research into interventions for preterm birth;
- Perform disparities research into maternal outcomes, preterm birth and pregnancy-related depression;
- Test the obstetric medical home model
- Support quality improvement measures and initiatives

Institute of Medicine's (IOM) Report Preterm Birth – Causes, Consequences, and Prevention

ACOG supports the Institute of Medicine's (IOM) 2006 Report, Preterm Birth – Causes, Consequences, and Prevention report. The IOM proposed a research agenda for investigating the problem of preterm birth and is an essential guide for focusing and directing research efforts to:

- Improve national data;
- Study the economic outcomes for infants born preterm;
- Improve the methods of identifying and treating women at risk for preterm labor;
- Study the acute and the long-term outcomes for infants born preterm;
- Study infertility treatments and institute guidelines to reduce the number of multiple gestations;
- Improve the quality of care for women at risk for preterm labor and infants born preterm;
- Investigate the impact of the health care delivery system on preterm birth;
- Investigate the etiologies of preterm birth;
- Study the multiple psychosocial, behavioral, and environmental risk factors associated with preterm birth simultaneously; and
- Investigate racial-ethnic and socioeconomic disparities in the rates of preterm birth.

Surgeon General's Conference on the Prevention of Preterm Birth

ACOG supports the implementation of the following recommendations adopted by the Conference:

- Biomedical Research
- Epidemiological Research
- Psychosocial and Behavioral Considerations
- Professional Education and Training
- Public Communication and Outreach
- Quality of Care and Health Services

PREEMIE Act Reauthorization

ACOG is proud of its support of the 2006 passage of the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE) Act. This legislation was passed unanimously by the House and Senate and signed into law to help identify the causes of prematurity and reduce the episodes of preterm labor and delivery.

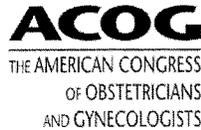
With the reauthorization of the PREEMIE Act nearing, ACOG strongly urges Congress to swiftly take up the issue and we look forward to working with you to perfect the reauthorization language.

Medical Liability

ACOG highly recommends exploring ways to reduce rates of caesarean delivery through state and federal experimentation of medical liability reform alternatives. These efforts should include as early offer programs, healthcare courts, voluntary alternative dispute resolution, and birth injury compensation funds, as well as caps on non-economic damages and other reforms like those found in Texas and California law.

Thank you again for the opportunity to provide this statement to the House Committee on Energy and Commerce, Subcommittee on Health on the issues of prematurity and infant mortality. We applaud your commitment and leadership on this issue, Chairman Pallone, and look forward to working closely with you and the Subcommittee.

Appendix



May 2010

**The American Congress of Obstetricians and Gynecologists' (ACOG's)
Making Obstetrics and Maternity Safer (MOMS) Initiative**

Pregnancy and childbirth is a joyous and safe experience for the majority of mothers in the United States, and ob-gyns play the leading role in delivering this care. Yet the US lags behind other industrialized nations in healthy births, and we know very little about why. While the recently enacted health care reform law will expand access to prenatal care - an essential component to improving birth outcomes - research is critically needed to understand how we can drive down our maternal and infant mortality and prematurity rates. Effective research based on comprehensive data is a key to developing, testing and implementing evidence-based interventions

ACOG is committed to leading this improvement as part of our imperative to make motherhood as safe as possible. Congress and the federal government have important roles to play by helping fund major research initiatives to help us understand the links and effective strategies to help ensure safe births and healthy babies. **ACOG's MOMS Initiative** is a multi-pronged approach that will help the U.S. develop and implement evidence-based interventions to improve maternal health.

- 1) **Understand the Causes, Improve Interventions for, and Reduce the Prevalence of Premature Births.**
- 2) **Focus on Obesity Research, Treatment, and Prevention.**
- 3) **Improve Surveillance and Data Collection On Maternal and Infant Health.**
- 4) **Support Maternal/Infant Health Programs at HRSA.**
- 5) **Research Disparities in Maternal Care, to Eliminate Disparities.**
- 6) **Develop, Test and Implement Quality Improvement Measures and Initiatives.**
- 7) **Test an Obstetric Medical Home Model**

1) Understand the Causes, Improve Interventions for, and Reduce the Prevalence of Premature Births.

Between 1990 and 2006, the U.S. experienced a 20% increase in the number of premature births. While in 2008 we saw a 3% decrease in preterm births, preliminary 2008 data from the National Center for Health Statistics (NCHS) show that preterm births still account for 12.3% of all births. In many cases the causes are unknown. Both the Centers for Disease Control (CDC) and the

National Institutes of Health's National Institute for Child Health and Human Development (NICHD) must expand existing research and evaluation of the factors behind these numbers, using improved national data systems to ensure consistent reliable statistics on preterm birth rates and expanding research into the causes and prevention of preterm birth.

NICHD's research activities may be augmented through integrated transdisciplinary research centers, as recommended by the Institute of Medicine and the Surgeon General's Conference on the Prevention of Preterm Birth. Patient-centered outcomes research, also known as comparative effectiveness research, should focus on evaluating the efficacy of interventions in different subpopulations for preterm labor, including different drugs and preventive efforts.

2) Focus on Obesity Research, Treatment, and Prevention.

Obese pregnant women are at increased risk for poor maternal and neonatal outcomes, and the prevalence of obesity in the United States has increased dramatically over the past 20 years. The most recent National Health and Nutrition Examination Survey (NHANES) for 1999–2002 found that approximately one third of adult women are obese. This problem is greatest among non-Hispanic black women (49%) compared with Mexican-American women (38%) and non-Hispanic white women (31%).

Several studies have consistently reported higher rates of preeclampsia, gestational diabetes, and cesarean delivery, particularly for failure to progress, in obese women than in non-obese women. Additional research and interventions are needed to address the increased risk for poor outcomes in obese women receiving infertility treatment, the increased incidence of birth defects and stillbirths in obese pregnant women, ways to optimize outcome in obese women who become pregnant after bariatric surgery, and the increased risk of childhood obesity for their babies.

3) Improve Surveillance and Data Collection Efforts On Maternal and Infant Health.

- Modernize state birth and death records systems to comply with the 2003-recommended guidelines.

Only 75% of states and territories use the 2003 birth certificates and 65% have adopted the 2003 death certificate. Additional funding must be provided to NCHS' National Vital Statistics System (NVSS) to support states and territories in implementing the 2003 birth certificate and modernizing their infrastructure to collect these data electronically to expand the scope and quality of data collected. Funding to support the phasing in of the 2003 death certificate and electronic death records in states and territories must also be made available. CDC should also work with the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator to pilot-test the integration of electronic birth and death records and electronic medical records.

- Assist states in setting up maternal mortality reviews.

National data on maternal mortality is inconsistent and incomplete due to the lack of standardized reporting definitions and mechanisms. To capture the accurate number of maternal

deaths and plan effective interventions, maternal mortality should be addressed through multiple, complementary strategies. The CDC should provide funds to states for implementation of maternal mortality reviews that conduct regular reviews of all deaths within the state to identify causes, factors in the communities, and strategies to address the issues. Combined with adoption of the recommended birth and death certificates in all states and territories, CDC could then collect uniform data to calculate an accurate national maternal mortality rate. Results of maternal mortality reviews will inform research needed to identify evidence based interventions addressing causes and factors of maternal mortality and morbidity. Only 15 to 20 states operate maternal mortality reviews today.

- Improve the CDC Safe Motherhood Program to study pregnancy-related deaths.

To better understand maternal complications and mortality and to decrease disparities among populations at risk of death and complications from pregnancy, the CDC's Division of Reproductive Health's Safe Motherhood Program supports national and state-based surveillance systems to monitor trends and investigate health issues; conducts epidemiologic, behavioral, demographic, and health services research; and works with partners to translate research findings into health care practice, public health policy, and health promotion strategies.

One such program is the Pregnancy Risk Assessment Monitoring System (PRAMS). PRAMS was initiated in 1987 because infant mortality rates were no longer declining as rapidly as they had in prior years, and the incidence of low birth weight infants had not significantly improved in the previous 20 years. Research indicates that maternal behaviors during pregnancy may influence infant birth weight and mortality rates. The goal of the PRAMS project is to improve the health of mothers and infants by reducing adverse outcomes such as low birth weight, infant mortality and morbidity, and maternal morbidity. PRAMS provides state-specific data for planning and assessing health programs and for describing maternal experiences that may contribute to maternal and infant health. Currently 37 States participate in the PRAMS; this program should be expanded to all States.

- Develop a Maternity CAHPS.

Understanding the experience and perspective of mothers is paramount in improving the delivery of maternity care. The Consumer Assessment of Healthcare Providers and Systems (CAHPS) program developed through the Agency for Healthcare Research and Quality (AHRQ) is the gold standard for patient experience surveys at the health plan, hospital, and clinician levels. Survey topics cover the communication skills of providers (important for shared decision making and informed consent) and the accessibility of services. Currently, the CAHPS Consortium has products that cover dental care, primary care, and newly released in 2009, surgical care. ACOG urges AHRQ to fund the development of maternity CAHPS in 2010.

4) Support Maternal/Infant Health Programs at HRSA

- Continue support of and expand the Fetal and Infant Mortality Review (FIMR).

FIMR brings local ob-gyns and health departments together to solve community problems related to infant mortality. Since 1990, the Maternal Child Health Bureau has worked in cooperative agreement with ACOG to run the National Fetal Infant Mortality Review (NFIMR) program. NFIMR provides training and assistance to enhance cooperative partnerships among local community health professionals, public health officers, community advocates and consumers to reduce infant mortality. The goal is to improve local services and resources for women, infants and families, to remove barriers to care, and to ensure culturally appropriate, family friendly services. Such efforts are crucial to understanding and addressing infant health disparities in communities at highest risk and are a component of many existing Healthy Start Initiatives. A rigorous national evaluation of FIMR conducted by Johns Hopkins University concluded that FIMR is an effective perinatal initiative.

- Improve funding for the Maternal Child Health Block Grant.

The MCHB Grant is the only federal program that exclusively focuses on improving the health of mothers and children by ensuring access to quality care, especially for those with low-incomes or limited availability of care.

5) Perform Disparities Research into Maternal Outcomes.

Women of racial and ethnic minorities face higher rates of diseases including obesity, cancer, diabetes, heart disease, and HIV/AIDS, when compared with white women. There is also a disproportionately higher rate of pre-term birth among African American women that cannot be accounted for by known risk factors. HHS must support research into the causes of health disparities and develop and evaluate interventions to address these causes. Continued and expanded collection of data capturing racial and ethnic information is essential in understanding and reducing disparities.

6) Develop, Test and Implement Quality Improvement Measures and Initiatives.

The American College of Obstetricians and Gynecologists is an active leader in the national quality measurement arena. We have a standing executive committee seat on the American Medical Association (AMA)-convened Physician Consortium for Performance Improvement® (PCPI) and are active members of the National Quality Forum, AQA (formerly Ambulatory Care Quality Alliance), and the Surgical Quality Alliance (SQA). ACOG is currently engaged through the PCPI in development of maternity care quality measures.

The PCPI process is the gold standard for national development, testing, and maintenance of scientific evidence-based clinical performance measures at the physician/clinician/group level, balanced with stakeholder engagement, public comment, and transparency and spearheaded by clinician ownership, accountability and professionalism. We look forward to maintaining and improving current measures, developing new clinical measures in other facets of obstetrical and gynecologic care and expanding national data collection and aggregation initiatives on all aspects of women's health care through both voluntary data registry participation for physicians and facilities and mandatory certification and accreditation programs

like American Board of Obstetrics and Gynecology Maintenance of Certification and The Joint Commission.

ACOG urges Congress and the Administration to support these efforts and assist in the dissemination and voluntary adoption of quality measures in both the Medicare and Medicaid programs.

7) Test an Obstetric Medical Home Model

The testing of a women's medical home, with particular attention to maternity care, is an important opportunity to facilitate the improvement of health outcomes in the United States and reduce duplicate and inappropriate utilization of services. Medical homes are rooted in the principle that care coordination, increasing health care access, patient-provider communication, and collaborative care are fundamental to improving patients' health. This delivery model has the potential to address the unique issues that arise during pregnancy and may be able to address troubling health disparities in certain populations of pregnant women. CMS should test a model in the Medicaid program, which finances approximately 42% of the nation's births.

ACOG looks forward to partnering with Congress and the Administration on the MOMS Initiative to improve maternity outcomes for women and babies. For more information please contact Nevena Minor, Manager, Government Affairs at nminor@acog.org or 202-314-2322.

