

PARENTS RAISING CHILDREN: PREMATURE BABIES

HEARING
BEFORE THE
SUBCOMMITTEE ON CHILDREN AND FAMILIES
OF THE
COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS
UNITED STATES SENATE
ONE HUNDRED EIGHTH CONGRESS
SECOND SESSION
ON

EXAMINING CAUSES, RESEARCH AND PREVENTION OF PREMATURE
BIRTHS

May 13, 2004

Printed for the use of the Committee on Health, Education, Labor, and Pensions



U.S. GOVERNMENT PRINTING OFFICE

94-317 PDF

WASHINGTON : 2005

For sale by the Superintendent of Documents, U.S. Government Printing Office
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PARENTS RAISING CHILDREN: PREMATURE BABIES

THURSDAY, MAY 13, 2004

U.S. SENATE,
SUBCOMMITTEE ON CHILDREN AND FAMILIES, COMMITTEE ON
HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, in room SD-430, Dirksen Senate Office Building, Hon. Lamar Alexander (chairman of the subcommittee) presiding.

Present: Senators Alexander, Bond, and Dodd.

OPENING STATEMENT OF SENATOR ALEXANDER

Senator ALEXANDER. Good morning. This hearing of the Subcommittee on Children and Families will come to order.

This is another in a series of subcommittee hearings on the job of being a parent in America today. Last year, our subcommittee held six hearings focusing on support for military families raising children. Last month, we held a hearing on how workplace flexibility can help working parents raise children in the world today.

This morning, I would like to turn our attention to the very start of being a parent—the delivery of the baby, particularly the delivery of some of the most vulnerable babies, premature babies, those born very early and very small. We will focus on what we can do to help lower the premature birth rate as well as help mothers delivering premature babies and the babies themselves.

The percentage of babies born prematurely, 3 weeks or earlier, has risen to a national average of 12 percent, about one out of every eight babies. This means that 1,305 babies are born prematurely every day in the United States of America.

Unfortunately, in my State of Tennessee, the rate is even higher. Tennessee has the fourth highest rate of preterm births in the country. Fourteen percent of Tennessee babies are born prematurely. In an average week in Tennessee, 210 babies are born prematurely.

Premature babies are 14 times more likely to die in the first year of life. As Governor, through what we called our Healthy Children Initiative, Tennessee achieved the lowest infant mortality rate in the State's history. Unfortunately, these rates are on the rise again.

Senator Dodd and I are cosponsors of a bill, S. 1726, The Prematurity Research Expansion and Education for Mothers who Deliver Infants Early, or—obviously, we have a shorter name for

that—the PREEMIE Act. Our bill expands research into the causes of prematurity so that we can reduce the rate of premature births. Our bill also increases research and education on how to care for mothers who deliver prematurely and babies who are born prematurely.

In the House, the PREEMIE Act is sponsored by Representatives Upton and Eshoo, and they have sent over a letter in support of this hearing we are holding today. Senators Lugar and Lincoln have also submitted statements of support. Senator Bond of Missouri is here today, and when I conclude in just a moment, we will hear from him.

By unanimous consent, I ask that their letters be included in the record.

By unanimous consent, I also ask that outside groups be given 1 week to submit statements to be included in the record for this hearing.

[The prepared statements of Senators Lugar and Lincoln follow:]

PREPARED STATEMENT OF SENATOR LUGAR

I would like to thank the Chairman, Mr. Alexander, and the Ranking Member, Mr. Dodd, for calling this hearing. The rise in premature birth throughout the country and in my own State—despite all of our achievements in medicine—is astounding. Nationally, more than 480,000 babies were born preterm in 2002. Nearly 13 percent of Indiana’s infants are born preterm and in half of the cases, doctors cannot identify the cause. Prematurity is the leading cause of infant death in the first month of life. Many of these infants will suffer lifelong health problems—such as cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss—and some will die. Reducing the number of premature births will improve the health of hundreds of thousands of infants born each year.

Aside from these human costs, the financial cost of caring for preterm infants is enormous. The March of Dimes estimates that the national hospital bill for infants with a diagnosis of prematurity/low birthweight was \$13.6 billion in 2001.

I am pleased to be a cosponsor S. 1726, the “PREEMIE Act,” legislation that seeks to expand and coordinate research on the prevention of preterm birth and the most effective care for babies when they are born preterm.

Along with Senator Lincoln, I am also a sponsor of another bill, S. 1734, the “Prevent Prematurity and Improve Child Health Act,” which seeks to improve Medicaid and SCHIP to reflect our current state of knowledge on preterm birth. For example, medical research tells us that smoking is a considerable risk factor for preterm and low birthweight infants. Our bill takes this knowledge and translates it into practice by ensuring that smoking cessation services and pharmaceuticals are available for pregnant women enrolled in Medicaid.

My wife Char and I have been long-time volunteers for the March of Dimes and I am pleased that they are committing such an enormous amount of time, energy and resources into conquering the stubborn problem of preterm birth with their 5-year Prematurity Campaign. Both of these bills have the potential to make

a real difference in many lives and I hope that our colleagues will consider joining us in this effort.

PREPARED STATEMENT OF SENATOR LINCOLN

I want to thank the Chairman and the Ranking Member for holding a hearing on this important issue. We are very fortunate to have the leadership of Senator Alexander and Senator Dodd on an issue as important as preterm birth. As a mother of twin boys, I understand the critical role of prenatal care in ensuring a safe delivery. I was lucky that my boys were delivered safely and were not premature, but not every woman is lucky enough to have access to the quality prenatal care that I did.

I support S. 1726, the PREEMIE Act, and commend my colleagues for their leadership on this issue. As you may know, I have introduced a related bill—the Prevent Prematurity and Improve Child Health Act of 2003, which seeks to reduce the incidence of prematurity and improve the health of women of childbearing age and children by expanding access to health care. I was joined in this effort by my colleagues Senators Richard Lugar and Jeff Bingaman.

The number of premature births is increasing at an alarming rate. According to data from the National Center for Health Statistics, more than 480,000 infants were born prematurely in 2002—a 29 percent increase since 1981 and the highest level ever reported in the United States. Prematurity, which is defined as birth at less than 37 completed weeks of gestation, is the leading cause of infant death in the first month of life. Today, one in eight infants is born too early. Unfortunately, in my own State of Arkansas, the problem of preterm births is even more astounding. In 2002, nearly 13 percent of births were preterm, ranking Arkansas 36th in the Nation. This is a clear wake-up call: we must take action to reduce the number of premature births, improving the health of hundreds of thousands of infants born each year.

Premature birth can happen to any family. In fact, nearly half of premature births have no known cause and, in too many cases, families are left asking “Why my child?” Increasing our investment in uncovering the causes of preterm birth and ways to prevent it is essential to giving doctors, nurses and parents-to-be more information about having a healthy baby.

But we do know some of the factors associated with increased risk of delivering too soon, including maternal age, multiple births, a history of preterm delivery, stress, infection, smoking, and drug use.

Nationally, the number of preterm births is increasing but I'm proud to say that in Arkansas, we're fighting back and have seen the number of premature babies decrease every year since 1999. We increased access to prenatal care for women by expanding Medicaid eligibility to 200 percent of the Federal poverty level. Unplanned pregnancies and pregnancies spaced too close together are risk factors for preterm birth. Through a Medicaid family planning waiver, Arkansas is making family planning services available to any woman with income below 200 percent of poverty, whether she is eligible for Medicaid or not.

Senator Lugar and I, along with Senator Bingaman, have introduced S. 1734, the “Prevent Prematurity and Improve Child Health Act,” to give States increased flexibility and the Federal resources needed to improve access to prenatal care for low-income pregnant women. This bill, before the Finance Committee, would give States new options to cover pregnant women under the State Children’s Health Insurance Program (SCHIP) and to cover low-income legal immigrant pregnant women and children under Medicaid and SCHIP. Additionally, this bill tackles a major prematurity risk factor—maternal smoking—by improving and expanding coverage for pharmaceuticals and counseling to help pregnant women in Medicaid quit smoking. This bill also gives States the tools they need to help low-income women avoid another risk factor for premature birth—spacing pregnancies too close together. In recent years, a number of States, including Arkansas, have sought and received Federal permission in the form of waivers to provide Medicaid-financed family planning services and supplies to income-eligible uninsured residents whose incomes are above the State’s regular Medicaid eligibility ceilings. This bill would make it possible for States to extend Medicaid coverage for family planning services without having to obtain a Federal waiver. Finally, some infants and children with disabilities, such as those born preterm, have private health insurance with limited benefits that do not meet their health needs. This legislation would allow SCHIP to serve as a wrap-around program for income-eligible children who need extra medical benefits, just as Medicaid currently does.

There are still many unanswered questions on the causes and prevention of preterm birth. But with increased support for medical research, I am confident that we can roll back the rate of preterm births. And as the distinguished panel of researchers gathered here finds new interventions to improve infant birth outcomes, I will work with my colleagues here in the Senate to turn those research results into practice.

[Letter of support of Representatives Upton and Eshoo follow:]

May 13, 2004.

Hon. LAMAR ALEXANDER,
Chairman,

Hon. CHRISTOPHER DODD,
Ranking Member,
Subcommittee on Children and Families,
615 Hart Senate Office Building,
Washington, D.C. 20510.

DEAR SENATOR ALEXANDER AND SENATOR DODD: As the sponsor and original co-sponsor of the House companion measure to the PREEMIE Act, we are writing to commend you and thank you for your leadership on this vitally important public health issue. The hearing you are holding today on the PREEMIE Act will give much-needed public attention to the silent crisis of premature births in our Nation.

As you are aware, each day 1,305 babies are born too soon, and the rate of preterm birth increased 27 percent between 1981 and 2001. Tragically, premature infants are 14 times more likely to die in their first year of life, and premature babies who survive may suffer lifelong consequences, including cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss. Preterm delivery can happen to any pregnant woman, and in nearly half of the cases, no one knows why.

Underscoring the imperative to deepen our understanding of the causes and ways of preventing prematurity, the National Center for Health Statistics recently released data showing that in 2002, *for the first time since 1958*, our Nation’s infant mortality rate rose. The Center attributes this rise to an increase in neonatal infant

deaths, with the causes including not only birth defects but also disorders related to short gestation and low birth weight.

The goals of the PREEMIE Act are to reduce the rates of preterm labor and delivery, promote the use of evidence-based care for pregnant women at risk of preterm labor and for infants born preterm, and reduce infant mortality and disabilities caused by prematurity. These goals will be met by expanding Federal research related to preterm labor and delivery and increasing public and provider education and support services.

Again, thank you for your leadership in meeting this compelling public health challenge.

Sincerely yours,

REP. FRED UPTON.
REP. ANNA ESHOO.

Senator ALEXANDER. I hope that today's hearing will shed some light on the current state of research on premature birth—causes, prevention, best treatment practices and more. Hopefully, we will learn where there are gaps in what we still need to work on to help lower the rate of premature births. By decreasing the rate of premature births, we hope to reduce infant mortality and disabilities caused by prematurity.

I am looking forward to hearing from our witnesses this morning.

In our first panel, three experts from our top Federal health agencies—the National Institutes of Health, the Centers for Disease Control and Prevention, and the Health Resources and Services Administration—are here to talk with us about research and programs their agencies are involved with related to premature birth.

Thank you all for being with us today.

Our second panel will include the president of the March of Dimes, which has taken the lead, and we will hear more about this effort this morning; a practicing physician and a researcher experienced in the field of premature births, as well as a mother from Tennessee who delivered a baby girl weighing one pound, 10 ounces when she was just under 26 weeks pregnant.