Ms. CASTOR. Thank you, gentlemen. Your testimony was outstanding.

Let me start by asking about a subject that you each very briefly touched on, and that is the inaccurate gestational dating. It seems like there is a concern out there about if the recommendation is you go fully to term at 39, 40 weeks, how do you really measure, especially in certain subgroups, that you have an accurate due date, and then how do we—is it the same based on socioeconomic factors and education or is there something a little more concrete that we can get? I would like to hear from all of you on that.

Dr. LAWRENCE. Thank you for that question. Obviously whenever you have any recommendations on timing of delivery, having accurate dates of that pregnancy is crucial, and we have published guidelines on how you determine when somebody is at least 39 weeks' gestation, and those guidelines clearly state that you have to have had an ultrasound at least in the early second trimester to confirm an estimated date of confinement, or due date, so you are sure they are 39 weeks, or you have to have had 36 weeks of pregnancy following a serum or urine pregnancy test, or you had to be able to have documented fetal heart tones for 30 weeks since they were first documented. All three of those methodologies will confirm that somebody is at least at 39 weeks' gestation. I know that there is discussion about earlier first-trimester scanning. We think that that is an interesting opportunity also. We have discussed this several times and Dr. Fleischman and I have discussed this several times. I know in Great Britain they do something called a booking scan. But when our committees look at this and carefully weigh the benefit and the costs of those ultrasounds at that 16-, 18-, 19-week gestation, not only do you get a very accurate gestational age calibration plus or minus seven to nine days, you also get a good anatomy evaluation of that fetus. So there is a whole lot more benefit found and so because of that our committees have been unable to say we should recommend two scans at this point in time.

Dr. MAHAN. We had talked about this before we testified, but the 39 weeks that ACOG recommends, I think we should look at that again in the college because if a woman is entirely normal, why should you even have the 39-week recommendation? You know, Mother Nature tells you when term is because labor starts, and the Institute for Health Care Improvement basically recommends that we wait for labor to begin and see how labor goes, again in normal people. You certainly have to count on all the things Dr. Lawrence said for somebody who is high risk if you are going to have to deliver them early.

Dr. FLEISCHMAN. We go back to the Institute to Medicine report in 2006 that clearly recommended early ultrasounds in the first trimester as the most accurate gestational dating, which would, I think, give us combined with history a very important public health program in order to assure that the kinds of complex things that Dr. Lawrence is saying are the appropriate ways if you don't have the earliest ultrasounds. I think if we did that as almost every obstetrician in American has in their office, the ultrasound machine, at the earliest times to find the fetal viability as well as the fetal gestational age, we would be making better decisions at

the end of pregnancy. We know time and time again from intervention studies that if you put off at least until 39 weeks, and I am not disagreeing with Dr. Mahan, but at least until 39 weeks you run a very low risk of prematurity, and if you don't have accurate gestational dating you increase the risk of premature birth.

Ms. CASTOR. Mr. Shimkus.

Mr. SHIMKUS. Thank you, Madam Chair. I concur with you. It is great testimony. One thing I really enjoy about this subcommittee on health care, it is a caring profession. I mean, everybody is doing it for the right reason, whether it is adults, and this one of course on the unborn children. So with all our fights and battles, it is really great to have people who are very concerned.

Dr. Mahan, I really enjoyed your testimony. I have questions for you. I am an old Army infantry guy, and you know, we just keep it simple, and it seems like your testimony kind of keeps it simple. God has created phenomenal human beings—not your words, mine. The body tells us when. We shouldn't be doing things that aren't natural unless we have to, I think if I could summarize. And then there is ways to incentivize that financially because we are a big payer. We are a third payer in a lot of the health care delivery system. And so why not use that tool? We did miss that opportunity, but then maybe there are other opportunities to relook at that. I really enjoyed the testimony.

Dr. Fleischman, you state that there are several factors that have caused the increase in elective inductions, that is kind of leading on this debate, and Cesarean deliveries. You do mention in your statement about the litigious environment and defensive medicine. Can you talk about that? I am from Illinois. We have had a huge medical liability crisis. We had a Supreme Court campaign turn on this, and even though that was the primary reason because all our physicians were leaving the State, it wasn't enough and then we have gone back to that. So I know we don't like to talk about it, but it is in your statement. Talk about that for me, will you?

Dr. FLEISCHMAN. Well, we are very sympathetic to the obstetric practitioners concerning their concerns and fears about the litigious environment. We believe the best way to prevent lawsuits is to have the highest quality care, to set standards, to set guidelines and to practice appropriately with appropriate accountability. That protects both the patient and the doctor, and I think we are moving in those directions. We have the national quality forum and the joint commission and others setting standards. We have CMS now to set standards around perinatal health and quality measures. We think that high-quality practice is the way for the obstetric community to assure that they are actually able to protect themselves and their patient.

Mr. SHIMKUS. And I appreciate that, but how do you tie that in to the litigious—I get it. I mean, if we don't have problems, then you don't have lawsuits, but how do you tie that in to the courtroom drama that unfolds? Is it making sure—I have been through this for years now as far as the public policy guys, make people that say I am sorry. I mean, how do you tie that to the courtroom? That is the issue?

Dr. FLEISCHMAN. Well, I think—

Mr. SHIMKUS. I mean, your words. I am not putting—you talked about the litigious environment and defensive medicine.

Dr. FLEISCHMAN. Well, we can stand up tall if we practice high-quality medicine based on ACOG guidelines and appropriate care, and if we do that, then even if we make our way to the courtroom, we can have a reasonable defense of good high-quality practice and decrease the incentives on the part of those who are bringing those lawsuits—

Mr. SHIMKUS. But you are not willing to talk about the courtroom dilemma that they still face regardless of this.

Dr. LAWRENCE, do you want to weigh in on medical liability?

Dr. LAWRENCE. Thank you very much. Medical liability is just a huge issue in our practice, and you all have heard this, I am sure, before, but, you know, over 90 percent of practicing obstetrician/gynecologists have been sued, and I would tell you 90 percent of anybody isn't doing bad things, and I think each of you know that.

Mr. SHIMKUS. I always usually say in any organization, you may have 10 percent who are bad actors. Unfortunately, we find that here. I found that in the military. You find that in schools. I would agree, 90 percent—

Dr. LAWRENCE. But not 90 percent.

Mr. SHIMKUS. I would have to agree, 90 percent, there is something else going on.

Dr. LAWRENCE. And the thrust of your question, you know, ACOG works hard to put forth guidelines enabling medical staffs and local community hospitals to create practice parameters and protocols to help take care of these patients. The problem for us is that even when you do all that, even when you do it all right, that does not guarantee a perfect outcome. Reproduction has never been perfect. Sadly, reproduction will never be perfect. There will always be adverse events. There will always be situations that are not predictable. And somehow in this process, if the providers are doing everything right, we should not be held accountable for an adverse outcome that we could not have prevented, and that is true in the VBAC situation that I mentioned. It is true in many other situations in managing patients whether they are high-risk patients or whether they are deemed to be low risk and then all of a sudden there is a cord prolapse or all of a sudden there is an abruption or all of a sudden there is a vasa previa. I have been there. I have jumped in and done those deliveries. And fortunately, they usually go OK but not always, but if you do it right, somehow the liability system has to recognize that and deal with this other than within a tort arena.

Mr. SHIMKUS. Madam Chair, I am not going to follow up with a question, but if I may just again thank you all, and I am going to follow up with a written question on Medicaid expansion and reimbursement rates and other things that I would like to get into but time is not going to allow me to do that.

Ms. CASTOR. Thank you very much.

Dr. Christensen.

Mrs. CHRISTENSEN. Thank you, Madam Chair.

Dr. Mahan, true informed consent, how do you define that and how do you arrive at that?

Dr. MAHAN. I think it needs to be based on—and I have worked with the National Coalition to Improve Maternity Services on this for the past year, especially for informed consent for Cesarean, and we based all of our efforts on science, evidence based, but what we were finding, and this is among studies of upper-income people, upper middle-class people, was that it was really a last-minute sort of glossed-over thing that this is all going to be OK. So in the attachments that you will get is a copy of the—it is called the risks of Cesarean section, a checklist that women should be given at about 32 weeks of pregnancy, not at term, so that she and her partner can go through it, look at the differences—

Mrs. CHRISTENSEN. Both sign?

Dr. MAHAN. Pardon?

Mrs. CHRISTENSEN. Are both supposed to sign it?

Dr. MAHAN. I believe so, yes, and so is the care provider. Now, this is just a suggestion. It has not been adopted except by this particular group. But for instance, when the mother looks at the section possible problems for my baby, my baby is more likely to have breathing difficulties—this is after Cesarean—it is normally best for labor to begin, so on and so on and so on, and my baby is more likely to die than if it was born vaginally, which is not a high chance but it is statistically more likely to do that. The mother needs to know that.

Mrs. CHRISTENSEN. Thank you. And your third immediate recommendation, I would ask you and Dr. Lawrence and perhaps Dr. Fleischman as well, what is the data on outcomes in vaginal birth after Cesarean, and does ACOG recommend that after the first Cesarean that women go through vaginal delivery?

Dr. LAWRENCE. ACOG, in fact following the NIH consensus conference that we just participated in, have a new practice bulletin about discussing vaginal birth after Cesarean section, and in there we do recommend that women be offered a trial of labor after Cesarean section, assuming that that section was for a non-recurring cause, assuming that there wasn't like she had—

Mrs. CHRISTENSEN. If it was a breech and—

Dr. LAWRENCE. Correct, like a breech, and we do recommend that those patients be counseled and offered that procedure. Institutions have to be able to provide the services to support that procedure, and the problem with VBAC is where the risk of a uterine rupture and spontaneous labor is low, it is less than 1 percent. If, however, it occurs, the same Dr. Lu that Dr. Mahan used as a reference earlier has a study from Los Angeles County that shows you have 12 minutes to get that baby born or that baby will probably not survive, and if it does survive will be severely handicapped. So because of liability concerns, many institutions and many providers have said I am not willing to put that baby at that much risk. At that same NIH consensus conference on VBAC, one of the attendings from Parkland stood up and gave a scenario of a perfectly managed VBAC, everything was doing fine. In fact, this patient had delivered vaginally after her previous Cesarean section, which puts her in a lower risk. Everything was going great. The uterus ruptured, crash Cesarean section, baby delivered. Baby did not do well. An \$11.5 million settlement against the institution and the physicians. And that group no longer does VBACs. So that is

the scenario that vaginal birth after Cesarean section has placed many obstetrical providers, and that is the reason that the concern has been raised about that procedure.

Dr. MAHAN. And I would follow up with that, and I agree, and I think that was an excellent conference, but the issue that we have to deal with now is that, you know, I think Dr. Spong's studies that she has helped publish have shown that VBAC is slightly safer for the mother and baby other than a repeat Cesarean. You can lose babies and mothers with a repeat Cesarean. The problem that we need to deal with, and it is tied up with the liability issue, is that since so few hospitals are providing VBAC—now, USF, we do do that in our practice group. Women in communities that can't get it are turning to home birth because they can't get it anywhere else and they had such a bad experience with their first pregnancy that they don't want to go back to the hospital and we are really worried about that too. So it is another reason to deal with the liability crisis.

Dr. FLEISCHMAN. I think the fundamental question, and I agree with these gentlemen, but the fundamental question is, how do we decrease primary Cesarean sections that are done unnecessarily, and we know that if we induce a woman when she's not ready to deliver, she is highly likely to result in a Cesarean section, and then we put the woman in the position of, you know, the question of vaginal birth after Cesarean. I think that is the real challenge.

Ms. CASTOR. Thank you very much.

Mr. Pitts.

Mr. PITTS. Thank you, Madam Chairman.

Dr. Fleischman, you mentioned Institute of Medicine. The Institute of Medicine recently published a 570-page resource book entitled "Preterm Birth: Causes, Consequences and Prevention." On pages 517 and 518, abortion is noted as an "immutable" risk factor. However, the risk factor is avoidable if women are given risk information prior to pregnancy. I would like each of you to respond to this, and I know of 59 studies that have found that women with prior induced abortions are at increased risk for premature birth and low birth weight. The question is two parts. Do your organizations acknowledge abortion as a risk factor, and is it included in your information searches? Are you aware of efforts to inform women about such a risk factor? Each of you, please. Dr. Fleischman?