Senator Dodd, who is the ranking Democratic member of this subcommittee, has been a longstanding supporter of children's issues. He will be arriving as soon as he can, but he expects to be here.

And we are delighted to have with us today Senator Kit Bond of Missouri, who as a Governor was active in children's and families' issues and has carried that interest with him to the U.S. Senate.

I would like to ask Senator Bond if he would like to say a few words now.

OPENING STATEMENT OF SENATOR BOND

Senator BOND. Thank you very much, Mr. Chairman.

As fellow gubernatorial colleagues, we used to work together as Governors back in the good, old days, when we could give orders and things happened. It was a lot of hard work, but we could get some things done, and I remember well the great cooperation that I had with my neighbor from Tennessee when we were both in the Governor's office.

Back early on in my term, I had a great interest in birth defects and prematurity prevention. As Governor, I was approached by many people who were concerned about the tremendous infant

mortality. At that time back in the early seventies, if somebody had a baby under 5 pounds, you were really worried about it. So we went to work and secured dollars to fund the very fine neonatal care units at our hospitals and these remarkable institutions with dedicated men and women who serve there and are doing a tremendous job of saving low birth weight babies and babies with severe birth defects.

I have seen a lot of infants like that grow to be healthy youngsters, and now I am getting old enough that some of them are young adults now. And that is a great step forward. But by the time I began my second term in the 1980's, I was talking about what a great job we were doing saving these babies, but the doctors and nurses said: Why don't we do something to reduce the incidence of birth defects and prematurity and the problems that bring the tiniest of infants to these very high-tech, specialized care units—not that we don't like the units, but let us do them and ourselves a favor and try to keep them from having to go into that kind of care.

So when I came to the Senate, I worked with colleagues on both sides of the aisle, with my colleague from Connecticut, Senator Dodd and the March of Dimes on how we deal with the serious and compelling health problems facing families. I have to apologize, because this committee, the HELP Committee, has very important IDEA legislation on the floor, and I am supposed to go over and speak. As I said, being a Senator, you cannot set your time anymore. Somebody calls and tells you when you have to be on the floor. So I am going to have to leave for the floor, and I would not be surprised if Senator Dodd is not having that same problem.

But during the last session of Congress, working with Senator Dodd, we passed legislation that he and I introduced to renew the Federal commitment to finding the causes of birth defects and preventing those for which we know the causes. The determination of the importance of folic acid is one important step, but that is one of only many steps that we need to take.

I am very proud of the important work being done by the National Center on Birth Defects and Developmental Disabilities at the CDC in this area. But I am concerned, as our chairman and ranking member, that Congress has not yet addressed the serious and growing problem of premature birth and low birth weight babies.

My State of Missouri is not in quite as bad shape as Tennessee, but still, 12.7 percent of births are preterm—an increase of over 11 percent over the last decade—and that is troubling. Preterm labor can happen to any pregnant woman, and the causes of nearly half of all preterm births are unknown. It is difficult enough to deal with the problem when we know what the causes are, but when we do not know what the causes are, that is really a challenge.

To address this issue, I am very happy to be a cosponsor of this important PREEMIE legislation. We have got to do something to block these acronyms, Mr. Chairman. People keep getting more and more ingenious in coming up with acronyms, and "PREEMIE" does sound good. It will expand Federal research into the causes and prevention of prematurity.

I look forward to working with my colleagues on this committee and in the Senate to pass this important legislation as quickly as we can, if anything can happen quickly in the Senate these days, because I think a Federal investment is critical to help find the causes of premature births and gain more knowledge to save more babies.

I thank the chair and look forward to hearing the witnesses before I have to leave.

Senator ALEXANDER. Thank you, Senator Bond, for your leadership, both as Governor and as Senator.

Let me introduce the witnesses on the first panel, and then I will ask you to make your presentations. If you can summarize them to some extent and not take more than 10 minutes for your presentation, that will leave us more time for questions, and then we have a second panel of witnesses that we would like to get to.

Dr. Duane Alexander is director of the National Institute of Child Health and Human Development at the National Institutes of Health. Much of the research of the Institute relates to healthy pregnancies, the delivery of healthy babies, and the development of healthy children.

Dr. Alexander earned his B.S. degree at Penn State and his M.D. at Johns Hopkins.

Dr. Peter Van Dyck is associate administrator of the Maternal and Child Health Bureau at the Health Resources and Services Administration. The Bureau works to promote and improve the health of mothers, children, and families, particularly those who are poor and lack access to care.

Dr. Van Dyck earned a master of science degree in physiology, a medical degree from the University of Illinois, and a master's of public health degree in maternal and child health from Berkeley.

Dr. Eve Lackritz is the chief of the Maternal and Infant Health Branch within the Division of Reproductive Health at the Centers for Disease Control. CDC addresses the problem of preterm births with public health surveillance, State and community health programs, and epidemiologic and laboratory research.

Dr. Lackritz earned her M.D. from Ohio State.

We look forward to your testimony, and why don't we begin with Dr. Alexander?

STATEMENTS OF DUANE F. ALEXANDER, M.D., DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, NATIONAL INSTITUTES OF HEALTH; PETER C. VAN DYCK, M.D., ASSOCIATE ADMINISTRATOR, MATERNAL AND CHILD HEALTH BUREAU, HEALTH RESOURCES AND SERVICES ADMINISTRATION; AND EVE LACKRITZ, M.D., CHIEF, MATERNAL AND INFANT HEALTH BRANCH, DIVISION OF REPRODUCTIVE HEALTH, NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION, CENTERS FOR DISEASE CONTROL AND PREVENTION

Dr. ALEXANDER. Thank you, Mr. Chairman. Good morning. Good morning, Senator Bond.

I very much appreciate the chance to be here to talk about the critical health challenge of prematurity and very much appreciate also your interest in this issue and your championship of it.

Last year during the celebration of the 40th anniversary of the National Institute of Child Health and Human Development, we took stock of our efforts to advance research in fields like prematurity and infant mortality that fall within the Institute's mission. Infant mortality is a major index of a Nation's health.

Since the founding of NICHD, the infant mortality rates in the United States have dropped by more than 70 percent, from 24 to a low of 6.8 per 1,000 live births in 2001, with much of this decline resulting from NICHD-sponsored research on care of low birth weight infants, on Sudden Infant Death Syndrome and other factors.

For example, research efforts of NICHD and other institutes resulted in survival rates for very premature infants with respiratory distress syndrome going from 5 percent in the 1960's to more than 95 percent today, an incredible change due to advances in respiratory technologies and availability of prenatal steroids and replacement lung surfactant.

Sadly, even with these important accomplishments, we are still far from solving the problem of prematurity, and our improvements in infant mortality have come about in spite of, not because of, what has happened with prematurity rates, which have actually worsened.

Premature birth before 37 weeks of gestation poses great risks to the infant. In addition to mortality, it accounts for one in five children born with mental retardation, one in three who has some visual impairment, and almost half of the babies with cerebral palsy.

For the mother, not only is preterm labor a leading cause of hospitalization for a pregnant woman, but she faces a greatly increased risk of having a second premature infant in the future.

Few other medical challenges fall so squarely within the mission of NICHD, which is "to assure that every individual is born healthy and wanted, that women suffer no adverse consequences from the reproductive process, and that all children reach adulthood free of disease and disability and able to achieve their full potential for a healthy and productive life."

We are focusing on prematurity using every mechanism at our disposal, including investigator-initiated grant applications from scientists around the country, our own requests for grant proposals in specific areas, intramural research in our own laboratories and clinics, conferences and workshops, and most of all in our multicenter networks in Maternal-Fetal Medicine, which deliver about 120,000 babies a year, and our Neonatal Network, which cares for about 60,000 babies every year.

With these numbers of pregnant women and infants that we are able to care for at these hospitals, staffed by some of the leading clinician-researchers in the field working collaborative, we have an opportunity to quickly and thoroughly test new preterm delivery prevention and management strategies.

Until recently, tested strategies to prevent preterm birth in high-risk women failed to produce effective, reliable results because too few patients were studied, and conditions were not well-controlled. The Maternal-Fetal Medicine Network was established to overcome these problems. This network, in one of the few concrete break-

throughs on this tremendously difficult front, published in the *New England Journal of Medicine* in 2003, our network scientists demonstrated that weekly injections of 17-alpha-hydroxy-progesterone can reduce preterm birth by one-third among women at increased risk of preterm delivery because they had previously had a preterm delivery.

Not only were the women who were treated with progesterone one-third more likely to carry their babies to term, but their infants also had a much lower rate of life-threatening complications.

The 463 women involved in this study were considered to be at high risk for preterm birth because they had had a previous preterm delivery, at an average of about 31 weeks instead of the normal 40. As in many clinical trials, some of the women enrolled received the hormone being tested, the progesterone, and some received a placebo injection.

The reduction in preterm birth that occurred in African American women as well as nonAfrican American women was so dramatic that our scientists terminated the study early so we could make the results available to practitioners.

Shortly after, a committee of the American College of Obstetricians and Gynecologists notified its members of this success and recommended that women who had had a previous preterm delivery be considered for treatment with progesterone.

Now let me talk for just a minute about some other efforts in preventing preterm labor. Over the years, we have supported a number of studies to examine the effectiveness of various proposed interventions for preterm labor, and this research has had some surprises.

For instance, studies have shown that bed rest, which until very recently was the most common preventive approach, was not effective in preventing preterm labor or delaying preterm birth, and in some cases may have actually made the situation worse.

Other studies have examined the effectiveness of different drugs in suppressing contractions early in preterm labor, although no consistently effective treatment has yet been identified.

Yet another Maternal-Fetal Medicine Network trial demonstrated that home uterine activity monitoring, an expensive and highly touted regimen claimed to reduce preterm delivery, was completely ineffective for this purpose, thereby saving money and wasted effort by ending this useless practice.

Many NICHD-supported studies have been trying to answer the basic question of why women with no known risks experience preterm labor. During the course of these studies, researchers explored the relationship between a condition called bacterial vaginosis and preterm labor. In 1999, we completed a large study that recruited pregnant women who had asymptomatic bacterial vaginosis to explore this association and the results of antibiotic treatment for it. This study found no difference in preterm labor or delivery between women who received an antibiotic and women who received a placebo, and then we stopped the growing practice of treating women who had asymptomatic bacterial vaginosis with antibiotics unnecessarily.

Scientists in other NIH institutes are looking for other clues to the cause of preterm labor and treatment for premature infants.

For example, the National Institute of Environmental Health Sciences is supporting research on whether exposure to certain environmental contaminants during pregnancy relates to preterm birth.

And the National Heart, Lung, and Blood Institute is supporting studies on prevention of chronic lung disease in surviving premature infants.

In addition, NICHD's newest intramural branch, the Perinatology Research Branch, is devoted to the study of preterm birth and its consequences. Among other developments, this branch has provided evidence that many premature newborns were critically ill prior to birth due to intrauterine infection, and is exploring the role of intentional selective premature delivery in order to help these babies receive earlier treatment in order to survive.

We were able to rule out bacterial vaginosis as a direct cause of prematurity and, building on the progress that we have made, we will continue to conduct more research on understanding the causes of this condition, whether there is an identifiable subgroup of infected women who are particularly at risk, how we can prevent and treat prematurity, and further work on how best to manage or treat newborns who have been born prematurely.

We thank you for this opportunity to discuss NICHD's research in prematurity and for your interest in this topic, and I will be glad to answer any questions later.

Thank you.

Senator ALEXANDER. Thank you.

[The prepared statement of Dr. Alexander follows:]

PREPARED STATEMENT OF DUANE F. ALEXANDER, M.D.

Last year, during our celebration of the 40th anniversary of the Institute, we had an opportunity to take stock of our efforts to advance research in the fields that fall within our mission. Infant mortality is a major index of a Nation's health, yet the infant mortality rate in the United States remains far higher than it should be, given the advantages we have compared to many countries with lower rates. We were gratified to realize that since the founding of NICHD, infant mortality rates in the United States have dropped more than 70 percent (to an all-time low of 6.8 per 1,000 live births in 2001), with much of this decline resulting from NICHD-sponsored research on care of low birth weight infants, Sudden Infant Death Syndrome, and other factors. For example, resulting from the research efforts of NICHD and other Institutes, survival rates for very premature infants with respiratory distress syndrome have gone from 5 percent in the 1960s to 95 percent today, due to advances in respirator technologies and the availability of replacement lung surfactant.

Sadly, even with these important accomplishments, we are still far from solving the problem of prematurity. Preterm birth (before 37 weeks of gestation) poses great risks to the infant. At least one in eight infants about 476,000—is born prematurely in the United States each year. Over the last 20 years, preterm birth in this country has actually increased by 21 percent. Preterm birth is the leading cause of death among African-American infants, contributing substantially to racial and ethnic health disparities in infant mortality, and is one of the top causes of all neonatal and infant deaths. In addition, preterm babies are more likely to have long-term health problems, such as a higher incidence of developmental disabilities. Premature delivery accounts for one of five children born with mental retardation, one of three who have some visual impairment, and almost half of those babies with cerebral palsy. Over the longer term, for the baby, for reasons we cannot explain, preterm birth carries with it an increased risk for cardiovascular disease and diabetes as an adult. For the mother, not only is preterm labor a leading cause of hospitalization of women, but she faces a greatly increased risk of delivering prematurely in the future.

Few other medical challenges fall so squarely within the mission of the NICHD, which is “to assure that every individual is born healthy and wanted, that women suffer no adverse consequences from the reproductive process, and that all children have the opportunity to fulfill their potential for a healthy and productive life unhampered by disease or disability.” We are focusing on prematurity using every mechanism at our disposal, including investigator-initiated grant applications from scientists across the country, our own requests for grant proposals in specific areas, conferences and workshops, and most of all, our multi-center networks the Maternal-Fetal Medicine Units, which deliver about 120,000 babies each year, and the Neonatal Network, which cares for about 60,000 babies every year. As you can see, the numbers of pregnant women and infants we are able to care for at these hospitals, staffed by some of the leading clinician-researchers in the field working collaboratively, gives us an opportunity to quickly and thoroughly test new preterm delivery prevention and management strategies.

Until recently, most previously tested strategies to prevent preterm birth in high-risk women failed to produce effective, reliable results because too few patients were studied and conditions were not well controlled. The Maternal-Fetal Medicine Network was established to overcome these problems. In one of the few concrete breakthroughs on this tremendously difficult front, published in the *New England Journal of Medicine* in 2003, we reported that our scientists who participate in the MFMU network had demonstrated that weekly injections of 17-hydroxy-progesterone, can reduce preterm birth by one-third among women at increased risk of preterm delivery because they had previously had a preterm delivery. Not only were the women treated with progesterone 30 percent more likely to carry their babies to term, their infants also had a much lower rate of life-threatening complications. The 463 women involved in the study were considered to be at high risk for preterm birth because they each had previously spontaneously delivered a baby early, at an average of about 31 weeks. As in many clinical trials, some of the women enrolled received the hormone being tested (the progesterone), while some received a placebo injection. The reduction in preterm birth for African American women as well as non-African American women—was so dramatic that the scientists halted the study early to make the results available to practitioners. Shortly thereafter, a committee of the American College of Obstetricians and Gynecologists notified its members of the success of this trial, recommending that women who had had a previous preterm delivery be considered for treatment with progesterone.

Let me talk for a moment about preventing preterm labor, one of the best ways to reduce the numbers of preterm births. Over the years, we have supported a range of studies to examine the effectiveness of various preventive measures for preterm labor, and this research has revealed some surprises. For instance, studies have shown that bed rest, which until very recently was the most common preventive approach, was not effective in preventing preterm labor or in delaying preterm birth. In some cases, bed rest may have actually made the situation worse. One possible explanation for these findings may be that active pregnant women are better able to expand their blood volume, which is necessary for a successful, full-term pregnancy. Other studies have examined the effectiveness of different drugs in suppressing uterine contractions early in preterm labor, although no effective treatment has yet been identified. Yet another Maternal-Fetal Medicine Network trial demonstrated that Home Uterine Activity Monitoring, an expensive, highly touted regimen claimed to reduce preterm delivery, was completely ineffective for this purpose, thereby saving money and wasted effort by ending this useless practice.

Many NICHD-supported studies have been trying to answer the basic question of why women with no known risks experience preterm labor. During the course of these studies, researchers noted a relationship between bacterial vaginosis and preterm labor. In 1999, NICHD completed a large study that recruited pregnant women who had asymptomatic bacterial vaginosis to explore this possible association and results of treatment for it. Although the study found no difference in preterm labor between women who received an antibiotic and women who received the placebo, the research provided important clues about other possible treatments. It also stopped the growing practice of treating women who have asymptomatic bacterial vaginosis with antibiotics unnecessarily. Scientists at other institutes are looking for other clues to the cause of preterm labor. For example, the National Institute of Environmental Health Sciences is supporting research on whether exposure to certain environmental contaminants during pregnancy relates to preterm birth.

In addition, NICHD’s newest intramural branch, the Perinatology Research Branch, is devoted to the study of premature birth and its consequences. Among other developments, the Branch has provided evidence that many premature newborns were critically ill prior to birth due to intrauterine infection, and is explor-

ing the role of premature delivery in order to help these babies receive earlier treatment in order to survive.

We were able to rule out bacterial vaginosis as a direct cause of prematurity, and building on the progress we have made, we will conduct more research on understanding the causes of this condition, how we can prevent and treat prematurity in pregnant women, and further work on how best to manage or treat newborns who have been born prematurely.

Thank you for the opportunity to discuss NICHD's research on prematurity and for your interest in this important topic. I am happy to answer any questions you may have.

Senator ALEXANDER. Dr. Van Dyck?

Dr. VAN DYCK. Thank you. Good morning, Mr. Chairman, Senator Bond.

I am Peter Van Dyck, the director of Maternal and Child Health in the Health Resources and Services Administration. I want to thank you for the opportunity to testify today about prematurity and the related HRSA programs and activities.

HRSA, or the Health Resources and Services Administration, is often referred to as "the access agency" that provides health care and social services to millions of low-income Americans, many of whom lack health insurance and live in remote rural communities and inner-city areas where health care services are scarce.

We work in partnership with States and local communities. In fact, the bureau that I direct, the Maternal and Child Health Bureau, has a long history of working toward reducing prematurity and low birth weight as we strive to improve the health of our Nation's mothers and children.

We recognize that low birth weight and preterm birth constitute a significant and costly health problem for this Nation. Our efforts in this area include various programs and initiatives.

One program that has had a significant impact on prematurity is the Maternal and Child Health Block Grant, which is authorized by Title V of the Social Security Act. All of the Title V Block Grants issued through HRSA's Maternal and Child Health Bureau address aspects of prematurity and stipulate that grantees are required to submit annual performance measures.

For the block grant, national core performance measures are collected from each State. Some pertain to prematurity, which include the percent of very low birth weight infants among all live births in each State as well as the percent of very low birth weight infants who are delivered at facilities that are capable of delivering high-risk mothers and neonates.

Approaches to reducing prematurity vary throughout the States from direct care to enabling services to infrastructure building, the building of the public health system, and each State tracks annually performance goals that include preterm infants as well as related performance measures such as increasing early access to prenatal care and decreasing the disparate ratio of black-white infant mortality rates.

Based upon the specific needs of their State, these programs also develop and report on individual State performance measures targeting low birth weight, preterm birth and infant mortality. For example, Michigan measures the percent of preterm births; Delaware measures the percent of low birth weight black infants among all live births to black women, and New Jersey reports the percentage of black nonHispanic preterm infants.

Another HRSA program that deals with prematurity is the Healthy Start Program. Healthy Start supports 114 projects located in 96 communities across the Nation that have excessive rates of prematurity, low birth weight and infant mortality.

Healthy Start strives to institute the best community-oriented methods to assure that high-risk pregnant women and their infants gain early access to necessary services during pregnancy and are followed through a continuum of care until 2 years postdelivery or postpartum.

This program emphasizes outreach, case management, screening and referral for perinatal depression, and health education interventions to reduce risk factors such as smoking, alcohol and substance abuse. Selected projects are also examining interventions to address interconceptional care for women and infants identified at high risk following delivery to prevent future occurrences of these adverse pregnancy outcomes and optimize the development of the low birth weight/preterm infant over the next 2 years.

HRSA also supports a number of research projects that address factors associated with preterm birth or relevant clinical practices. Multiple projects are using a new type of analysis to gain a better understanding of how multiple levels of influence—community or neighborhood factors as well as individual factors—are associated with adverse outcomes in pregnancy.

For instance, several investigators are using multilevel hierarchical modeling to examine community-level factors associated with preterm birth, particularly the racial/ethnic disparity in rates of preterm delivery.

A study on “Assessing the Stress and Preterm Birth/Low Birth Weight Relationship,” because strenuous working conditions and occupational fatigue in pregnancy have been associated with preterm delivery and low birth weight among working women, will test the extent to which occupational stressors vary by race and ethnicity and how stressors, including racial discrimination, impact the risk for preterm birth and/or low birth weight. By investigating the relationships between stress during pregnancy, placental corticotrophin-relating hormone, and antenatal leave, this study will help identify the risks and protective factors that contribute to pregnancy outcomes among working women.

HRSA also supports and manages the Departmental Advisory Committee on Infant Mortality. This is the national advisory committee established to advise the Secretary of Health and Human Services concerning the issue of infant mortality, including such causes as low birth weight/preterm birth, and the most appropriate steps that might be taken to address this problem. It also provides expert advice on how best to coordinate the variety of Federal, State, local and private programs and efforts underway that are designed to deal with health and social problems impacting on infant mortality.

We are also proud of the fact that HRSA’s community health centers have fewer low birth weight babies than the national average. As part of the HRSA strategy to close the gap in health disparities, HRSA-supported health centers will develop a cutting-edge process to improve and change their systems of delivering perinatal care. The aims of this Perinatal/Patient Safety Pilot Collaborative are to

develop comprehensive perinatal system change interventions based on the Care Model. The Care Model emphasizes evidence-based, planned, integrated collaborative care that will generate major improvements in process and outcome measures for perinatal care and will establish and document the safety of the perinatal system for both infants and mothers.

HRSA's Bureau of Primary Health Care also has a best practices project specifically addressing low birth weight. It is a study to identify programs, policies and procedures of selected health centers that resulted in lowering the rates of low birth weight among racial/ethnic minority infants. A secondary aim of the project was to distinguish practices that could be replicated in other supported health centers with the hope of reducing low birth weights in those centers as well, particularly those in communities of color.

In the next 6 to 9 months, the results of this study will be disseminated via presentations at professional meetings and in publications in peer-reviewed journals.

The committee asked us specifically to address the Health and Human Services Interagency Coordinating Council on Low Birth Weight and Preterm Birth. That title is much too long to even develop an acronym for.

HRSA co-chairs and staffs this coordinating council. In response to recommendations of the Advisory Committee on Infant Mortality, Secretary Thompson asked HRSA and the National Institutes of Health to organize this council. I am proud to serve as co-chair of this council along with my colleague Dr. Duane Alexander, Director of the National Institute for Child Health and Human Development—and I might mention as well that Dr. Lackritz is an important member of that committee as well.