Dr. FLEISCHMAN. At the March of Dimes, we continually monitor those data that you have mentioned, and the most recent data from modern techniques in termination do not give convincing evidence of that as a significant risk factor for preterm birth, and we do not raise that issue within our materials.

Mr. PITTS. Dr. Mahan?

Dr. MAHAN. I don't know the answer to that. I know that one of my—I just read the executive summary of that report. One of my problems with it was that it was a little behind the times because it really wasn't dealing with the elective induction/Cesarean issue. But one of the things I bring out in my testimony that I hope you will read is that one of the key things to improved maternal health and infant health in the United States is interconception care and preconception care so that—especially interconception care of

women who have already had a low-birth-weight baby. Right now essentially we just drop them and we wait to see when they are going to have the next pregnancy when we know that it would be help if we spaced their pregnancy for at least two years and so I think following the diabetic woman who just had a pregnancy, making sure she is in good shape, following the woman who had a low-birth-weight baby, trying to get her out there for 2 years before she gets pregnant again, if we can provide—you know, in Florida we woke up last year and the CDC told us that we are 51st of all the States plus D.C. in providing reversible contraception to women, and this is the 50th anniversary of the Pill. When the Pill came out and I was a student in Chicago, the average family size was six and a half, and now it is one and a half. If we want to reduce abortion if it does cause this problem, we have got to stop putting our heads in the sand about helping people space their pregnancies.

Mr. PITTS. Dr. Lawrence?

Dr. LAWRENCE. Well, I would like to have a couple points. First off, I am aware of the data. We do review that data. And I also agree with Dr. Fleischman that more recent studies with more recent technologies don't show a real correlation between induced pregnancy termination and premature birth. I also think that Dr. Mahan is right on target here, and I think one of the benefits of the health care reform law is that now patients are going to be able to have ongoing continual care, and as Dr. Spong said earlier, the best way to have a healthy baby is to have a healthy mommy and ongoing well women's health care rolled in with contraceptive care, rolled in with preconception care is a major factor in helping to reduce preterm birth and improve maternal and infant outcomes.

Mr. PITTS. Thank you.

Dr. Fleischman, I didn't quite get your response. Do you believe comprehensive medical malpractice reform would potentially help providers stop practicing defensive medicine?

Dr. FLEISCHMAN. I guess the detail of what the comprehensive medical malpractice reform means—

Mr. PITTS. Well, like they have in California or Texas.

Dr. FLEISCHMAN. Well, we have not taken a position on that at the March of Dimes.

Mr. PITTS. OK. What about you, Dr. Mahan?

Dr. MAHAN. Absolutely.

Mr. PITTS. And Dr. Lawrence?

Dr. LAWRENCE. I am in total support. If we get comprehensive medical liability reform, it will help not only OB/GYN but all areas of medicine.

Mr. PITTS. Dr. Mahan—

Ms. CASTOR. I am sorry.

Mr. PITTS. Oh, I am out of time.

Ms. CASTOR. We would like to get Dr. Burgess in before we adjourn.

Mr. PITTS. Thank you. My time is up.

Ms. CASTOR. Dr. Burgess.

Mr. BURGESS. We have a series of crucial votes and the entire Nation hangs in the balance in 15 minutes, so we will have to take off and do those. I appreciate you all being here today. I appreciate

you staying with us. Listening to your testimony, your answers to some of the other questions is certainly intriguing.

Dr. Fleischman, I am going to answer Mr. Pitts's last question for you. Defensive medicine is learned behavior and physicians are probably not likely to unlearn that behavior overnight. There may be—certainly it will help but when I am criticized by the President because we did liability reform in Texas, and McAllen, Texas, is still a high-cost place to get health care, you are not going to change it overnight even as good as our law has been in Texas. I don't think there is any question—you know, Dr. Mahan, you talk about VBACs, and I remember the studies that came out of Los Angeles while I was still in practice and I think they just absolutely threw up their hands and stopped offering VBACs for a while because of the liability issue, and certainly, Dr. Lawrence, your story of what the group in Dallas got into the \$11 million settlement, if we are paying \$1,000 more for a VBAC but we get hit with an \$11 million judgment, that is 11,000 VBACs we are going to have to do to cover the cost of that \$11 million judgment, and as you guys know, the numbers just don't work out.

We do have to undertake a more sensible medical justice system in this country. I don't know what it is. I like early offer but what is happening in Texas now with a trifurcated cap on non-economic damages seems to be working and it seems to be working in a big way and not just holding down costs of premiums for practicing physicians but holding down costs for institution that self-insure for liability, allowing smaller not-for-profit hospitals to have more money to invest in capital improvements, nurses' salaries and the very things we want our smaller nonprofit hospitals to do in our communities. So I certainly stand behind what is happening in Texas. I would have liked to have seen us do more in the health care law that passed but unfortunately we didn't do it.

Now, Dr. Mahan, your discussion on Medicaid, you said for Medicaid to stop paying for elective inductions and elective Cesarean sections in any stage of pregnancy. That may be great in theory but we have a problem back home where you can have a hard time finding a doctor who will take a patient's Medicaid because the reimbursement rates are so much lower than commercial insurance, and as a consequence are we likely to make it even tough for that woman to get prenatal care because we have now created a more hostile environment within the Medicaid system. The practicing physician is going to look at it and say well, you know, maybe I was about to get over the funding problem but I am darn sure not going there when they are telling me how to practice.

Dr. MAHAN. Well, I thought that too but we are working on the issue in Florida now because we did study it and find an association between the rising rates of Cesarean and the rising rates of late preterm, and that will be published pretty soon, and we found that our colleagues in obstetrics around the State and they found this already ahead of us in North Carolina and Ohio, that they understand that this is producing bad outcomes in both women and babies that otherwise would have been normal, but that they should not be delivered by Cesarean or induced if they are normal people because the outcomes are worse, and I think we are finding that most of the OBs as we approach them on this and saying we

are producing a lot of bad babies because of this are extremely willing to listen to that and to change their practice. And I agree that from State to State the Medicaid rates are a problem but, you know, half of our births are Medicaid and these are doctors taking care of them and they seem to be willing to step in and reverse this thing.

Mr. BURGESS. Now, in the health care law that just passed, there was some protection for primary care that Medicaid rates would be 75 percent of Medicare rates, but in your State are OB/GYNs considered primary care?

Dr. MAHAN. I don't think so.

Mr. BURGESS. I don't think so either. And of course, in the law we don't know because that is all up to the Secretary of Health and Human Services and we are not having the types of hearings that would allow us to get an idea of what their thinking is over there so we are just all going to be surprised one day. But even then, if there is a funding cliff that occurs in 2 years' time and even if we were to get OB/GYNs designated as primary care so that they would get 75 percent of the Medicare rates, that funding cliff kicks in in 2 years' time and we are back to the preexisting Medicaid. So all this becomes terribly difficult and terribly complicated.

I guess just one last observation. Dr. Lawrence, you referenced the medical home. That is what the generalist OB/GYN, at least when I was practicing, that is what we were, and Dr. Mahan says we shouldn't have those anymore, the generalists are not helpful, let us go to midwives and perinatologists. But you seem to see value in the medical-home model, and I would just submit to you, the physicians of my generation, that is what we were trained to do.

Dr. LAWRENCE. And I think we still train OB/GYNs to do that. We are the care coordinators for well women's health care essentially from the late teenage years up until early years to years after menopause, and we definitely are the care coordinators and providers for obstetrical patients, and we are the ones who are able to intervene when those acute crises occur.

Ms. CASTOR. Thank you, Doctor, very much.

We are going to have to bring the hearing to a close, but I would like to ask Dr. Fleischman to help bring us to a close and spend 1 minute on the implications for brain development because you have a terrific visual exhibit here that I am afraid they won't be able to see at home, but if you could describe the difference in brain development from 35 weeks to 39 to 40 weeks to close us out for the hearing, I would appreciate it.

Dr. FLEISCHMAN. We developed this visual for a project in Kentucky to help women understand that one-third of the growth and development of the brain occurs between 35 and 39 or 40 weeks, that all those neurons, all those nerve cells that interact with each other are continually growing in those last 5 weeks and that that growth and development is critically important to the fetus. It can happen outside the uterus but it happens better inside a uterus if the fetus is not in any jeopardy. And that has been very helpful both to help clinicians understand what they can stay to women and it helps women to not push hard for inappropriate early deliveries.

Ms. CASTOR. Well, thank you very much. You all have been outstanding. All of the witnesses were just terrific today. That concludes all the questioning.

In closing, I want to remind members that you may submit additional questions for the record to be answered by the relevant witnesses. The questions should be submitted to the committee clerk within the next 10 days. The clerk will notify your offices of the procedures.

Without objection, this meeting of the Subcommittee is adjourned.

[Whereupon, at 5:40 p.m., the Subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

**Statement of Chairman Henry A. Waxman
Energy and Commerce Committee
Subcommittee on Health
Hearing on “Prematurity and Infant Mortality: What
Happens When Babies Are Born Too Early?”**

Mr. Chairman: Thank you holding today’s hearing on a very important, and unfortunately, not well understood, medical challenge – babies being born too early.

Over the last many years, prematurity has grown to become, in the view of many, a significant public health problem. And despite the encouraging news reported by CDC just yesterday -- pre-term birth rates have dropped by 4% over the past two years -- prematurity remains an ongoing concern. For good reason:

- When babies are born before they are fully developed, they have an increased risk of dying and of lifelong disability.

- Prematurity is the single largest cause of infant mortality in this country. Fully 30% of babies who are lost in the first year of life die from prematurity-related causes.
- Babies who survive early birth may suffer from a number of acute health complications, including brain damage, blindness, and underdeveloped lungs. These babies are also at increased risk for long term cognitive and physical developmental delays. And it is now clear that these risks exist not only for babies born very prematurely, but also for babies born at 36 or 37 weeks – just shy of a full term pregnancy.
- Pre-term birth is a problem that affects all people, but alarming disparities persist among certain racial and ethnic minorities, particularly African Americans. African American babies are 50% more likely to be born early than white babies and prematurity has been the leading cause of death for these infants for more than a decade.

- All of this -- and more -- has resulted in a world infant mortality ranking for the United States that is embarrassingly low. Whether we are in the middle of the pack among our sister nations or closer to the bottom -- an analysis we should leave to demographers and statisticians -- there is no doubt that we are not where we should and must be.

Despite these disturbing facts, progress -- as underscored by CDC's findings announced yesterday -- has been made on a number of fronts. Perhaps best known is the ground-breaking work of the nation's network of neonatal intensive care units. These are the specialty sections of hospitals where highly-trained health professionals take care of the most fragile babies and infants -- children who would have otherwise died several decades ago.

But clearly, there is still much work to do. Experts are starting to understand the risk factors associated with prematurity, but the root causes remain generally unknown. As well, in many cases, we don't know how to prevent premature labor or to stop it once it has begun. And the impact on a baby's health when doctor and patient deliberately decide on an early delivery -- through a so-called "c-section" -- is a topic of hot debate.

These uncertainties leave no question, however, that in this country, too many babies are being born early, and too many of those are dying. I hope that today's hearing will help us understand how we can begin to reverse this trend and, in turn, improve the health of our truly most vulnerable people -- our nation's newborns.

I thank today's witnesses for joining us and look forward to their testimony.

Statement of the Honorable Anna G. Eshoo
Committee on Energy and Commerce, Health Subcommittee
Hearing on “Prematurity and Infant Mortality: What Happens When Babies Are
Born Too Early?”
May 12, 2010

Mr. Chairman, thank you for holding this hearing on premature births and infant mortality. I think it’s fitting that we discuss this important issue as Mother’s Day was just celebrated. The birth of a child is a miraculous event and I know speaking from experience that every mother hopes for a full-term, healthy child. No mother would choose to have a baby born prematurely and the health risks that ensue.

I first introduced the *PREEMIE Act in 2003* with my colleague Representative Upton to expand and coordinate research activities on preterm labor and delivery and infant mortality. The legislation also directed the CDC to conduct research on the relationship between prematurity, birth defects, and developmental disabilities. While I’m proud to say that legislation was signed into law in 2006, our work in this area is not done.

According to the CDC, more than half a million babies in the U.S.—or about 1 in every 8—are born prematurely every year. Unfortunately, that number is on the rise. Between 1990 and 2006, the preterm birth rate rose by more than 20 percent in the United States. While the causes for preterm births are varied, the harmful consequences to the mother and baby can be long-term...and expensive.