This group includes representatives from 12 agencies and/or offices in the Department and two liaison members from the Secretary's Advisory Committee on Infant Mortality. And the staff work is supported by HRSA.

The purpose of the Coordinating Council is to galvanize multidisciplinary research, scientific exchange, policy initiatives, and collaboration among the Department's agencies and to assist in targeting efforts to achieve the greatest advances toward the national goal of reducing infant mortality.

In particular, Secretary Thompson requested the development of a Department-wide research agenda on low birth weight and preterm birth, which we know are major contributors or major factors for infant mortality. Subsequently, Deputy Secretary Allen expanded the charge of the committee by requesting us to focus attention to racial/ethnic disparities and to Sudden Infant Death Syndrome as contributors to infant mortality.

This Coordinating Council is working in conjunction with the Advisory Committee on Infant Mortality to further efforts to formulate recommendations for a coordinated research agenda for the Secretary.

Clearly, challenges for the Coordinating Council include efforts to assure adequacy of data on low birth weight and preterm births, uncovering new knowledge and developing a coordinated research agenda on preterm birth and low birth weight, and delivering and financing relevant health care.

Currently, the Council is compiling an “Inventory of Research and Databases Pertaining to Low Birth Weight and Preterm Birth and Sudden Infant Death Syndrome.” This is a compilation of current and planned activities within the department that address preterm birth and low birth weight.

Then, we will use this information to examine gaps and identify priorities for future research addressing these issues.

Many of our programs at HRSA, especially those that provide direct and enabling services to women, provide a variety of education and training opportunities for providers concerned with preterm labor, high-risk pregnancy, and risk factors. We have taken a proactive approach to reducing the risk of preterm labor and other adverse perinatal outcomes including depression and tobacco use during pregnancy.

By partnering with Federal, State and local governments as well as the public and private sectors, as well as professional and faith-based organizations, HRSA provides leadership in improving access to and improving the quality of health care and services for millions of Americans. We are hard at work identifying and translating into everyday practice across the Nation the very best evidence-based interventions to overcome barriers to the Nation’s health care.

Thank you for the opportunity to appear before the committee and share with you some of HRSA’s activities.

Senator ALEXANDER. Thank you, Dr. Van Dyck.

[The prepared statement of Dr. Van Dyck follows:]

PREPARED STATEMENT OF PETER C. VAN DYCK, M.D.

Good morning, Mr. Chairman and Members of the Committee. I am Dr. Peter Van Dyck, the Health Resources and Services Administration’s Associate Administrator for the Maternal and Child Health Bureau in the Department of Health and Human Services. Thank you for the opportunity to testify today about prematurity and the related HRSA programs and activities.

The Health Resources and Services Administration (HRSA)—often referred to as the “access” agency—provides health care and social services to millions of low-income Americans, many of whom lack health insurance and live in remote rural communities and inner-city areas where health care services are scarce. We work in partnership with States and local communities. The Bureau I direct, the Maternal and Child Health Bureau, has a long history of working towards reducing prematurity and low birth weight as we strive to improve the health of our Nation’s mothers and infants.

We recognize that low birth weight and preterm birth constitute a significant and costly health problem for this Nation. Our efforts in this area include various programs and initiatives.

1. One program that has a significant impact on prematurity is the Maternal and Child Health Block Grant authorized by Title V of the Social Security Act. All Title V Block Grants, funded by Title V and issued through HRSA’s Maternal and Child Health Bureau address aspects of prematurity and stipulate that grantees are required to submit annual performance measures. For the block grant, national core performance measures are collected. Pertaining to prematurity, these include:

- Percent of very low birth weight infants among all live births.
- Percent of very low birth weight infants delivered at facilities for high-risk deliveries and neonates.

Approaches to reducing prematurity vary throughout the States from direct care to enabling services to infrastructure building. Each State tracks annually performance goals that include preterm infants as well as related performance measures such as increasing early access to prenatal care and decreasing the disparate ratio of black-white infant mortality rates. Based upon the specific needs of their State, these programs also develop and report on individual State performance measures targeting low birth weight, preterm birth, and infant mortality. Some examples of specific State performance measures include: Michigan which measures the percent

of preterm births; Delaware which measures the percent of low birth weight black infants among all live births to black women; and New Jersey which reports the percentage of black non-Hispanic preterm infants.

2. Another HRSA program that deals with prematurity is “The Healthy Start” program. Healthy Start supports 114 projects located in 96 communities across the Nation which have excessive rates of prematurity, low birth weight and infant mortality. Healthy Start strives to institute the best community-oriented methods to assure that at-risk pregnant women and their infants gain early access to necessary services during pregnancy and are followed through a continuum of care until 2 years post-delivery. This program emphasizes outreach, case management, screening and referral for perinatal depression and health education interventions to reduce risk factors such as smoking, alcohol and substance abuse. Selected projects are also examining interventions to address interconceptional care for women and infants identified as high-risk following delivery, to prevent future occurrences of these adverse pregnancy outcomes and optimize the development of the low birth weight/preterm infant over the next 2 years.

3. HRSA supports the African American-Focused Risk Reduction component of the Department’s Closing the Health Gap Initiative on Infant Mortality. This is supported with funding from the Healthy Start program in conjunction with funds from the Department’s Office of Minority Health. The goal is to reduce African American infant mortality due to low birth weight/preterm birth and Sudden Infant Death Syndrome (SIDS), the primary areas of infant mortality disparities for the African American population. HRSA will pilot projects in four States selected on the basis of having significant African American births and high infant mortality rates due to low birth weight/preterm births and SIDS. South Carolina, Michigan, Mississippi and Illinois will implement pilot projects in one to two communities within each State that: (1) build on existing activities that contribute to infant mortality reduction; and (2) employ evidence-based interventions that could contribute to reductions in low birth weight/preterm births. Awards are expected to be made this summer.

4. HRSA also supports a number of research projects that address factors associated with preterm birth or relevant clinical practices:

- Multiple projects are using a new type of analysis to gain a better understanding of how multiple levels of influence—community or neighborhood factors as well as individual factors—are associated with adverse outcomes in pregnancy. For instance:

- Several investigators are using Multi-Level Hierarchical Modeling to Examine Community-Level Factors Associated with Preterm Birth, particularly the racial/ethnic disparities in rates of preterm delivery.

- Another study is investigating Modifiable Neighborhood-Level Factors and Low Birth Weight: This research project seeks to identify modifiable neighborhood level factors that are associated with intrauterine growth retardation and preterm birth in Louisiana during 1997–2000. The study will use several data sets, including the Louisiana birth certificate database and the Pregnancy Risk Assessment Monitoring System (PRAMS) survey for individual-level variables, and the U.S. census and various State health department databases for neighborhood level variables. The analysis will assess the relationships between neighborhood factors and pregnancy outcomes, and measure the extent to which the effects of the neighborhood factors are mediated by individual level biologic and behavioral factors.

- Assessing the Stress and Preterm Birth/Low Birth Weight Relationship: Strenuous working conditions and occupational fatigue in pregnancy have been associated with preterm delivery and low birth weight among working women. This study will test the extent to which occupational stressors vary by race/ethnicity and how stressors (including racial discrimination) impact the risk for preterm birth and/or low birth weight. By investigating the relationships between stress during pregnancy, placental corticotrophin releasing hormone (CRH) and antenatal leave, this study will help identify the risks and protective factors that contribute to pregnancy outcomes among working women.

- Collaborative Ambulatory Research Network: Using a network of practicing obstetrician-gynecologists, this project assesses current practice patterns, the relevant knowledge base and opinions around various issues related to maternal and fetal health. The findings will have implications for changes in provider education and practice.

In addition, HRSA is involved in translating Research into Policy and Programs. Initial work will focus on Women’s Periodontal Health and Pregnancy Outcomes. A forum, planned for Fall 2004, will summarize the evidence around periodontal disease and preterm birth and identify relevant provider, system, and community actions for policy and program development.

5. HRSA supports and manages the Departmental Advisory Committee on Infant Mortality (ACIM). This is the national advisory committee established to advise the Secretary of HHS concerning the issue of infant mortality, including such causes as low birth weight/preterm birth, and the most appropriate steps that might be taken to address this problem. It also provides expert advice on how best to coordinate the variety of Federal, State, local and private programs and efforts underway that are designed to deal with health and social problems impacting on infant mortality.

6. We are proud of the fact that HRSA's health centers have fewer low birth weight babies than the national average. We can improve on that at the primary, community health level. As part of the HRSA strategy to close the gap in health disparities, HRSA-supported health centers will develop a cutting edge process to improve and change their systems of perinatal care. This initiative will be a part of the Perinatal/Patient Safety Pilot Collaborative. The aims of the Pilot Collaborative are to develop comprehensive perinatal system change interventions based upon the Care Model (which emphasizes evidence based, planned, integrated collaborative care) that will:

- Generate major improvements in process and outcome measures for perinatal care, for example, decreased infant mortality disparity for African Americans and decreased rates of maternal and infant HIV transmission, low birth weight/preterm infants and sudden infant death syndrome; and

- Establish and document the safety of the perinatal system for both infants and mothers. HRSA's Bureau of Primary Health Care also has a "best practices" project specifically addressed to low birth weight. It's a study to identify programs, policies and procedures of selected health centers that resulted in lowering the rates of low birth weight among racial/ethnic minority infants. A secondary aim of the project was to distinguish practices that could be replicated in other supported health centers with the hope of reducing low birth weights in communities of color. In the next 6 to 9 months, the results of this study will be disseminated via presentations at professional meetings and through publications in peer-reviewed journals.

The committee asked us specifically to address the Health and Human Services (HHS) Interagency Coordinating Council on Low Birth Weight and Preterm Birth. HRSA co-chairs and staffs this coordinating council. In response to recommendations of the Advisory Committee on Infant Mortality (ACIM), Secretary Thompson asked HRSA and the National Institutes of Health (NIH) to organize this HHS Interagency Coordinating Council. I'm proud to serve as co-chair along with Dr. Duane Alexander, Director of NIH's National Institute of Child Health and Human Development. The group includes representatives from 12 agencies and/or offices in the Department and 2 liaison members from the ACIM. The staff work for the Coordinating Council is being supported by HRSA.

The purpose of the Coordinating Council is to galvanize multidisciplinary research, scientific exchange, policy initiatives, and collaboration among the Department's agencies and to assist in targeting efforts to achieve the greatest advances toward the national goal of reducing infant mortality. In particular, Secretary Thompson requested the development of a department-wide research agenda on low birth weight and preterm birth, major contributors to infant mortality. Subsequently, Deputy Secretary Allen expanded the charge by requesting the Coordinating Council to include in its focus attention to racial/ethnic disparities and to Sudden Infant Death Syndrome (SIDS) as contributors to infant mortality.

The Coordinating Council is working in conjunction with the Advisory Committee on Infant Mortality to further efforts to formulate recommendations for a coordinated research agenda for the Secretary. Challenges for the Coordinating Council include efforts to assure adequacy of data on low birth weight and preterm births, uncovering new knowledge and developing a coordinated research agenda on preterm birth/low birth weight, and delivering and financing relevant health care. Currently, the Coordinating Council is compiling an "Inventory of Research and Databases Pertaining to Low Birth Weight and Preterm Birth and Sudden Infant Death Syndrome." This is a compilation of current and planned activities within the Department that address preterm birth and low birth weight. The Coordinating Council will use this information to examine gaps and identify priorities for future research addressing these issues.

The Coordinating Council is also contributing to the research coordination component of the HHS initiative mentioned earlier, "Closing the Health Gap Initiative on Infant Mortality", in two ways:

- The group has broadened its task to identify HHS research and programmatic activities pertaining to low birth weight/preterm birth prevention in African Americans and Sudden Infant Death Syndrome (SIDS) Prevention in African Americans and American Indian/Alaska Natives.