A March CDC report finds that almost 1 in 3 births in the U.S. are now performed via C-section. Mothers who go into premature labor have a much higher likelihood of a C-section. This method of delivery involves major abdominal surgery, and is associated with higher rates of surgical complications, maternal re-hospitalization, and complications requiring neonatal intensive care unit admission. In addition to health and safety risks for mothers and newborns, hospital charges for a cesarean delivery are almost double those for a vaginal delivery, imposing significant costs.

In 2005 alone the economic cost of preterm birth in the United States was at least \$26.2 billion, and the average first-year medical costs were approximately *ten times greater* for preterm babies, compared to full-term babies.

These national numbers are frightening, nothing could be more frightening, and so is the experience of having your baby whisked away to endure medical procedures because it was born prematurely. I look forward to hearing from our witnesses today and learning more about how we can prevent dangerous preterm births.

Opening Statement
Honorable Ranking Member Joe Barton
Subcommittee on Health
May 12, 2010

Mr. Chairman, thank you for holding this hearing on prematurity and infant mortality. According to the Centers for Disease Control (CDC), prematurity is the leading risk factor for infant mortality. It has often been cited that the US is ranked 29th in the world and has among the worst infant mortality rates compared to other industrialized countries.

While any infant death is a tragedy, I believe it is important that the Committee understand how mortality reporting requirements differ among countries. I would like to understand if these statistics are really comparing apples to apples. For example, some European countries classify

live births differently. In the United States, all live births at any birth weight or gestational age are required to be reported. However, in France, only live births at either 22 weeks of gestation or later, or at 500 grams of birth weight or more are required to be reported. Furthermore, there are differences among nations about registering a child's birth even at the provider and hospital level which may lead to underreporting of mortality data. These reporting variations can lead to mortality numbers that are inaccurate.

I am pleased that the American College of Obstetricians and Gynecologists (ACOG) is testifying today. I would like this Committee to recognize the importance of medical liability reform on these providers. The new health care law contains no real liability reform; instead it only provides grants to States to test alternatives

to civil litigation. According to a “2009 Survey on Professional Liability” conducted by ACOG, more than 63 percent of ob-gyns report making changes to their practice due to the risk or fear of liability claims or litigation; 60% have made changes to their practice because liability insurance is either unavailable or unaffordable. Albert L. Strunk, ACOG deputy executive vice president is quoted as saying:

"This latest survey shows that the medical liability situation for ob-gyns remains a chronic crisis and continues to deprive women of all ages—especially pregnant women—of experienced ob-gyns. Women's health care suffers as ob-gyns further decrease obstetric services, reduce gynecologic procedures, and are forced to practice defensive medicine."

Medical liability reform works. If this Committee truly cares about reducing prematurity and infant mortality, then we need to ensure that there will be enough providers practicing in the field so that more women have healthier babies.

While the issue of infant mortality is important there are other pressing issues this Committee has failed to examine. Physicians will experience a 21 percent payment cut in Medicare reimbursement at the end of this month, yet this Committee has not held a single hearing on this issue in the past two Congresses.

Mr. Chairman, it is also important that Members of this Committee also have an opportunity to question Secretary Sibelius about implementation of the 3,000 page

health law. As each day passes, Americans are growing wearier as new details emerge of how this law will dramatically alter the delivery of health care in this country as it stands today.

Finally, this is the third time that CDC is testifying before this Committee since the March 2010 Subcommittee markup of HR 847, the 9/11 health program bill. Mr. Chairman, you have expressed your desire to pass HR 847; however, CDC has not once come to testify about the parameters of this new entitlement program.

Mr. Chairman, I yield back the balance of my time.



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

Archive
cc: Carr
Schneider
Katz
Granniger
Clark

May 10, 2010

The Honorable Nancy Pelosi
Speaker of the
House of Representatives
Washington, D.C. 20515

The Honorable Harry Reid
Majority Leader
United States Senate
Washington, D.C. 20510

The Honorable John Boehner
Minority Leader
House of Representatives
Washington, D.C. 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, D.C. 20510

Dear Speaker Pelosi, Senator Reid, Senator McConnell, and Representative Boehner:

Just over a month ago, Congress passed and President Obama signed the Affordable Care Act. We wanted to provide an update on the Administration's implementation of this landmark new law that will give the American people control over their own health insurance by holding insurance companies accountable, bringing down costs, and giving Americans more insurance choices.

Over the last month, the Administration, including the Departments of Health and Human Services, Labor, and Treasury, has worked expeditiously but carefully to implement the early insurance market reforms called for in the Affordable Care Act and to strengthen the health care system for all Americans. We have made significant progress. A brief update on our implementation efforts is provided below.

Adult Child Coverage: Today, the Departments of Health and Human Services, Labor and Treasury issued new regulations to extend coverage to young adults by allowing them to stay on their parents' health care plan until age 26. Before Congress passed the Affordable Care Act, many health plans and issuers could – and, in fact, did – remove young adults from their parents' policies because of their age, leaving many college graduates and others with no insurance. Today, about 30 percent of young adults are uninsured, representing more than one in five of the uninsured Americans. This rate is higher than for any other age group. The Affordable Care Act and the regulations announced today will help close the coverage gap for young Americans. While the new provision takes effect for policies and plan years beginning on or after September 23, 2010, more than 65 insurance companies have voluntarily agreed to provide coverage to young adults before the deadline. On April 27, the Internal Revenue Service released new guidance specifically stating that children can be covered tax-free on their parents' health insurance policies. According to analysis by the Department of Health and Human Services of this provision, adding young adult coverage would increase average family premiums by an average of 0.7 percent, while allowing 1.2 million young Americans coverage under their parents' plans through employers or the individual market.

Pre-existing Conditions: Effective for policies or plan years beginning on or after September 23, the Affordable Care Act will prohibit health insurers from excluding coverage of children because of pre-existing conditions. We will soon be issuing regulations to implement that important policy. When questions were raised about whether insurers would work to avoid covering children with pre-existing conditions, we called on the nation's health insurance companies to provide coverage to these vulnerable Americans. On March 29, health insurance companies agreed to ensure that children with pre-existing conditions were not denied coverage.

Adults with pre-existing conditions also suffer under the old industry rules that allowed insurance companies to carve out needed benefits, charge sky-high rates or deny coverage altogether. In 45 states across the country, insurance companies can discriminate against people based on their pre-existing conditions when they try to purchase health insurance directly from insurance companies in the individual insurance market. In 2014, discrimination based on pre-existing conditions will be banned under the Affordable Care Act. In the meantime, a new transitional high-risk pool program was included to help provide affordable health insurance coverage to people who are uninsured because of pre-existing conditions. This high-risk pool program will operate until health insurance exchanges are implemented in 2014. States may choose whether and how they participate in the program, which is funded entirely by the federal government. If states choose not to run the program, individuals can apply for insurance from a federal fallback high-risk pool. The program begins on July 1, 2010.

Over the course of the last month, the Administration has engaged in significant outreach to determine the needs of states in implementing the program. As of May 3, 30 states have indicated that they want to operate their own transitional high-risk pools, while 18 have said they would prefer a federal fallback high-risk pool for eligible citizens in their state. For those that wish to run a state-based program, applications were sent today, May 10, to expedite the implementation. To ensure states can obtain all the information they need to establish this program, a working session will be scheduled in the near future to give states an opportunity to ask questions and receive technical assistance directly from our subject matter experts.

Early Retiree Reinsurance Program: On May 4, the Department of Health and Human Services issued a regulation implementing the \$5 billion early retiree reinsurance program, which will be launched on June 1, 2010, several weeks ahead of the June 21 start date required by law. We worked closely with large employers, early retirees, and other interested parties in developing this regulation. The Business Round Table released a positive statement in support of the program. Participating employment-based plans will receive reimbursement for a portion of the costs of certain medical claims associated with providing health benefits to early retirees age 55 through 64, as well as for retirees' spouses and dependents. The amount of this payment to the plan sponsor is 80 percent of the costs attributable to that claim, provided the amount of the claim is between \$15,000 and \$90,000. Both self-funded and insured plans may apply, including plans sponsored by private entities, state and local governments, nonprofits, religious entities, unions, and other employers.

Rescissions: Effective for policies or plan years beginning on or after September 23, the Affordable Care Act prohibits some of the worst insurance company practices, including the practice of rescinding coverage from policyholders when they become sick and need it most. We are pleased that the insurance industry announced they will immediately follow the new rules rather than wait for the new law to make it illegal and we will watch closely to ensure they keep their word.

Small Business: The Affordable Care Act provides tax credits to small employers who purchase health insurance for employees. An estimated 4 million small businesses nationwide could qualify for the tax credit, which will provide a total of \$40 billion in relief for small firms over the next 10 years. Small businesses can take advantage of the tax credit immediately, and, last month, the Internal Revenue Service released guidance and began delivering postcards to the estimated four million small businesses and tax-exempt organizations to make them aware of the tax credit.

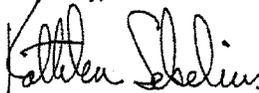
Lowering Premiums: A new policy in the Affordable Care Act -- the "medical loss ratio" -- creates new incentives for insurance companies to be more efficient, and ensures that consumer premiums are being used to pay for medical care rather than excessive and unnecessary administrative costs. The law requires large-group plans to spend 85 percent of premium dollars (80 percent in the small group market) on clinical services and activities that improve health care quality. Insurers offering coverage in the small group and individual markets must allocate at least 80 percent of premiums to such services and activities while those in the large group market must spend at least 85 percent of premiums on benefits. It also calls for the National Association of Insurance Commissioners (NAIC) to establish uniform definitions and methods for calculating medical loss ratios. While the law requires NAIC to submit such definitions and methods for the Secretary's review by December 31, 2010, at our request, NAIC has agreed to accelerate delivery to June 1, 2010.

Medicare Part D Doughnut Hole: As required by the new law, the U.S. Department of Health and Human Services plans to issue \$250 rebate checks to Medicare beneficiaries who have reached the "doughnut hole" in prescription drug coverage. We expect the first checks to be mailed on June 15, and additional checks to be mailed roughly every six weeks thereafter until the end of the year. The Centers for Medicare & Medicaid Services projects four million beneficiaries will receive a check in 2010 -- about 80,000 of them in the June 15 initial mailing, followed by larger mailings throughout the summer and fall. As part of our effort to ensure seniors can afford the prescription drugs they need, we will increase efforts to prevent Medicare fraud and scams targeted at seniors related to the mailing of these rebate checks.

Over the course of the coming weeks, our team across government will continue to work diligently to produce the regulations and guidance necessary to implement this landmark new law, and we look forward to working with you to deliver the benefits of the Affordable Care Act to the American people.

May 10, 2010
Page 4

Sincerely,



Kathleen Sebelius

cc The Honorable Max Baucus, Chairman
Senate Committee on Finance

The Honorable Charles Grassley, Ranking Member
Senate Committee on Finance

The Honorable Tom Harkin, Chairman
Senate Committee on Health, Education, Labor and Pensions

The Honorable Michael Enzi, Ranking Member
Senate Committee on Health, Education, Labor and Pensions

The Honorable Henry Waxman, Chairman
House Committee on Energy and Commerce

The Honorable Joe Barton, Ranking Member
House Committee on Energy and Commerce

The Honorable Sander Levin, Chairman
House Committee on Ways and Means

The Honorable Dave Camp, Ranking Member
House Committee on Ways and Means

The Honorable George Miller, Chairman
House Committee on Education and Labor

The Honorable John Kline, Ranking Member
House Committee on Education and Labor

**THE AMERICAN ASSOCIATION OF PROLIFE
OBSTETRICIANS AND GYNECOLOGISTS**

**INDUCED ABORTION AND THE RISK OF SUBSEQUENT PREMATURE
BIRTH: General comments and Summary of the pertinent literature.**

Preterm Birth has become a very significant and extremely expensive medical reality in the United States (and other countries as well). Premature birth (birth before 37 weeks) has **increased 27% since 1981. In 2002 the premature (preterm, or PTB) rate was 12.1% of all live births** (and over 17% of all African-American births).

In 2003, the American College of ObGyn and the March of Dimes foundation announced a major campaign to decrease the number of premature births in America. Partnering with them in this campaign were the American Academy of Pediatrics, and the Association of Women's Health, Obstetrics, and Neonatal Nurses.