- The group was asked to identify evidence-based interventions that can contribute to reductions in SIDS, reductions in low birth weight/preterm births, and infant mortality associated with low birth weight/preterm births. In its deliberations, the group discussed interventions that have been shown to be effective through a systematic search and review of the best available scientific evidence. Overall, the scientific literature reveals few successful interventions to prevent low birth weight/preterm births, although there are confirmed interventions that improve the survival of these infants. The interventions that the Coordinating Council identified will be utilized in the implementation of future health disparities initiatives.

Many of our programs at HRSA, especially those that provide direct and enabling services to women, provide a variety of education and training opportunities for providers concerning preterm labor, high-risk pregnancy, and risk factors. We have taken a proactive approach to reducing the risk of preterm labor and other adverse perinatal outcomes, including depression and tobacco use during pregnancy. Through a cooperative agreement with the American College of Obstetricians and Gynecologists, we have worked to educate obstetric and women's health providers to be able to recognize and address the critical public health issues associated with these events.

By partnering with Federal, State and local governments, as well as the public and private sectors and professional and faith-based organizations, the Health Resources and Services Administration provides leadership in improving access to and improving the quality of health care and services for millions of Americans. We are hard at work identifying and translating into everyday practice across the Nation the very best evidence-based interventions to overcome barriers to the Nation's health care.

Thank you for the opportunity to appear before this committee and summarize HRSA's activities that address prematurity. I would be happy to answer your questions.

Senator ALEXANDER. Dr. Lackritz?

Dr. LACKRITZ. Thank you. Good morning, Mr. Chairman, and thank you for this opportunity to join you today to discuss one of the most devastating health issues facing women, children, and families in America today.

I am from CDC. I am a Commissioned Officer in the U.S. Public Health Service, and I am a pediatrician. And, like all pediatricians across the country, I have spent years working on hospital wards combatting this problem of prematurity. But all too often, I have had to inform parents that their tiny baby had brain damage, or debilitating handicaps, or would not be able to survive, all because they were born too soon.

Now that I am at CDC, I can see the toll that prematurity is taking on the entire Nation. This epidemic of prematurity is the second leading cause of death among infants. It is the leading cause of death among African American infants. And it is the leading cause of numerous disabilities, including mental retardation, cerebral palsy, blindness, and lung disease.

We as a Nation cannot afford to lose this battle that is so critical to the lives of these babies. The issue before us here today is whether we can learn how to prevent babies from being born too soon, prevent this death and disability, and prevent the toll that prematurity takes on our Nation's families.

I will outline now how CDC, with all of our governmental and nongovernmental partners, formulates a prevention response to prematurity. We use four basic actions.

First, CDC conducts monitoring and surveillance for prematurity. It is a direct parallel with CDC's work in tracking infectious diseases. These monitoring systems provide critical information about how many babies are born premature. We identify risk factors. It

enables us to track trends and to find key opportunities for where to focus prevention.

One of CDC's most important monitoring system for prematurity is called PRAMS, the Pregnancy Risk Assessment Monitoring System. PRAMS supports 31 States. It asks a sample of women who have recently delivered babies about most of the major issues that affect prematurity risk, from prenatal care to obesity, stress, physical abuse, and alcohol and tobacco use. PRAMS has been an invaluable resource to States. It helps them define how to direct their programs and their policies.

These health monitoring systems like PRAMS provide data for action. CDC's second major role is to provide direct assistance to States and Tribes and local health departments and communities on how to analyze and use data to make important decisions for local policy and programs.

CDC now has 16 epidemiologists physically located in State health departments and in the Indian Health Service specifically focused on maternal-infant health.

We also support community-driven programs that promote innovative prematurity programs that are in tune with local needs and cultures, such as Healthy African American Families in Los Angeles, the REACH program in Michigan and California—REACH stands for Racial and Ethnic Approaches to Community Health—and CityMatCH. CDC resources help those communities in greatest need to promote awareness of prematurity and help reduce these racial and ethnic disparities.

CDC's third role is to move research to action. There have been promising new discoveries such as NIH's study of progesterone injections, but we still do not know if women will accept these painful weekly injections or pay for preventive treatment or be able to attend weekly clinic appointments. CDC takes those hard steps with States and communities to move scientific discoveries to widespread public health practice and then measures the impact that they make.

CDC's fourth major role is public health research in the field and to respond to new and emerging threats to infant health and prematurity. We learned about the use of a chewing tobacco product called Iq'mik, which is widely used among Alaska Natives in the Yukon Delta region. The way it is prepared results in free-basing of nicotine and results in incredibly high levels of nicotine in the blood.

Analysis of CDC's PRAMS data found that well over 60 percent of women were using this product during their pregnancies. CDC scientists responded by initiating a field investigation to assess this risk in pregnant women and helped develop a prevention response.

In closing, the solutions to the problem of prematurity must come through better prevention, and better prevention comes through strong public health prevention research. CDC addresses the problem of prematurity in the way that we face all of our epidemics—using all of our tools of health monitoring systems, integrated epidemiologic research, and social, behavioral, biomedical, and laboratory disciplines, and working with State and communities. Our prevention agenda includes three priorities.

One is to research the causes and risk factors for prematurity. Second is investigating new ways to identify women at risk early in their pregnancy so we can intervene. And third is moving new research discoveries to public health practice, to save lives and prevent disabilities among America's babies.

The challenges are many. The solutions are very complex. We are committed to building close partnerships with NIH and HRSA and the March of Dimes and our other public and private partners so that we can move forward in an effective and coordinated fashion.

We know that we face many challenges, and these answers are not going to come easily. We are prepared to address these challenges and make a difference to the families of this Nation.

Thank you again for this opportunity to be here today. I would be happy to answer any questions.

[The prepared statement of Dr. Lackritz follows:]

PREPARED STATEMENT OF EVE LACKRITZ, M.D.

Good morning Mr. Chairman and Members of the Subcommittee. I am Dr. Eve Lackritz, Chief of the Maternal and Infant Health Branch in the National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention. I am also a Commissioned Officer in the U.S. Public Health Service and a pediatrician. I am pleased to be here today to participate in discussions of the problem of preterm birth, which is one of the most devastating health issues facing women, children, and families in America today. I would like to take this opportunity to 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 by defining priority areas where CDC, in partnership with other governmental and nongovernmental agencies, need an expanded, comprehensive prevention research agenda, and an action plan for the prevention of preterm birth.

BACKGROUND

In terms of the health of women and infants, preterm birth is a public health priority. Preterm labor is the leading cause of hospitalization among pregnant women. Preterm delivery is the second leading cause of death among infants, second only to deaths from severe birth defects. The crisis is particularly acute among African Americans. Complications from preterm births are the leading cause of death for African American infants today. This national epidemic of prematurity affects 12 percent of all births in the United States and 17 percent of births among African Americans.

We have very few health threats of this magnitude, and this health threat goes well beyond the burden of infant mortality. Preterm delivery is the leading cause of developmental disability in children, including cerebral palsy and mental retardation, and is an important cause of blindness and chronic lung problems. Infants who are born premature are more than two times more likely to have a birth defect than infants who are born at term. Premature infant births extract a huge financial toll on our healthcare resources. Hospital care of preterm infants costs over \$13 billion each year. This is just for hospital care at their birth. Additional costs include hospitalization of mothers and continued care of children, including costs for repeat hospitalizations, medical visits, rehabilitation, and special services for children with special needs. But the toll of preterm delivery is not just financial. It tears at the fabric of our families and our communities, and takes an enormous emotional toll on mothers and fathers. Taken together, it is clear that preterm delivery is a public health priority.

As a pediatrician, like tens of thousands of my colleagues across the country, I spent years working in the hospital wards struggling to combat the problem of prematurity, fighting to keep babies alive who were unable to survive on their own. All too often, I had to inform parents that their premature son had brain damage, or that their tiny daughter had debilitating handicaps, or that their newborn child would not be able to survive—all because they were born too early. Medical care has become more sophisticated over the years resulting in improved survival of preterm infants. But we are still left with unacceptably high rates of death and disability. It is clear that the solution to the problem of preterm delivery must come

through better prevention. And better prevention can occur only through research to understand the reasons why too many women deliver too many infants too early.

CURRENT RESEARCH AND CHALLENGES

CDC, as the Nation's prevention agency, addresses the problem of preterm delivery through research and programs, focusing on both the social and biomedical factors that affect preterm risk. CDC formulates a prevention response by identifying populations at risk, assisting in implementation of prevention programs, and monitoring progress of prevention efforts. CDC's work is achieved through three basic mechanisms: public health surveillance, support for State and community based programs, and epidemiologic and laboratory research.

Surveillance

Surveillance is the core of CDC's work, the way in which we monitor how many infants are born premature, determine if trends are getting better or worse, define risk factors, and target prevention programs. 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 two key surveillance systems that are used for preterm birth.

The first major surveillance system focuses on the collection of vital records such as birth and death certificates. For preterm birth, this is the backbone of health surveillance, where risk factors are evaluated such as the mother's education, tobacco use, race, and the infant's birthweight. Vital records allow epidemiologists to follow trends, risk factors, and identify areas with high rates of preterm births. Although this system provides useful information, it is also a system facing some critical technology challenges. In this computer age, our data systems are antiquated. More flexible, timely, and responsive surveillance systems are needed to get vital information more quickly and effectively to decision-makers. It is an important time to move to a new, electronic vital records system, whereby risk factors for preterm birth and low birthweight can be measured and reported with greater speed and precision. CDC is working with partners in States and other Federal agencies to develop the nationwide standards and practices needed to implement this system, and the President has requested funding to support this effort in his fiscal year 2005 budget request.

CDC's second key 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, stressful life events, and physical abuse. PRAMS provides vital information to program managers and decision-makers in 31 States and New York City, supporting the development of important policies and programs in maternal and infant health. Examples of policies and programs informed by PRAMS data include:

- PRAMS data on statewide breast-feeding initiation and duration prompted staff at the Maine Medical Center to examine breast-feeding practices at their hospital. The study results, along with state-level data from PRAMS, were used to improve breast-feeding education and support in the Neonatal Intensive Care Unit.
- In New Mexico and North Carolina, PRAMS data were used to demonstrate the benefit of Medicaid coverage on early initiation of prenatal care.
- In Florida, North Carolina, Colorado, and Maine, PRAMS data are used to monitor knowledge about the benefits of folic acid and provide information to healthcare providers and community leaders for improving knowledge and use of folic acid.

While PRAMS only covers 31 States, other States recognize the utility of PRAMS and are requesting assistance and participation. CDC is working to include as many States in this surveillance system as possible. States are asking CDC to help them analyze and use data for health policy and programs related to preterm delivery and infant mortality.

In addition to these two key surveillance systems, CDC also uses more focused surveillance efforts to address specific health issues. As required under Public Law 102-493, CDC collects and analyzes data from all clinics that use infertility treatment termed Assisted Reproductive Technology (ART). CDC and other partners have used this system to evaluate the impact of ART on preterm birth and low birthweight, but there is still much to be learned in this area. Linking the ART surveillance data with State birth and death files provides a population-based database to examine maternal and infant health outcomes associated with this rapidly advancing technology. This activity was first initiated in 2001 when CDC developed a collaborative project with the Massachusetts Department of Public Health. Although recent research has indicated that ART is not driving the epidemic of

preterm delivery in the U.S., it is important to continue to monitor its impact on preterm delivery.