This campaign has identified a number of risk factors of premature birth, including infection, maternal or fetal stress, , bleeding or abruption, uterine stretch, maternal age, weight, smoking, drug use, and genetic component. **But, they conclude, "There is no known cause in HALF of premature births."** AAPLOG is very concerned that **they fail to mention induced abortion as a risk factor. It simply does not come up on their radar screen (nor on their Website).** Yet the existing medical literature **strongly confirms** that induced abortion may play a significant role in premature (preterm) birth (PTB) in a subsequent pregnancy. **At least 59 studies have demonstrated a statistically significant increase in premature birth or low birth weight risk in women with prior induced abortions.**

The March of Dimes failure to mention induced abortion as a risk factor for preterm birth is consistent with the published position of the American College of Obstetrics and Gynecology. The ACOG Practice Bulletin #26 (April, 2001) states: "Long term risks sometimes attributed to surgical abortion include potential effects on reproductive function, cancer incidence, and psychologic sequelae. However, the medical literature, when carefully evaluated, clearly demonstrates no significant negative impact on any of these factors with surgical abortion." This Bulletin was replaced in Oct, 2006 with Practice Bulletin #67, which does not repeat this misinformation. However, neither is there correction of this misinformation in any ACOG literature we have seen to date. (Dec 2008). Consistent with this position, the ACOG Amicus Brief for the 2006 Ayotte US Supreme Court Case declares authoritatively: "..... Contrary to the claims of the State and its amici, there is simply no reliable evidence that abortions are harmful to minors' health. Extensive reviews have concluded that there are no documented negative psychological or medical sequelae to abortion among teen-aged women. Minors who obtain an abortion are not at greater risk of complications in future pregnancies, future medical problems, or future psychological problems." AAPLOG does not feel this sweeping conclusion can be justified in the medical literature. To the contrary, there is a

very strong case in the medical literature implicating induced abortion as a risk factor for preterm birth, and as a factor in the escalating PTB rate seen over the past 30 years. Understand and addressing the risk factors for the preterm birth 'epidemic' is crucial because **low birth weight (LBW)** and **preterm birth (PTB)** are the most important risk factors **for infant mortality or later disabilities**, as well as **for lower cognitive abilities and greater behavioral problems**. In addition to the huge human cost, the economic cost required to properly care for these premature babies is a severe challenge to medical care system.

Following are comments on several of the prominent studies focusing on the association between induced abortion and risk of subsequent preterm birth.

THE THORP REVIEW

Reference: Thorp, et. al., Long term Physical and Psychological Health Consequences of Induced Abortion: Review of the Evidence; (OB GYN Survey, Vol 58 #1, 2002):

12 of 24 studies showed an association between Induced Abortion and PTB, showing a risk up to double the expected risk. Thorp identified a **"DOSE RESPONSE" effect, i.e., the more IA, the higher the risk.**

THE CALHOUN-ROONEY REVIEW

Calhoun, B, Rooney, B; Induced Abortion and Risk of Later Premature Birth; (Journal of American Physicians and Surgeons, Volt 8, #2, 2003):

Calhoun and Rooney reported on 1993 Australian study by Lumley of 121,305 births. See Table 1 for results:

Gestational age	Number of prior IAs			1998 study
	1	2	3	4+
20-27 wks(XPB)	1.6	2.5	5.6	9
28-31 wks	1.5	1.1	2.6	
32-36 wks	1.1	1.6	2.4	

Table 1: Premature birth risk by # of prior induced abortions compared with outcome of first pregnancies.(Lumley, "The epidemiology of Pre term birth, Baillieres "Clinical OBGYN, 1993:7(3)477-498). Also Lumley in Prenatal Neonatal Med 1998; 3:21-24) (244,000 live births)

Most of the induced abortions reported in this study were by **vacuum aspiration**, which would be the **least traumatic** method for the cervix. Nevertheless, these IA's resulted in the significant increases in PTB. Notice that **the Extreme Preterm Birth (XPB) category is inordinately affected**, with **doubling** of XPB with just 2 IA's, an increase of over **5 times** the expected rate with 3 IA's, and **an astounding nine-fold increase with 4 or more induced abortions** (the latter figure from a 1998 study by Lumley, analyzing 243,679 live births.)

THE BAVARIAN STUDY

Calhoun and Rooney reported on a 1998 study from Bavaria of 106,345 births. See Table 2 for results.

Martius, et al; "Risk factors..." EuroJ.ObGynReproBiol1998;80:183-189)

Gestational age	Number of prior IAs		
	1	2	3 or more
<32 weeks	RR 2.5	RR 5.2	RR 8.0
<37 weeks	1.5	2.1	3.6

Note again, the dose response (more IA's produce more PTB). Note also the inordinate increase in Early Preterm Birth (under 32 weeks) associated with repeat induced abortion--an eightfold increase after 3 induced abortions

THE DANISH STUDY

Calhoun and Rooney reported on 1999 Danish study, which showed that a mid trimester abortion by D&E, (dilatation and evacuation) increased the risk of PTB substantially. This seems logical, as the D&E procedure necessarily results in more cervical trauma than a simple suction curettage. One prior D&E more than doubled the PTB rate, and two prior D&E's increased the risk 12 times higher than the rate for women with no abortion history.(Zhou, Sorenson, Olsen, "Induced abortion and subsequent pregnancy duration," Obstet Gynecol 1999;94:948-953)

THE EUROPOP STUDY

A 2004 EUROPOP Study of 17 countries (7719 patients) concluded that the risk of very preterm birth (22 to 32 weeks), compared to women with no abortion history, increased by 50% (1.5 times higher) after one abortion, and increased by 80% (1.8 times higher) after 2 abortions. (Human Reproduction, Vol 19, No. 3, 29 Jan 2004, pp. 734-740)

THE EPIPAGE STUDY

Moreau C, et al."Previous induced abortions and the risk of very preterm delivery" Br J OBGyn,2005;112:430-437.

Previous induced abortions and the risk of very preterm delivery: results of the EPIPAGE study. (2837 patients) Among women who had one or more abortions, compared to women with no abortion history, there was a 50% increase (1.5 times higher) in very preterm births,(22-32 wks); two or more abortions resulted in a 160% increase (2.6 times higher). In this particular study they also looked at extremely preterm deliveries (22-27 weeks) and found a 70% increase (1.7 times higher) for those who had at least one prior abortion.

THE IOM REPORT

The most recent and complete commentary on the preterm birth question is found in the Institute of Medicine's newly published (National Academy of Science Press, July 06) 570 page resource book entitled "" *Preterm Birth: Causes, Consequences, and*

Prevention." This report has been applauded by ACOG, SART, and ASRM as an exceptional work on this adverse pregnancy result. ACOG is a co-sponsor of this work.

With a careful search, one will find a single reference to induced abortion as a risk factor for PreTerm Birth, found in the Appendix, on page 517-18, where abortion is noted as an "immutable" risk factor (meaning, once this pregnancy has started, there is no intervention to correct for the increased risk. Example of immutable factor: Congenital incompetent cervix). Obviously, in the case of induced abortion, this risk factor is totally avoidable, if the woman is given adequate informed consent prior to the abortion and chooses NOT to have the abortion. The truth is, induced abortion is a preventable risk factor for future preterm birth: **Do not have the abortion, and you will not have the associated increased risk of preterm birth.**

The latest statistics in the USA (2002) show a preterm (less than 37 weeks) birth rate of 12.7%. Of these, Early Preterm Birth (EPB—under 32 weeks, infants weighing under 1500 grams, or about three pounds.) is at 7.8%, the highest rate in the past 30 years of stats. As noted in the studies above, previous 'induced abortions' have an inordinately increased association with "extreme" (<27 wk) and "early" (<32 wk) premature deliveries (compared to 32 - 37 week premature births.) Thus, abortion very likely will also have an inordinately increased association with cerebral palsy and other disabilities linked to extreme prematurity.

The total prematurity rate for women in America before 1970, before abortion became legal and common, was approximately 6%. It is of interest to note that **in Ireland, where induced abortion is illegal, the prematurity rate in 2003 was 5.48%**, less than half the U.S. rate of 12.3%. Is there a message here??

Further very interesting statistics come from the Polish experience. Between 1989 and 1993, Poland's induced abortion rate decreased 98% due to a new restrictive abortion law. The Demographic Yearbook of Poland reports that, between 1995 and 1997 the rate of extremely preterm births (<28 weeks gestation) dropped by 21%. Is there a message here??

Induced abortion has a significant association with subsequent premature birth, and particularly "very" premature birth (i.e, before 32 weeks gestation). "Very" premature birth has a significant association with cerebral palsy and other developmental difficulties.

AAPLOG calls upon the involved medical disciplines, (in particular, perinatologists and neonatologists) to recognize this reality, and to act in the best interest of the women and babies who are at risk. Public education and adequate informed consent are an essential place to start. But all physicians caring for women must be cognizant of this preventable risk factor, and educate their vulnerable patients accordingly.

Updated 12-08

Eighteen (18) Statistically Significant studies showing an association of Abortion with subsequent Very PreTerm Birth, and Abortion with Very Low Birth Weight

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* studies that included spontaneous and induced abortions (SIA) but did not report PTB/LBW risk separately for each
 + studies that found dose/response (the more SIAs, the higher the risk)

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Okonofus FE, Onwudiegwu U, Odutayo R. Pregnancy outcomes after illegal induced abortions in Nigeria: a retrospective referenced historical study. *Africa J Med Science* 1994;23:165-169

* studies that included spontaneous and induced abortions (SIA) but did not report PTB/LBW risk separately for each

+ studies that found dose/response (the more SIAs, the higher the risk)

!! Significant Abortion/VPB (Very Preterm Birth) and/or Abortion/VLBW (Very Low Birth Weight)

The American Association of ProLife Obstetricians and Gynecologists
www.aaplog.org

THE MOST RECENT STUDY ON ABORTION AND SUBSEQUENT PRETERM BIRTH

2008

Is induced abortion a risk factor in subsequent pregnancy?

Voigt M, Olbertz D, Fusch C, Krafczyk D, Briese V, Schneider KT. The influence of previous pregnancy terminations, miscarriages and still-births on the incidence of babies with low birth weight and premature births as well as a somatic classification of newborns.

Z Geburtshilfe Neonatol. 2008 Feb;212(1):5-12.

1Department of Obstetrics and Gynecology, Ernst-Moritz-Arndt-University of Greifswald, Germany.

Abstract Objective: To determine whether a history of terminations of pregnancy influences subsequent pregnancies in terms of pregnancy risks, prematurity and neonatal biometrics. Patients and methods: Based on the perinatal statistics of eight German federal states, data of 247,593 primiparous women with singleton pregnancies born between 1998 and 2000 were analyzed. The control group consisted of primiparous women without previous induced abortions. Maternal age was adjusted for. Results: There was an overall trend towards an increased rate of preterm delivery at ≤ 36 weeks' gestation and early preterm delivery at ≤ 31 weeks' gestation in women who had previous pregnancy terminations. For the cohort of 28-30 years, the observed rates of prematurity in women with one and with ≥ 2 previous induced abortions were 7.8% and 8.5%, respectively, compared to 6.5% in the control population ($P=0.015$). Preceding terminations of pregnancy did not alter the rate of small-for-gestational-age newborns. Psychosocial stress and symptoms associated with prematurity such as cervical incompetence and vaginal bleeding before and after 28 weeks of gestation occurred more frequently in women with previous induced abortion compared to the control group ($P<0.0001$). Conclusion: The rate of preterm births increases with the number of preceding abortions. Similarly, symptoms associated with prematurity are more common. The rate of small-for-gestational-age newborns was not affected by preceding terminations of pregnancy.

AAPLOG Comment: This appears to be a very clean retrospective study with large numbers. In the article, all 3 factors, elective abortion, spontaneous abortion, and stillbirth, had independent and additive effects on the risk of preterm birth in subsequent pregnancy when compared to women with no previous EAB, SAB, or stillbirth. With one EAB there was a 30% increase in < 32 week preterm birth. With 2 or more previous EABs the < 32 week preterm birth risk was increased by 90%. A previous SAB (and even more so a stillbirth) also increased the risk of < 32 week preterm birth. Our initial focus should be to recommend that women with previous EAB, SAB, or Stillbirth be watched carefully for evidence of preterm cervical change and/or preterm labor. Normally, this information would be made available to all women contemplating an elective abortion. However, like the more than 60 previous studies demonstrating an association between induced abortion and subsequent preterm birth, this study will also likely simply be ignored by the American ObGyn, MFM, and Neonatal medical specialty groups.

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Sept 08

ABORTION AND PRETERM BIRTH

THE IOM REPORT: A CRACK IN THE STONE WALL

The ACOG has a firmly declared position on long term complications of induced abortions. Simply stated, they declare: THERE ARE NO SIGNIFICANT LONG TERM COMPLICATIONS. Lest you feel we are being unfair to the ACOG, we quote from the ACOG Practice Bulletin #26, unchanged since 2001, and re-validated as an ACOG position in their 2006 Compendium of Selected Publications: "Long term risks sometimes attributed to surgical abortion include potential effects on reproductive function, cancer incidence, and psychologic sequelae. However, the medical literature, when carefully evaluated, clearly demonstrates no significant negative impact on any of these factors with surgical abortion." This Bulletin was replaced in Oct, 2006 with Practice Bulletin #67, which does not repeat this misinformation. However, neither is there correction of this misinformation in any ACOG literature we have seen to date. Additionally, the ACOG sponsored Amicus Brief in the January 2006 Supreme Court case on parental notification (Ayotte vs Planned Parenthood of Northern New England), states unequivocally, "The evidence belies any serious long term health consequences of abortion for minors. Contrary to the claims of the State and its amici, there is simply no reliable evidence that abortions are harmful to minors' health. Extensive reviews have concluded that there are no documented negative psychological or medical sequelae to abortion among teen-aged women. Minors who obtain an abortion are not at greater risk of complications in future pregnancies, future medical problems, or future psychological problems." That Brief should be current enough to define ACOG's declared position on long-term abortion complications).

However, in July, 2006, National Academy of Science's Institute of Medicine produced a book entitled "Preterm Birth: Causes, Consequences, and Prevention." This is a 570-page volume with the very latest and most complete information. A July 06 ACOG news release highly praises this new work, and notes that "ACOG is pleased to be a cosponsor of this report because the impact of preterm birth is a major public health problem both in the US and worldwide." If one scrutinizes the report very carefully,

one will find, in the Appendix, one will find a single entry (on page 517-18) in which induced abortion is noted as an "immutable" risk factor (meaning, "once you are pregnant, if you have a history of previous induced abortion, this is an unalterable risk factor."

There are a few things on the "immutable" list that can be changed by action prior to pregnancy--the first is multiple gestations, which sometimes can be changed, when related to assisted reproductive techniques. A couple others, which MIGHT be able to be changed, are low pre-pregnancy weight and urogenital infections.

The elephant in the "risk factor room" is induced abortion, which can be changed by simply not obtaining the induced abortion in the first place--this would be primary prevention. There may not be any current secondary prevention, but there certainly can be primary prevention.

The "immutable" risk factor of induced abortion could be abolished as a risk factor in virtually all circumstances with adequate informed consent and some forward thinking. . .

But what about the ACOG position of denial of a risk association? What about the Amicus Brief issued for the 2006 Supreme Court case? They state categorically, concerning induced abortion, that the medical literature "clearly demonstrates no significant negative impact on" "reproductive function." They assure the Supreme Court Justices that induced abortion in "minors" renders them "not at greater risk of complications in future pregnancies." So what are we to believe?---the ACOG Amicus brief, or the ACOG sponsored and publicly praised IOM report? These positions seem to contradict each other. Perhaps a crack has developed in the stone wall of denial.

ACOG is a partner in the national March of Dimes campaign to reduce the number of premature births. To date, the word "abortion" has not appeared on the MOD website information concerning preventable risk factors for preterm births. Surely ACOG will advise MOD that the recent Institute of Medicine textbook validates the abortion as a risk factor, so MOD can, in turn, adequately inform the women they seek to serve regarding this completely preventable "immutable" preterm birth risk factor.

**Disparities in Preterm Birth:
The Patterns Tell Us We Need to Address Social Factors.**

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Submitted to the Subcommittee on Health of the House Committee on Energy and
Commerce, relevant to a hearing on Preterm Birth May 12, 2010

Key points

- The large and persistent black-white disparity in preterm birth (PTB) is not explained by the recognized causes of PTB; for example, black women are less likely than white women to smoke, and the disparity persists after considering diet and drug use.
- African and Afro-Caribbean immigrants to the U.S. have PTB rates similar to those of U.S. whites. This pattern strongly suggests that the causes of the black-white disparity are social, rather than genetic.
 - Other features of the social patterns of PTB also point to social causes. Although PTB rates decline with increasing income or education among black women as well as white women, the *relative* black-white difference in PTB rates (the ratio of the rates) is much larger among more educated/affluent women than among poor/less educated women. This also suggests social rather than genetic causes.
- The observed patterns of PTB are consistent with a potential role for stressful circumstances experienced by women during childhood; stress could be related to financial hardship or awareness of racial discrimination.
 - Financial hardship and insecurity are stressful, and regardless of their current income or education, black women are more likely than white women in similar current socioeconomic circumstances to have experienced worse economic circumstances while growing up. This could help explain why the racial disparity in PTB is greater among more educated/affluent women than among poorer/less educated women.
 - The patterns also could be explained by chronic stress associated with awareness of racial discrimination – for example, a woman may be aware that she belongs to a socially less-valued group, and may be considered inferior based on her racial group, even if she does not personally experience overt incidents of racial discrimination. This awareness could

**Racial Disparities in Preterm Birth:
The Patterns Tell Us We Need to Address Social Factors**

Trends in the black-white disparity in preterm birth

For decades, large disparities in birth outcomes have been observed between babies born to African-American (black) women and those born to European-American (white) women. Adverse birth outcomes – that is, being born “too early” (premature or preterm birth, before 37 completed weeks of pregnancy) or “too small” (low birth weight, less than 5 ½ pounds)—are powerful predictors not only of infant survival, but of child health, development, and serious disability, and, according to recent research, also of chronic disease in adulthood. The disparities have been persistent, until recently when relative disparities began to narrow somewhat, for undesirable reasons: the rates of both preterm birth (PTB) and low birth weight (LBW) worsened among white women, with little (PTB) or no (LBW) improvement among black women. (For simplicity, throughout this paper “black” and “white” are used to refer only to non-Hispanic women.)

The known causes of adverse birth outcomes do not explain the disparities. Known causes of both PTB and LBW include use of tobacco, excessive alcohol (particularly in the first trimester), use of illegal drugs, low pre-pregnancy weight, inadequate weight gain during pregnancy, very short maternal stature, and chronic disease. Studies taking these factors into account, however, have still observed sizable black-white disparities, and the disparities persist even after taking income or education into account.

A number of other causes have been suspected, but to date no definitive evidence has established any of them. Many researchers have hypothesized that infections – principally genital infections such as Bacterial Vaginosis or oral/gingival infections—were the cause, because these infections are more common among black women. This seems unlikely, however, because experiments in which the infections were successfully treated have not consistently improved birth outcomes, suggesting that there are unmeasured factors associated with the infections that are the actual causal agents. Some scientists have thought that exposure to certain environmental toxins might be the answer, and others have implicated work that is physically demanding –e.g., requiring one to be on one’s feet for extended periods of time during pregnancy—but neither theory has consistent evidence to support it.

A widely held theory is that the differences are genetic in nature, but no one has identified a “PTB” or “LBW” gene or set of genes. The processes involved in PTB are likely to be complex, involving cascades of factors that may interact with multiple other factors; it is reasonable to question whether such complex cascades of factors would be likely to sort out through the process of natural selection along racial/ethnic lines. Furthermore, as will be discussed later in this paper, black immigrants to the U.S. from Africa and Afro-Caribbean nations have birth outcomes that are relatively similar to those of white women in the U.S., while the birth outcomes of U.S.-born daughters of those immigrants look like those of other African-American women. These patterns suggest an

Among both black and white women, PTB and LBW rates decline (improve) with increasing income or education. However, the *relative difference* (the ratio of the rates) between black and white birth outcomes actually *increases* (worsens) with higher income or education. For example, in recent statewide data from California (where one in 7 US births occur), among poor women, blacks had 1.3 times the rate of LBW as whites; among women with incomes over two times the poverty level, however, black women were more than twice (2.5) times as likely as white women to have a LBW birth. The same pattern has been seen in national data, and patterns are similar for PTB. As with the birth outcomes of immigrants and their U.S.-born daughters, it also is difficult to explain this pattern as genetically based.

How could this perhaps counter-intuitive pattern be explained? Why would higher income/education black women do worse relative to their similar-income/education white counterparts? Two explanations seem reasonable, both having to do with stress: stress related to unmeasured financial hardship or insecurity, and stress related to awareness of racial discrimination.

Financial hardship is stressful, and experiences of chronic stress, particularly during childhood, may have the most potential for damaging physiologic systems with potential implications for PTB. Health studies rarely measure socioeconomic experiences in childhood, and black women of a given *current* income or education are far more likely than their same-current-income/education white counterparts to have experienced worse socioeconomic conditions as children. There may be less difference between currently poor black and white women in how poor they were in childhood and the characteristics of the neighborhoods they lived in as children, than between currently non-poor black and white women. Worse socioeconomic conditions could be stressful in themselves, and contribute to family disruption, which adds to the stress. More affluent black women may face more stress than similarly affluent white women due to greater needs to financially support family, friends, or partners, than their white counterparts. And college-educated black women face the added stress of having fewer similarly-educated black men with whom they might partner, given the high rates of incarceration and low rates of college graduation among black men in the U.S.

In addition to the stress of financial hardship and associated social stressors, chronically experiencing or anticipating discriminatory treatment could be stressful. Being aware of racial discrimination, and being vigilant to be prepared to respond to it if it occurs, also could be quite stressful. In focus groups with African-American women in California, my colleagues and I were stuck by the extent to which black women—both low-income and not low-income—carried around with them a constant, gnawing awareness and anxiety about when the next incident, overt or subtle, might occur to them or their children. More educated and affluent African-American women may ironically be more exposed to experiences of racial discrimination, because they are more likely to be working, shopping, and potentially residing with whites, than their less educated/affluent black counterparts. This theory must be tested empirically, but it is biologically plausible given what we know about the physiology of stress, which is discussed below.

response, with the potential for resulting in significant damage over time to organs and systems, as mentioned in the discussion of stress (above).

What are the solutions?

No one has definitive knowledge of the causes of racial disparities in birth outcomes, but we do know enough to know that there are no simple solutions. The patterns are social, and the solutions therefore must be social, whether or not there is any additional contribution that new biomedical therapies can make. The patterns strongly suggest a role for chronic social disadvantage, both related to economic hardship and its social consequences, and related to living in a society where racial discrimination still exists, perpetuated by societal structures such as racial residential segregation, even when there is no longer conscious intent to discriminate. The solutions to racial disparities in PTB are ones likely to address most racial disparities in health – initiatives that will bring economic and social opportunities to communities that are marginalized.

Because conditions in neighborhoods can be such an important –and modifiable-- determinant of a person's ability to escape poverty and its adverse health effects, efforts like the current federal administration's "Promise Neighborhoods" initiative –combining early childhood development programs, improving schools, supporting families, and engaging communities-- will be crucial for breaking the intergenerational cycle of poverty and despair that is one of the most important underlying factors of racial disparities in health in this country. Public dialogue about race and racism will also be important, but cannot take the place of concrete measures to change the material and social conditions of African-Americans. Achieving more equality in social and economic opportunities will ultimately contribute more to racial equality –in health overall, and in PTB in particular-- than discussions of racism.

I am collaborating with the California Department of Public Health Maternal, Adolescent, and Health Division (MCAH) to develop and implement a science-based approach to reducing the racial disparity in PTB in California, which focuses on empowerment, capacity-building and social support among African-American women. This approach should be considered for Healthy Start and throughout Medicaid.