Public Health Capacity

CDC provides assistance to States and communities to collect and analyze data for development of maternal-infant policy and programs responsive to local, tribal, and State-specific needs. Fifteen CDC scientists are assigned to State health departments and one to an Indian Health Service epidemiology center. These assignees have assisted State public health agencies with the spectrum of maternal and infant health issues including prematurity. For example, in Michigan, the assignee helped to identify the largest racial infant health disparity in the Nation. This finding led to the formation of eight community initiatives targeting high risk communities, legislative mandating of a State infant mortality summit, developing a State policy white paper on prevention, and implementing new initiatives at a time of budget crisis. In Mississippi, the assignee evaluated the health outcomes of the State's system of perinatal care. With a national goal of 90 percent, only 40 percent of very premature babies are born in Mississippi's perinatal centers. (The mortality rate of babies born outside the centers is 50 percent higher than those born in perinatal centers.) These findings have led to much discussion statewide and the development of a legislative plan to address these shortcomings in the State.

In partnership with the Health Resources and Services Administration (HRSA), the March of Dimes, local coalitions, and health departments, CDC epidemiologists worked with CityMatCH (a national organization of city and county health departments and maternal-child health program leaders) to develop Perinatal Periods of Risk (PPOR), a new approach to investigate a community's infant mortality problem. This simple method enables communities to quickly identify the problems so that they can move to action with prevention strategies. The uses of PPOR have been advanced through collaborative work in 12 cities across the country. PROR examines a community's fetal and infant mortality problems by mobilizing communities to address four primary prevention areas: maternal health and prematurity, maternal care, newborn care, and infant health. Prematurity was identified as the leading issue driving their infant mortality problem.

CDC works with a number of community-based organizations such as Healthy African American Families in Los Angeles and through CDC's Racial and Ethnic Approaches to Community Health (REACH) programs in Michigan and California. CDC provides technical assistance and helps build networks of local organizations, public health workers, and health care providers in communities with high preterm delivery rates and ethnic minority populations. These networks begin to help increase awareness about preterm delivery in the community and promote healthy pregnancies.

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

Epidemiologic Research

For more than 20 years, CDC has conducted research to understand the racial disparities in preterm delivery. Research has identified that stressful social factors, such as poverty, poor housing, and crime, exacerbate a woman's risk of preterm delivery. Bacterial vaginosis is also higher among African American women. CDC has conducted research evaluating interactions between adverse pregnancy outcomes and social factors, race, infectious processes and behaviors. For example, vaginal douching has been shown to be associated with low infant birthweight and bacterial vaginosis. More work is needed to elucidate the effects of these factors on preterm birth.

In addition, we must remain vigilant to new and emerging threats to preterm delivery. The CDC and Indian Health Service recently learned about the use of a chewing tobacco product called Iq'mik, which is used widely among Alaska natives in the Yukon Delta region. Iq'mik is prepared by mixing chewing tobacco with the ash of a punk fungus, resulting in free-basing of nicotine and high blood nicotine levels. Analysis of PRAMS surveillance data found that well over 60 percent of women in the Yukon region were using this product during pregnancy. CDC responded by initiating a field investigation to assess pregnancy risk and assist with a prevention response.

AN AGENDA FOR PREVENTION RESEARCH AND PROGRAM

There have been promising new discoveries in the field of preterm delivery, but many unanswered issues remain. CDC recognizes that a comprehensive prevention

research agenda is needed to better understand the multiple and complex causes of prematurity, address racial and ethnic disparities, and develop and implement effective strategies. Preterm delivery is one of the many challenging epidemics that CDC must address. We need to attack the problem of prematurity in the way that we face all other epidemics.

Action steps to address preterm birth include:

- researching the causes and risk factors for preterm delivery;
- identifying women at risk early in their pregnancy;
- moving new research discoveries to public health prevention;
- expanding community-based programs on prematurity.

1. Identifying Causes and Risk Factors for Preterm Delivery

A complex array of factors interferes with healthy pregnancy outcomes and racial disparities. We know now that low grade infections, sometimes silent infections such as vaginal infections or periodontal gum disease, are associated with risk of preterm birth; however, a decade of research by NIH and their partners suggests that treatment of infections may not be effective in preventing preterm delivery. Perhaps the inflammatory response to infection, and not the infection itself, is responsible for preterm labor and delivery. We know that tobacco and psychological stress from living in poor neighborhoods create the same damaging chemicals in the body as infection. These same damaging inflammatory factors have been identified as mediators of cardiovascular disease, and are increased by the same factors such as periodontal gum disease, smoking, and stress. Damaging by-products of inflammation that spread throughout the body may result in increased risk of premature birth, as they have with cardiovascular disease. Our research agenda includes examining the role of inflammation on preterm delivery and opportunities for intervention.

2. Early Detection and Screening

Biological markers associated with preterm delivery, such as markers for inflammation, are often present very early in pregnancy, weeks to months before a preterm birth; however, these laboratory markers have not been thoroughly researched or applied to clinical practice. Our research agenda includes determining if there are ways to identify women at risk early in their pregnancy, so that they may be referred to tertiary care medical systems or provided with interventions to reduce their risk. A prospective study evaluating the causes of preterm delivery and early detection of women at risk would inform the research greatly.

3. Moving Research to Prevention

NIH recently completed an exciting new study that found that weekly injections of 17-alpha hydroxyprogesterone reduced the risk of preterm delivery among women who had had a prior preterm infant. But many questions remain regarding how best to move this new research discovery to widespread public health practice. This progesterone product is not commercially manufactured and it is unknown if women in high risk populations will accept painful weekly injections or what other risk groups might benefit from this intervention.

In collaboration with NIH and other partners, a comprehensive research agenda is needed to evaluate drug availability, patient acceptability and adherence, and evaluate alternative routes of delivery such as a patch or suppository. Additional research is also needed to identify if other risk groups would benefit from progesterone therapy and evaluate how clinical practice has changed following these recent scientific findings. CDC can help address some of the operational challenges in moving research results to widespread public health practice.

4. Expansion of Community-Based Programs

CDC has made strides in working with communities to reduce racial and ethnic disparities in preterm delivery and infant mortality. Community-based programs serve to increase awareness about preterm birth, promote early initiation and continuity of prenatal care, and promote pregnancy health at the community level.

CONCLUSION

Prevention of preterm birth is an important public health priority. Reducing preterm delivery poses many challenges, and the solutions will not come easily. A comprehensive research agenda would begin to identify the multiple and complex causes of preterm delivery and develop effective interventions. Together we can make a difference for the infants and families of this Nation.

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

Senator ALEXANDER. Thank you, Dr. Lackritz, and thanks to all three of you for laying a very strong base about what we know and what we do not know today about this mystery of why so many babies come sooner than they should and what the effects of it are on them and on our country.

I will ask a few questions before we go on to the second panel. Before Senator Bond left, he asked if I would ask a question, and it is something, Dr. Van Dyck and Dr. Lackritz, that you both talked about—perhaps you did, too, Dr. Alexander. You talked about community health centers and the role of community health centers in the research and in moving what we know out to where it does some good.

Is there more that any of the three of you could say about the role of community health centers and what the priorities should be for community health centers over the next few years as we think about how to prevent prematurity?

Dr. VAN DYCK. Community health centers are a HRSA-run program, so perhaps I will start.

Community health centers form an important backbone in the health care delivery system of the Nation, and many, many poor pregnant women come to health centers for their care. The community health centers form an important part in inner cities as well as in rural areas of the overall delivery of health care.

As part of the President's initiative, there is an expansion of the community health centers over the next several years, and I think an important expansion to try to improve access to care.

Specifically, there is a new pilot collaborative around perinatal care which I described briefly, to try to get five or six or eight or ten people together to determine what the best practices might be to deliver the best perinatal care and help prevent preterm birth and prematurity and infant death. You then implement those practices in a small number of centers that have good data, so you can follow and track whether there has been improvement. If there is improvement, which often happens, that model can be replicated in other centers.

This perinatal collaborative is beginning as we speak, and will be begun in up to six centers by the end of this year.

So I think community health centers play an important part in the overall structure and delivery of this kind of care.

The second piece is they probably form a wonderful opportunity to translate evidence-based research into practice, and I think that is one of the aims of our Low Birth Weight Committee, to identify those evidence-based practices which can work and try to find vehicles for the delivery of those practices in addition to the private sector—Healthy Start sites, community health center.

So I think that as this Low Birth Weight Committee matures, and the findings come out, this will be an important piece of strengthening the delivery of care in community health centers.

Senator ALEXANDER. Thank you.

Dr. Lackritz?

Dr. LACKRITZ. I think there are two ways of thinking about community care. One is from the provider perspective, that people have

access, and providers know what to do. The second is patient-centered. There are three direct areas in this. The patients need to have knowledge; they need to have the right attitude and an understanding; and finally, we know that knowledge by itself does not change behavior, so there are a number of things that we need to focus on terms of promoting community awareness, understanding what can motivate women and what can promote healthy behaviors. There are a number of things related to preterm delivery in this area.

I think our experience is that we have learned to listen to communities. I do not think people, certainly women, take a direction that is just told to them. We need to understand how best to communicate how to get our message across and how to motivate the population, from any number of things from accessing prenatal care to douching to getting treatment for infections.

Senator ALEXANDER. Which is the bigger problem—finding and reaching out, communicating with pregnant mothers, or knowing what to tell them when you find them?

Dr. LACKRITZ. And having the research tools that will guide all three of those areas.

Senator ALEXANDER. What has come out here is that there is a great deal of unknown here—that is the point of the hearing, that we do not know why there is a great deal of prematurity. Dr. Alexander, you especially brought that out, and that many of the things that we thought work—you mentioned bed rest—I have two friends right now who are using bed rest in their pregnancies—but you said that in your research, it is not useful.

Dr. ALEXANDER. Yes, that is correct. One of the useful things about research is that it often shows that some of the things we have believed for many years are actually not true. So even a negative study has great value. It stops a practice that does not work. It ends some of the costs that are associated with that and some of the time and effort that go into that. And it also shows you that you have got to find some better way to treat this other than what you are doing, because what you are doing does not work.

Senator ALEXANDER. Based on what we know today—and we are delighted that Senator Dodd is here, and I will turn next to him for his remarks and any questions he might have before we go to the second panel—but if a pregnant mom were watching today, or later reading your statement, what are the two or three things that we do know that one ought to do to discourage prematurity? What actions can an individual take, based on good research and on science that we know today?

Dr. ALEXANDER. Let me start with that if I may. First of all, plan pregnancy. Fifty-four percent of the pregnancies in the United States, with all the information we have about what causes pregnancy—we know that pretty well, and we also have pretty good information on how to prevent pregnancy if we do not want to have it—in spite of all that, we still have 54 percent of pregnancies in the United States unintended, unplanned. And there is very clear information that those pregnancies are at greater risk for prematurity, low birth weight, than the intended, planned pregnancy.

So planning pregnancy is a start. Also, a woman before she gets pregnant getting her health in as good a status as it can be before

she gets pregnant, including starting to take folic acid before she is pregnant; also, a preconception examination and evaluation by a physician for general health status is also useful; stopping smoking if she is a smoker—of all the things we know that will reduce the prevalence of low birth weight, stopping smoking is number one on the list; it is the most effective thing we can do. But too many of our women are still smoking during pregnancy, and that is a significant contributor to low birth weight.

Also, getting prenatal care right from the start, with regular examination and follow-up, allows you to have detected things like preeclampsia or preterm labor at an early stage when we can try to intervene with a variety of things, many of which we still do not know how to do. But for example, we now have progesterone available for a woman who has had a preterm delivery before. We do not know yet if that works for other conditions. One of the priorities we have for our Maternal-Fetal Medicine Networks is to study progesterone for other conditions—twin and triplet pregnancies, for example, short cervical length, and women who have certain other conditions. We need to test this treatment and see if it will work for them as well.