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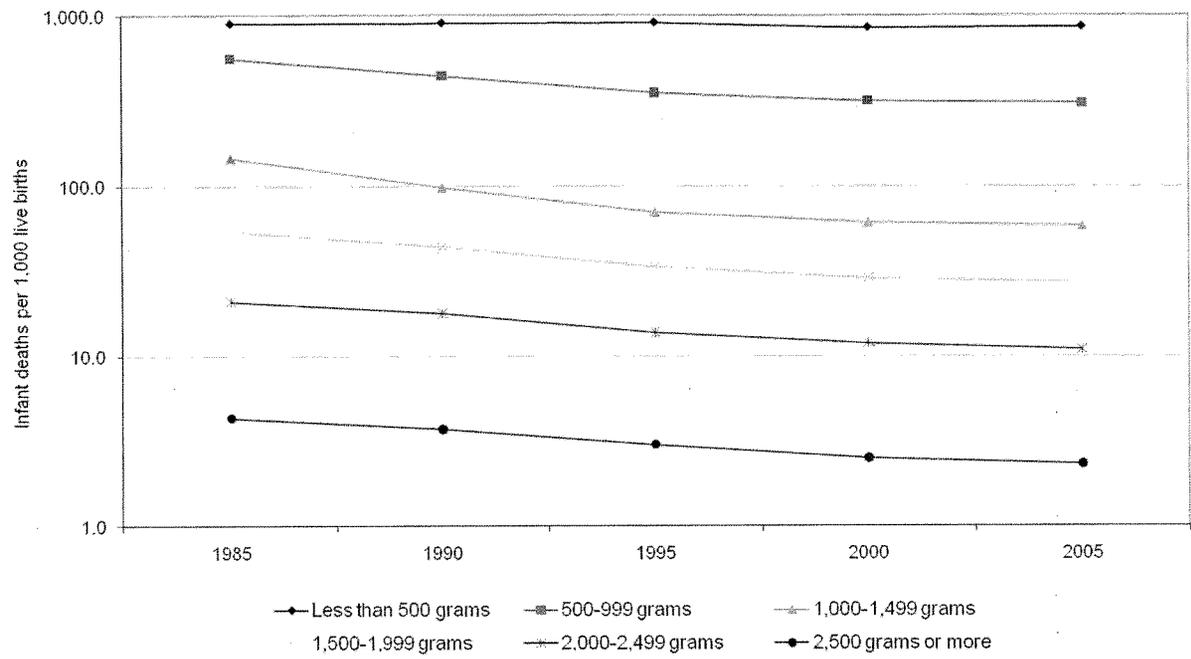
“Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early?”

Prepared Supplementary Handout for Hearing

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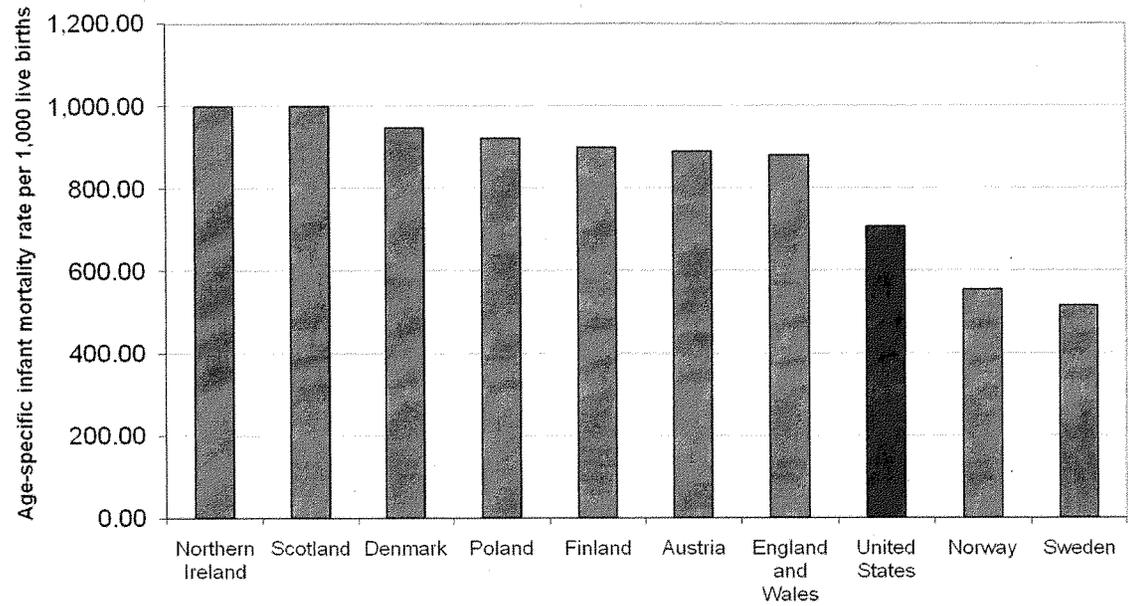
Committee on Energy and Commerce
Subcommittee on Health
U.S. House of Representatives
Washington, D.C.
May 13, 2010

Figure 1: U.S. Infant Mortality Rates by Birthweight, 1985-2005



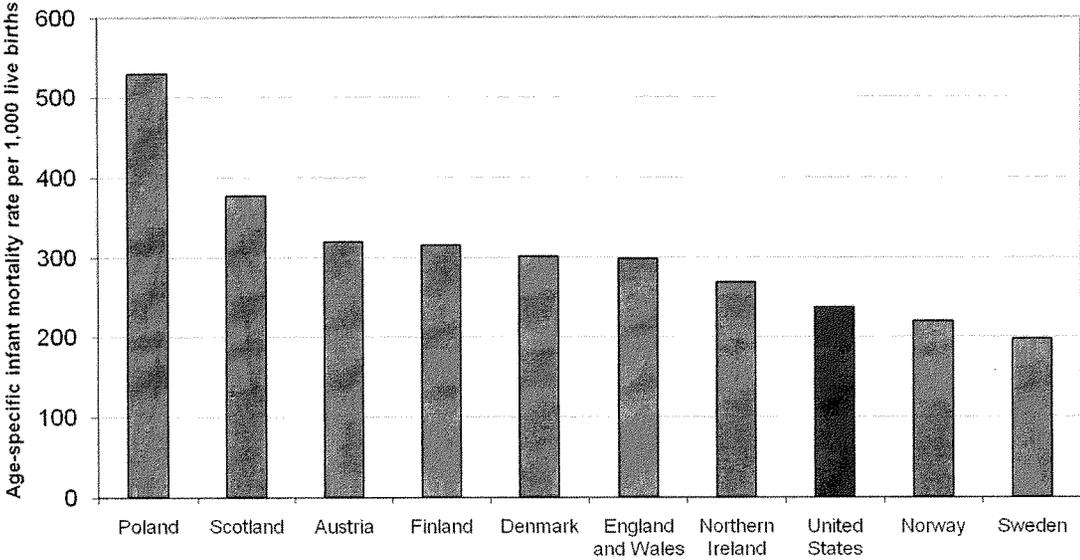
Source: CDC/NCHS, National Vital Statistics System, Linked Birth/Infant Death Data Set. From Health, United States, 2009. Table 18. Available at <http://www.cdc.gov/nchs/data/hus/hus09.pdf>.

Figure 2A: Infant mortality rate for early/premature births by gestation (22-23 weeks): USA vs. Selected European Countries, 2004



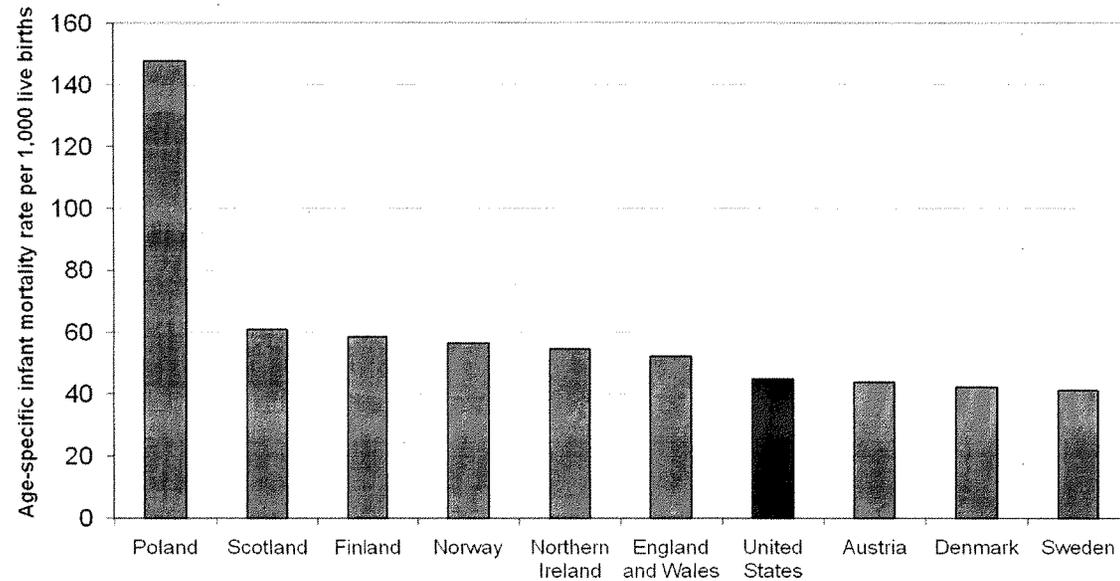
Source: NCHS linked birth/infant death data set (for U.S. data), and European Perinatal Health Report (for European data). From Marian F. MacDorman, Ph.D., and T.J. Mathews, M.S., "Behind International Rankings of Infant Mortality: How the United States Compares with Europe," NCHS Data Brief, Number 23, November 2009. Table 2, available at <http://www.cdc.gov/nchs/data/databriefs/db23.htm>.

Figure 2B: Infant mortality rate for early/premature births by gestation (24-27 weeks): USA vs. Selected European Countries, 2004



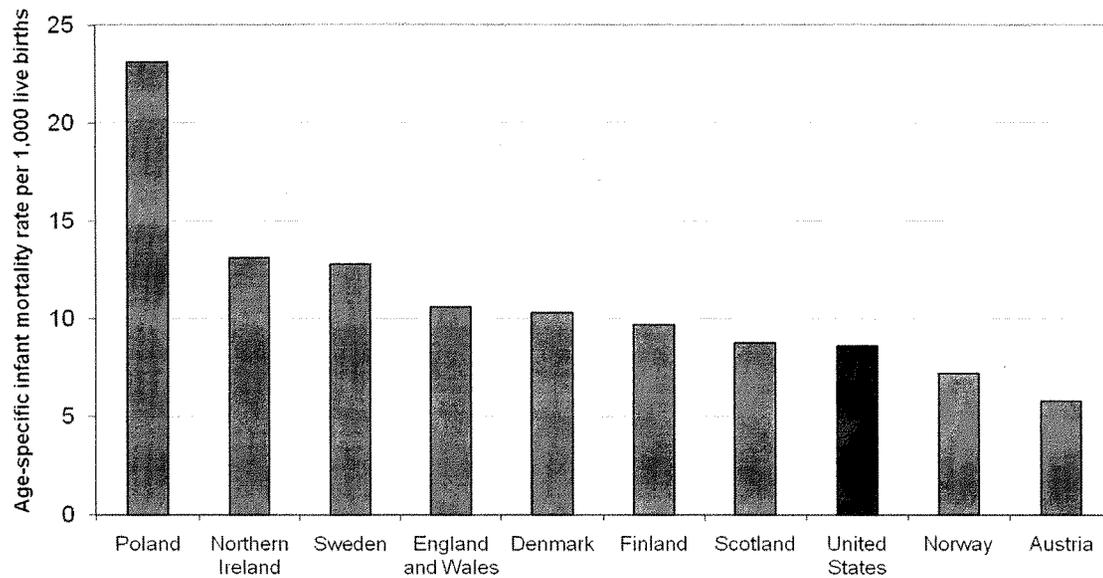
Source: NCHS linked birth/infant death data set (for U.S. data), and European Perinatal Health Report (for European data) From Marian F. MacDorman, Ph.D., and T.J. Mathews, M.S., "Behind International Rankings of Infant Mortality: How the United States Compares with Europe," NCHS Data Brief, Number 23, November 2009. Table 2, available at <http://www.cdc.gov/nchs/data/databriefs/db23.htm>.

Figure 2C: Infant mortality rate for early/premature births by gestation (28-31 weeks): USA vs. Selected European Countries, 2004



Source: NCHS linked birth/infant death data set (for U.S. data), and European Perinatal Health Report (for European data). From Marian F. MacDorman, Ph.D., and T.J. Mathews, M.S., "Behind International Rankings of Infant Mortality: How the United States Compares with Europe," NCHS Data Brief, Number 23, November 2009. Table 2, available at <http://www.cdc.gov/nchs/data/databriefs/db23.htm>.

Figure 2D: Infant mortality rate for early/premature births by gestation (32-36 weeks): USA vs. Selected European Countries, 2004



Source: NCHS linked birth/infant death data set (for U.S. data), and European Perinatal Health Report (for European data). From Marian F. MacDorman, Ph.D., and T.J. Mathews, M.S., "Behind International Rankings of Infant Mortality: How the United States Compares with Europe," NCHS Data Brief, Number 23, November 2009. Table 2, available at <http://www.cdc.gov/nchs/data/databriefs/db23.htm>.