But that is my short list. The others may have other suggestions.

Senator ALEXANDER. Well, that is pretty good list—plan the pregnancy, folic acid, good health, take an exam, no smoking, prenatal health care—that means get a doctor before you have your baby, not after—and progesterone, maybe.

Would you add to that, Dr. Van Dyck, Dr. Lackritz?

Dr. VAN DYCK. I would just like to say that there are still a lot of women who do not get prenatal care, do not have easy access to prenatal care, do not do the simple things related to prenatal because of poverty or lack of access to clinics.

Senator ALEXANDER. Do you have any idea what percent of women do not have access to a pediatrician or a medical facility before their babies are born?

Dr. VAN DYCK. Well, we know that up to 10 percent of women do not get prenatal care, and an even larger percentage do not get adequate prenatal care. So there are significant improvements that we can make even with what we know by providing better access to women and better education to women who do not access the good prenatal care that we have.

Senator ALEXANDER. Dr. Lackritz, would you like to add anything?

Dr. LACKRITZ. I agree. I think it gets back to our original message, that there is a lot that we do not know, but at the same time, there is a lot that we know and need to do better with. I think the tobacco cessation example is perfect. We do support some States on that, but we really could do more, and States are asking us to do more.

I think another good example is behaviors such as douching. It also demonstrates this interaction between biology and behavior. We know that bacterial vaginosis is associated with preterm delivery. We know that these vaginal infections are sometimes two to three times higher in African American women than in white women, and we know that African American women are more likely to douche during pregnancy.

So it is a matter of understanding if there is a biological interaction between these behaviors and the infectious processes, and how can we best intervene, both on the behavioral aspects as well; how can we motivate women and educate women on the dangers of certain behaviors.

Senator ALEXANDER. Thank you.

Senator Chris Dodd is a long-time member of this committee and a leader—depending on how the elections go, he is chairman of it sometimes—but in any event we work together on many issues and especially on this one, and we are partners and cosponsors of this legislation, announced it together and work on it together. I am delighted he is here.

Senator Dodd, we have heard from these witnesses. Why don't we go to you for any statement you might have, and when you have finished, we will go to the second panel so we have a good chance to hear from them. But take whatever time you would like.

Senator DODD. Thank you very much, Mr. Chairman, and I thank our witnesses.

I apologize for arriving late. I care so much about this hearing, and I cannot tell you how exciting it is to work with Lamar Alexander on these issues. It has been one of the real joys of my career in the Senate to have someone who is committed to these issues as much as Lamar is.

The witnesses will appreciate this—I have a 2½-year-old daughter, and I was with her this morning. I would normally come up with an excuse like there is a very important hearing, but I am going to be away for 3 or 4 days, and I did not want to go away without spending a little time with her this morning. So I apologize. I know we are not supposed to admit these things on CSPAN.

Senator ALEXANDER. I think your approval rating just went up.

[Laughter.]

Senator DODD. I am a first-time father, and I suspect I am a lot better at this today than I might have been 25 or 30 years ago. I am not sure I would have made the same decision this morning a number of years ago. So I apologize for that. But I am deeply grateful again to the chairman for being so involved and for caring so much about this, and the witnesses as well.

Let me just make a couple of opening comments, and then I have some questions.

I think Senator Alexander is asking a very good set of threshold questions that I think are important to try to get the magnitude of all of this.

I was talking to my sister—I have an older sister who is a grandmother of 13, with five children—and not too long ago, we were talking about this issue of prematurity in infants and so forth, and she was describing that when her first child was born—my sister was a smoker—she and the doctor both took a break to have a cigarette during the delivery of her first child. That is ancient history, going back about 40 years, but nonetheless that is how cavalier people were about that.

The single most important thing for people to do, as you point out, Dr. Alexander, is to stop smoking; if you had to pick one thing, that is the one thing that can make a difference.

But I had thought about this as being sort of a normal issue until I became aware of the statistics. I think every one of us knows someone today who was a premature child, so I just assumed this was a normal thing that happens with some frequency but not any huge health concern until I began to look at the numbers and discovered that one out of every eight children born is premature, 480,000 in the country; about 1,300 every day are born premature in this country. I have about 4,000 in Connecticut.

And looking at the numbers and where they are coming from and what is happening and what can be done—obviously, the legislation that we have introduced here, along with our colleagues in the House, by the way—it is one of those unique situations where we have a companion bill exactly in the House of Representatives.

So I will just ask that a written statement be put in the record, if I can, rather than taking the time to read it now, and ask you some questions about this.

First of all, is there a profile that is developing in terms of economics, age? One thing that occurred to me when you were talking about some of the things to avoid is to what extent as a young child—we now have a lot of teenagers and even preteens in some cases delivering—is there a higher incidence of prematurity with younger women? Historically, one argues that younger, healthier women are actually better able to carry to term, but is that sort of a myth that we have been living with?

Economics is very important. I am glad the Senator asked that question. Is there a profile that has developed here so we can begin to see that there is a much higher rate of prematurity among mothers who come from lower economic circumstances? Obviously, there is data that would probably corroborate that, given access to health care and a variety of other things. I would be curious if we could begin to develop some sort of profile of that mother and what she is living with; it would be helpful.

And then, I was curious because I noticed that the traditional source of neonatal death for years was respiratory ailments, but that actually, respiratory ailments are on the decline—at least, the data points to that. So what are the new factors that are contributing to this increase since 1958 in the 2002 data?

I will ask the panel, whoever wants to respond.

Dr. LACKRITZ. All of us could probably answer this.

In terms of age, you get what we call a bimodal distribution—very young women are at increased risk of prematurity, and older women are at increased risk of prematurity.

The thing we try to focus on in public health is—we do have a well-described profile of women—what are the preventable factors. In some of these, the mother had a preterm birth. Well, I cannot really intervene in that—although even those types of issues, we know that we need to get those women early, monitor them closely, and make sure they know that they need to deliver in a tertiary care facility.

I think there are a number of important factors in terms of risk factors that we need to focus on. The main thing is race in America; that women who are African American have three times the rate of low birth weight than white women. Now, if you control for economics, yes, we also know that poor women are more likely to

be at risk. We know that women who live in urban areas that have a high crime rate and crowding and who live in stressful urban settings are at increased risk for preterm delivery.

Senator DODD. How much of an increase? What are we talking about here, Doctor?

Dr. LACKRITZ. I would say about twice as much—and we can see that that increase due to those environmental stresses is worse in African Americans. So if we look at poor white women living in stressful environments and poor black women, those African American women are suffering even more because of those social factors.

The interesting thing about race, though, too, is if we look at foreign-born women, that foreign-born black women actually have lower preterm delivery rates than black women who are born in the United States. So it is not purely generic, and it is not purely cultural, and it is not purely economic. It is clearly a combination of a number of factors that are influencing it. But if I had to say what is one of the most important things we need to focus on, it is this racial disparities issue that is driving a lot of the infant mortality problems we have in America today. It is a very big proportion.

Senator DODD. Dr. Van Dyck, do you want to comment?

Dr. VAN DYCK. I do not think so. I think that is the important profile.

Senator DODD. Dr. Alexander?

Dr. ALEXANDER. Let me just say a couple things about the rising rate of prematurity that we have seen lately and a couple of the factors that may be contributing to that. It is not exactly a profile of the risk, but there are some things that we do know about risk where the population is changing in a way that is increasing the likelihood of premature delivery.

One of those is the age at which women are having children. Older women have a higher likelihood of premature birth, and we are seeing a shift at ages at which women are having children. In the fifties, sixties, and seventies, the percentage of women who were older was declining, and prematurity rates declined at that time. In the last 2 decades, that percentage has increased, and with it, there has been the increase in prematurity. That accounts for a part of it.

Also, it is accounted for in part by the increase in obesity—obese women are more likely to have a premature birth. And there is also the fact that we tend to intervene more aggressively obstetrically when a pregnancy gets into trouble, when a fetus gets into trouble, and deliver it at an early age because we can save those smaller babies more effectively than we used to be able to.

Senator DODD. You triggered that—I meant to ask that in my preliminary question. In terms of death rates of infants, how has that changed? If you compare death rates of newborns, say, 20 years ago to death rates today—obviously, in a lot of these cases, given technology and the advancement of medicine, we can save a lot of these children—but not that many years ago. There is a question mark there.

Dr. LACKRITZ. And that links to your question about lung disease, too.

Senator DODD. Dr. Alexander, I am sorry. I apologize.

Dr. ALEXANDER. Let me address that. One way of looking at it is the average weight at which half the babies are born survive. Twenty years ago, 30 years ago, that was around 1,500 grams, or a little less than 3 pounds. Today it is around 700 grams—half the babies survive.

If you look at deaths from respiratory distress syndrome in premature babies, those have dropped dramatically because of the availability of surfactant, because we treat premature labor with steroids to try to mature the lungs, etc.

A way of looking at this that is quite dramatic is to look at what has happened with respiratory distress syndrome deaths. A case-in-point is John Kennedy, who was largely responsible for NICHD being established and advocating that with the Congress back when he was President. He had a premature son, Patrick, born in 1963. At his birth weight and gestational age, he developed respiratory distress syndrome. We had no idea what caused it, we had no effective treatment, and he died at 4 days of age because of no therapy. He had a 95 percent chance of dying then because we did not have effective treatments or knowledge of the cause.

Since then, we have found the cause, we have developed effective treatments, and if Patrick Kennedy were born today at that same gestational age and birth weight, instead of having a 95 percent chance of dying, he would have a 95 percent chance of surviving.

That is a dramatic example of the improvements. But we are having more premature babies born, and that is what we have got to attack. That is the major problem we have. Our numbers are going up, not down.

Senator DODD. Dr. Lackritz, you mentioned research into environmental contaminants and their link to premature birth. I think you touched on this a little bit in answer to my first question, but I wonder if there is a further elucidation that you would like to make about environmental contaminants and their effects. You mentioned that these numbers are higher in urban settings, and you mentioned stress and violence, but I am also wondering whether, despite all of our efforts in clean air and clean water—in Washington, DC, lead in the water that we have now discovered—to what extent are these kinds of environmental contaminants possibly contributing to these increased rates?

Dr. LACKRITZ. It has been a big question, and it is very hard to tease out, because getting hard data on that kind of thing, looking at was it lifetime exposure or was it early exposure, is it exposure during pregnancy—it is analytically a very complex question, but it is an obvious question that all of us are looking at now.

Dr. ALEXANDER. It is a question that is extremely important. The problem with the studies that have been done in the past is that the numbers have been too small, the follow-up has been too short, and we have only looked at one or two contaminants of the environment at a time.

What we have now before us is the opportunity to do a much more definitive study on environmental influences on premature birth, on birth defects, on a number of other situations that affect children.

You, as one of the prime sponsors of the Children's Health Act of 2000, included in that a directive to the NICHD to lead a consor-

tium of Federal agencies to develop and plan and conduct a National Children's Study, which is a longitudinal study of environmental influences on children's health and development. We are currently in the process of planning that study. The very first information that we will have from that study will be information on prematurity and birth defects, because the outcomes we will have in that will come first.

That study plans to enroll a cohort of about 100,000 women recruited during pregnancy, with extensive information gathered from them on environmental exposure history, also of the father, also DNA from both parents as well as from the infant, information on the course of pregnancy, as well as environmental sampling from the home, the community, whatever the mother is exposed to, as well as blood levels of a wide variety of environmental contaminants.