Table 1: Infant Mortality by Race, Education and Marital Status--USA, 1982 (Eight Pilot States, US Linked Birth and Infant Death Files, per 1,000 live births)

Years of Education	All Races	White	Black
All women	10.5	9.0	21.9
0 to 8	13.0	12.0	27.5
9 to 11	16.7	12.9	29.1
12	10.1	8.8	20.0
13 to 15	9.5	8.1	18.6
16+	8.6	7.9	20.6
Married women	9.1	8.4	18.2
0 to 8	11.1	10.6	24.5
9 to 11	12.4	11.1	24.9
12	8.9	8.4	16.4
13 to 15	8.5	7.8	16.8
16+	8.3	7.9	19.2
Unmarried women	20.7	16.2	25.2
0 to 8	20.7	18.1	29.8
9 to 11	24.9	19.2	30.7
12	18.6	14.6	23.1
13 to 15	19.9	15.1	20.9
16+	18.4	11.6	26.8

Note: The eight pilot states are Illinois, Indiana, Massachusetts, Michigan, Missouri, New Hampshire, Vermont, and Wisconsin. "All races" includes races other than black and white.

Source: National Center for Health Statistics, Pilot Linked Birth and Infant Death File, unpublished data. From Nicholas Eberstadt, "The Tyranny of Numbers: Mismeasurement and Misrule," AEI Press, 1995. Table 2.9.

Table 2: The "Hispanic Paradox": Infant Mortality, Low Birthweight, And Other Socio-demographic Characteristics for the US by Ethnicity, c. 2006

	Non-Hispanic White	Non-Hispanic African-American	American Indian/Alaskan Native	Asian-Pacific Islander	Hispanic/Latino	All USA
Low birthweight (% of live births)	7.3	14.0	7.5	8.1	7.0	8.3
Infant mortality rate (per 1,000 live births, 2003-5 data)	5.7	13.6	8.4	4.8	5.6	6.8
Child poverty rate (children under 18, percent)	9.5	33.0	N/A	12.0	26.6	16.9
% of women 18+ without HS degree	9.8	19.1	N/A	14.7	38.8	14.7
% of births with no prenatal care in first trimester	24.0	41.8	44.0	28.9	42.4	31.7

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Sources: Low birthweight data from CDC/NCHS, National Vital Statistics System, Birth File. From Health, United States, 2009. Table 11. Available at <http://www.cdc.gov/nchs/data/hus/hus09.pdf>;

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Educational attainment data from U.S. Census Bureau, Current Population Survey, 2006 Annual Social and Economic Supplement, Table 1a, available at <http://www.census.gov/population/www/socdemo/education/cps2006.html>.

**HHS Response to Questions for the Record from
The Honorable Zack Space**
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
May 12, 2010 Hearing on

Prematurity and Infant Mortality: What Happens When Babies Are Born Too Early?

1. What more can we do to foster the use of telemedicine for the prevention and treatment of prematurity?

Both the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) support activities that will foster the improvement of care through the use of telemedicine.

NIH defines “telemedicine” as the “use of electronic communication and information technologies to provide or support clinical care at a distance. Included in this definition are patient counseling, case management, and supervision/preceptorship of rural medical residents and health professions students when such supervising/precepting involves direct patient care.” The National Library of Medicine at the NIH has supported a National Telemedicine Initiative for many years that includes projects such as the Virtual Hospital and the National Laboratory for the Study of Rural Telemedicine (see <http://www.nlm.nih.gov/research/telemunit.html>). In addition, NIH’s Center for Information Technology is making constant efforts to improve the technologies critical for telemedicine to be successful in its Biomedical Imaging and Visualization Section (see <http://cit.nih.gov/Science/CollaborativeResearch/Telemedicine>). Although no clinical trials on the use of telemedicine to prevent or address prematurity are currently underway, other NIH-supported trials include using telemedicine for smoking cessation, and diabetes heart disease treatments, among others. The NIH would welcome grant applications proposing the use of telemedicine for other conditions, including preterm birth.

CDC agrees that telemedicine, and any technologies that foster communication between and among clinicians and hospitals, have the potential to increase the efficiency and accuracy of clinical assessment and treatments. This is particularly pertinent to the treatment of newborn preterm infants. The CDC, as a public health agency, does not interact with the provision of care at the individual level on issues of maternal and infant health. However, the CDC will continue to encourage well-organized, state-based perinatal regionalization as a strategy to care for high risk women and infants.

2. What more can we do to support evidence-based initiatives like the Ohio Better Birth Outcome Program?

NIH and CDC agree that a strong evidence base is essential to good patient care and support research within their missions to strengthen scientific knowledge on preterm birth. Some research examines which health care practices may be beneficial (and which may not be) in preventing preterm labor or caring for the mother and infant following a premature birth. Programs such as the Ohio Better Birth Outcome program can use new evidence resulting from this research to improve pregnancy outcomes in their own communities. Ohio also is fortunate to have the Ohio Perinatal Quality Collaborative (QPQC). Under the direction of a multi-disciplinary steering committee, the QPQC works from the obstetric perspective to decrease

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unnecessary intervention, particularly in the late preterm and early term gestations, and from the neonatal perspective to improve the quality of newborn care. The work of the QPQC has been presented at national meetings and published in peer-reviewed journals. We applaud the efforts of the QPQC, and the other states that have similar collaboratives.

June 15, 2010

The Honorable Zack Space
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Dear Representative Space:

Thank you for the opportunity to respond to your question regarding expanding Congressional support for evidence based initiatives like the Ohio Better Birth Outcome program. During my recent visit to the Nationwide Children's Hospital in October 2009 I was pleased to learn about the Ohio Better Births Outcome and the close affiliation between Nationwide and Ohio State University in several collaborative efforts to enhance outcomes of pregnancy.

Thus, building on the success of the Ohio program, there are many ways Congress can address and combat the serious and costly problem of prematurity. Specific initiatives include the following: (1) accelerate the implementation of various provisions included in the Patient Protection and Affordable Care Act (P.L. 111-148); (2) increase funding for prematurity research; (3) reauthorize the PREEMIE Act (P.L. 109-450) and (4) fund maternity care demonstration projects utilizing the new mandatory Prevention and Public Health Fund. Please find the Foundation's comments below further articulating our thoughts about the aforementioned items.

Accelerate Implementation of the Following Provisions Included in the Patient Protection and Affordable Care Act (P.L. 111-148)

- **Quality:** The development, dissemination and use of maternity and pediatric quality measures represent an important tool for improving maternity and pediatric health care and reducing preterm birth and infant mortality. The Children's Health Insurance Program Reauthorization Act (CHIPRA) took an important step forward in this arena by calling for the development of a core set of pediatric quality measures. Health reform furthers this effort significantly, calling for a National Strategy for Quality Improvement, development of a core set of adult quality measures for use in Medicaid, and creation of the Center for Medicare and Medicaid Innovation. As these provisions are implemented, it is critical that the unique needs of pregnant women, infants and children are recognized. These provisions are a critical opportunity to further development and use of maternity and pediatric quality measures.
- **Further definition of maternity and pediatric benefits:** The inclusion of maternity care and pediatric services in the essential benefits package will be instrumental in helping to ensure that pregnant women, infants and children have access to the health care they need. As these benefits are further defined, they should cover particular services that can help prevent preterm birth (such as early ultrasounds for accurate gestational dating) as well as those specialty services needed by infants and children who are born preterm.
- **Further definition of women's preventive health benefit** The requirement that all insurance plans cover preventive health services needed by women has the

potential to increase access to services that can lower the risk of preterm birth. As this benefit is further defined, it should include access to family planning and preconception care services. Family planning helps women appropriately space pregnancies, which has been found to reduce the risk of preterm birth. Preconception care allows providers to identify conditions or behaviors that can impact a future pregnancy and provide appropriate intervention.

- **Smoking Cessation:** The Foundation encourages state and federal policymakers to implement comprehensive Medicaid coverage of smoking cessation provisions. A comprehensive tobacco cessation benefit is crucially important for pregnant women given the well documented negative impact of smoking on pregnancy health and birth outcomes. Pregnant women on Medicaid are 2.5 times more likely than other pregnant women to smoke. Moreover, joint estimates by the CDC and CMS, have found that smoking-attributable neonatal health care costs for Medicaid total almost \$228 million. Clinical trials have shown that, for every \$1 invested in smoking cessation programs for pregnant women, \$7.75 are saved in short-term medical costs and an additional \$7.63 (in year 2002 dollars) are saved in long-term costs by preventing disability among low birth weight infants who survive.

Increase Funding for Prematurity Research

- **National Children's Study (NCS):** Currently in the pilot phase, the NCS is tracking the more than 150 children born to study participants. The data from this important effort will inform the work of scientists in universities and research organizations across the nation and around the world, helping them identify precursors to disease and to develop new strategies for prevention and treatment. The first data generated by the NCS will provide information concerning disorders of birth and infancy including preterm birth and its health consequences.
- **National Institute of Child Health and Human Development:** Increased funding will enable NICHD to maintain the momentum and investments made with support provided through the Recovery Act. It will also enable the Institute to expand its support for preterm birth-related research and to initiate establishment of a network of integrated transdisciplinary research centers as recommended by the Institute of Medicine and the experts who participated in the Surgeon General's Conference. The causes of preterm birth are multi-factorial and necessitate a collaborative approach integrating many disciplines. These new centers would serve as a national resource for investigators to design and to share new research approaches and strategies to comprehensively address the problems of preterm birth.
- **Centers for Disease Control and Prevention National Center for Chronic Disease Prevention and Health Promotion, Division of Reproductive Health:** This division works to promote optimal reproductive and infant health. In 2009, CDC created a robust research agenda to prevent preterm birth by improving national and state data to track preterm births; developing, implementing and evaluating methods for prevention; understanding the problem of late preterm birth; and conducting etiologic and epidemiologic studies of early preterm birth. Increased funding is needed for the division to continue their important work.

Reauthorization of the PREEMIE Act (P.L. 109-450)

- **Authorize Trans-Disciplinary Centers for Preterm Birth Research:** Through this approach the Director shall make awards of grants and contracts to public and/or nonprofit private entities to pay all or part of the cost of planning, establishing, improving and providing basic operating support for trans-disciplinary research centers for prematurity. Existing programs related to prematurity research include neonatal and maternal-fetal medicine multicenter research networks with a focus on clinical trials. This new program 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 this goal, these centers would benefit from close association or affiliation with other NIH-funded centers focused on clinical trials. Research should integrate clinical, public health, basic, and behavioral and social science disciplines together with bioinformatics, engineering, mathematical, and computer sciences to address this problem collaboratively.
- **Reauthorize preterm birth research line (PREEMIE Act, P.L. 109-450) :** Furthering CDC's robust research agenda the Foundation proposes expanding CDC epidemiological research to include: (1) on the clinical, biological, social, genetic and behavioral factors relating to prematurity; (2) to improve national data to facilitate tracking the burden of preterm birth; (3) to develop, implement and evaluate novel methods for prevention to better understand the growing problem of late preterm birth; (4) to conduct etiologic and epidemiologic studies of preterm birth; (5) to expand research on racial and ethnic disparities and (6) the effectiveness of community based interventions
- **Secretary's Advisory Committee on Infant Mortality:** Authorize and amend the scope of responsibilities and membership 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.
- **Education Demonstration Projects:** Authorize funding for the Health Resources and Services Administration 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.

Demonstration Projects

Utilizing the new mandatory Prevention and Public Health Fund created by the Patient Protection and Affordable Care Act (P.L. 111-148) the Foundation encourages Congress and the Administration to appropriate funding for evidence based initiatives such as the Ohio Better Birth Outcomes, the Kentucky Project, or other maternity care models designed to reduce the rate of preterm birth. These initiatives are innovative and may dramatically change the delivery of care and support services for pregnant women.

Moreover, according to a recent report released by the National Center for Health Statistics the preterm birth rate decreased by 5.3% in Ohio from 2006-2008. The Foundation believes this decrease is due to the collaborative efforts in this State. It is therefore critical to continue this important work and more broadly disseminate the information about this and other collaboratives to continue the trend to further decrease preterm birth rates. The March of Dimes would be happy to play a role in disseminating

the information about these collaboratives and to update you periodically on our other efforts to reduce the incidence of preterm birth.

Again, thank you for your interest in this topic and for the opportunity to respond to your question. Please know that March of Dimes volunteers and staff look forward to working with you to accelerate the nation's efforts to solve this very serious problem.

Sincerely,



Alan R. Fleischman, M.D.
Senior Vice President and Medical Director