All of these can be looked at at once, rather than just one or two. We can look at 100 and look at correlations between outcomes and the environmental exposures and the genetic makeup of mother and father and baby, and try for the first time, because of the large numbers that we will have in this study, to really put together the picture of what environmental influences are affecting pregnancy outcomes in terms of prematurity, low birth weight, birth defects, and developmental status, because we plan to follow these kids to age 21.

Senator DODD. That fits in very, very neatly in the sense of what we are doing.

Just a couple more quick questions. You mentioned SIDS, Dr. Alexander, Sudden Infant Death Syndrome. In fact, Don Imus the other day dedicated a week, or a significant portion of 1 week, of his show to not only raising money for this camp that he and his wife have, but also for SIDS, and I have been involved with it for a long time in my own State.

Tell me what the connection is here. You mentioned it all through your testimony. What is the connection between that and prematurity?

Dr. ALEXANDER. A premature baby is much more likely to die of SIDS. It is two to three times more prevalent among preemies than it is among term babies. So that is definitely a risk factor for SIDS and one of the reasons why those babies need to be watched even more carefully and why it is even more important for those babies than anybody else to be placed on their backs to sleep rather than on their tummies.

This is one of the real successes that we have had in reducing infant mortality in this country. The reason we made our goal of an infant mortality rate below 7 by the year 2000 in Healthy People 2000 was the fact that we were able to cut SIDS as much as we did with the Back to Sleep Campaign.

We have reduced Sudden Infant Death Syndrome from 1992 to 2002 by more than 50 percent just by the public information campaign to get parents to put their babies to sleep on their backs instead of on their tummies.

Senator DODD. I said Dr. Alexander, but actually, Dr. Van Dyck, you are the one who mentioned SIDS all through your testimony, and I apologize. Nonetheless, do you agree with this?

Dr. VAN DYCK. Absolutely. We are both involved in the Back to Sleep Program—all of us are—and work side-by-side.

Senator DODD. The last question I have for you—and Dr. Lackritz, I will address it to you, but others can comment as well—you testified about the risks that children face later in life as a result of prematurity—blindness, cerebral palsy. Has any link been found with emotional problems? We read every day about the increased problems with attention deficit disorder and depression. We have held hearings here and talked about the increasing rates of suicide or attempted suicide among children.

Are there any efforts or any studies ongoing to go beyond the physical ailments that one might associate with prematurity and to move into this growing problem of emotional disorders that we find your people suffering from?

Dr. LACKRITZ. During that premature period, it is a very critical period of brain growth that can affect a number of sequelae. There are a couple of things that go on. There is a very fragile blood supply in the brain that is sort of at the inner part of the brain, and that often bleeds in premature infants. That vascular bed is just not stable enough for a baby to be born. That alone is probably related to a lot of later sequelae.

The other point thing is, as you were saying, the link between lung and oxygenation and normal brain growth.

In terms of specifics like attention deficit disorder, I am not sure about that, and I could find out, but I think that in general, we are getting much better abilities to assess children psychologically, and we will be able to get more data as we go along.

Senator DODD. In this life study that we are doing, is there any possibility beyond what you are looking at to improve the idea of looking at the emotional responses of children as they mature?

Dr. ALEXANDER. Yes. The legislation asked us to study environmental influences not just from the physical environment but also from the behavioral, social, cultural, community, and family environment, and on a wide variety of outcomes, again, not just physical but behavioral, intellectual, how kids do in school, how they learn, how they grow and develop. So all of those things will be incorporated.

Senator DODD. Thank you, and I apologize again, Mr. Chairman, and thank you immensely. I thank all three of you, and I may have some additional questions for you. I know that Senator Alexander has covered a lot of ground already, so I will end there, and if I think of some more things, I will send them along to you.

But I am very excited—I had forgotten about this study that we authorized and thank you for reminding me. When are we likely to start getting some data?

Dr. ALEXANDER. The planning has been going on, actually, since around the time the legislation was passed. We have recruited staff to do the planning. We have conducted a number of pilot studies. At the present time, our plans call for actually starting to recruit the sample by the end of fiscal year 2000 if we get the funding to do it. The recruiting of the sample will take 3 to 4 years, and as I said, the first data we have will be pregnancy outcome, which will tell us a lot about prematurity.

Senator DODD. Great. Thanks.

Thank you, Mr. Chairman.
[Statement of Senator Dodd follows:]

STATEMENT OF SENATOR CHRISTOPHER J. DODD

Mr. Chairman, I would like to thank you for holding today's hearing on premature birth and low birthweight. I think when many of us hear about a baby being born early, we don't give much thought to what it means. After all, it is not all that uncommon—I'm sure that almost everyone in this room knows someone born prematurely. Thanks to modern medicine it is also not uncommon for a baby born early to end up healthy and happy.

But this feeling that prematurity is somehow "normal" or to be expected masks a growing health crisis. As we will hear from our witnesses today, prematurity has real consequences in health and economic terms. That's why this hearing is so important. We need to bring light to this issue that affects some of the most vulnerable members of our society: newborn babies.

As many of you may know, it was a little over 2½ years ago that my wife Jackie and I were blessed with a child of our own. As the ranking member (and in the past, chairman) of the Subcommittee on Children and Families, I have devoted much of my time and effort to improving the health of our Nation's children and infants.

And yet despite my personal and professional experience, I was shocked to learn about the magnitude of the problem of prematurity. I always understood the pain and hardship that can afflict a family when a child is born too small or too soon. But what is so striking about prematurity is how many parents face these enormous emotional and financial burdens. Nearly 1 out of every 8 babies in the United States is born prematurely—that's 1,300 babies each day, and over 470,000 each year (including more than 4,000 in my home State of Connecticut).

And despite all of the health care advances of the last decades, the problem of prematurity is not going away. According to recent data released by the National Center for Health Statistics, in 2002 the infant mortality rate actually increased for the first time since 1958. Much of this increase is attributable to infant death in the first month of life—of which prematurity is the leading cause. Since 1981, the premature birth rate has increased by 27 percent. This stands in stark contrast to some of the breathtaking medical discoveries of the past 2 decades. We can now treat and even cure many types of cancer, but we can't prevent babies from being born too soon.

The consequences of prematurity are devastating. As I mentioned earlier, it is the leading cause of neonatal death—a tragedy that no family should have to face. For those infants that survive, a lifetime of severe health problems is not uncommon. Prematurity has been linked to such long-term health problems as cerebral palsy, mental retardation, chronic lung disease, and vision and hearing loss. Premature babies have the deck stacked against them from the moment they are born.

As we will hear today from one of our witnesses, Kelly Bolton Jordan from Senator Alexander's home State of Tennessee, even in the fortunate cases where there are no life-long health con-

sequences, the experience of a premature birth takes an enormous emotional toll on a family.

Prematurity also carries a significant economic cost. According to a recent study conducted by the March of Dimes (represented here today by Dr. Jennifer Howse, the organization's President), hospitalizations due to prematurity cost a total of \$12 billion during the year 2000—accounting for nearly half of all hospital charges for infants in this country.

Given the emotional and economic toll that prematurity takes on this country, we know remarkably little about why it happens, and how it can be prevented. As we will hear from our witnesses, some of the risk factors associated with preterm birth are known, including advanced age of the mother, smoking, and certain chronic diseases. But nearly 50 percent of all premature births have no known cause. And because we know so little about the causes of prematurity, we also do not know how to prevent it.

For such a large (and growing) problem, it is astounding how little we know. It is critical that we make a national commitment to solving this puzzle. We must do everything we can to expand research—both public and private—into the root causes of prematurity.

Senator Alexander and I [along with Representatives Anna Eshoo and Fred Upton in the House] have introduced the Prematurity Research Expansion and Education for Mothers Who Deliver Infants Early—or PREEMIE—Act for precisely this reason. Our bill would coordinate and expand research related to prematurity at the Federal level. It would also educate health care providers and the general public about the risks of prematurity, and measures that can be taken before and during pregnancy to prevent it. Pregnant mothers need to know the warning signs and symptoms of premature labor—and they need to know what to do if they begin to notice those signs.

Finally, because we will never eliminate prematurity completely, our legislation would provide support services to families impacted by a premature birth. As we're investigating the causes of prematurity and increasing awareness in expectant parents, we need to reach out to the mothers and fathers across our country whose children are born too soon. We need to give them emotional support during the difficult days, weeks, and months that often follow a premature birth. We need to make sure that the doctors, nurses, and other hospital staff who care for premature babies are sensitive to the needs of their parents, their brothers, and their sisters. And we need to make sure that when the time finally comes to bring a premature baby home, parents have all the information they need to make that transition.

It is my hope that this legislation will complement and support some of the efforts going on in the private sector—such as the March of Dimes ambitious campaign to increase public awareness and reduce the rate of preterm birth. I am proud to say that one of the individuals leading our Nation's efforts to better understand prematurity is from my home State of Connecticut. We will hear from Dr. Charles Lockwood of the Yale University School of Medicine and Yale/New Haven Hospital in our second panel of witnesses. He and our other witnesses will certainly have more to say

about the efforts to combat prematurity in hospitals and research institutions throughout the country, and the importance of investing in this type of research.

Once again Mr. Chairman, I thank you for turning our attention to this important matter. I look forward to hearing from our witnesses.

Senator ALEXANDER. Thank you, Senator Dodd.

An increasing number of medical students are taking a year in public policy at some time in their preparation, and I think the careers of the three of you are good examples of why that is a good idea. This has been very, very helpful, and I thank you for coming this morning.

Dr. ALEXANDER. Thank you.

Dr. VAN DYCK. Thank you very much.

Dr. LACKRITZ. Thank you.

Senator ALEXANDER. I would like to invite the second panel to come forward, please.

Let me introduce the three witnesses. Dr. Jennifer Howse is president of the March of Dimes and has a distinguished career—a doctorate in child language development from Florida State; she is a member of Secretary Thompson's Advisory Committee on Genetic Diseases in Newborns; she is an advisor to the Secretary's National Commission on Infant Mortality.

She has been president of the March of Dimes since 1990, and under her leadership, the March of Dimes has significantly expanded its mission. She will tell us more today about the March of Dimes' latest campaign to reduce premature births.

Dr. Charles Lockwood is the Anita O'Keefe Young Professor and chairman of the Department of Obstetrics, Gynecology and Reproductive Sciences at Yale University School of Medicine. He will talk to us about the status of research on prematurity. He has a background at Brown University, at the University of Pennsylvania School of Medicine, and at Yale University.

And Ms. Kelly Jordan delivered a baby girl 3½-months early. She is from Memphis. Her daughter Whitney's pictures are with us today; she is a beautiful little girl.

Ms. Jordan is also vice president and senior financial advisor for Merrill Lynch.

We welcome all three of you. Why don't we start with you, Dr. Howse, then Dr. Lockwood, and then Ms. Jordan. And we want you to be able to say everything you would like to say. If you could summarize what you have to say in 5 to 7 minutes, we will have more time for questions, but please feel free to tell us what you would like us to hear.

STATEMENTS OF JENNIFER L. HOWSE, PRESIDENT, MARCH OF DIMES; CHARLES J. LOCKWOOD, M.D., CHAIRMAN, DEPARTMENT OF OBSTETRICS, GYNECOLOGY, AND REPRODUCTIVE SCIENCES, YALE UNIVERSITY SCHOOL OF MEDICINE; AND KELLY BOLTON JORDAN, MEMPHIS, TN

Ms. HOWSE. Thank you very much, Chairman Alexander and Senator Dodd.

We are very grateful to have your support around this important issue, and we are very grateful to have time for this hearing so

that you all can have an opportunity to learn first-hand from expert panels and concerned individuals about this growing problem of prematurity.

I think what you have heard this morning from the first panel is that this is a serious problem with serious consequences, a problem that is growing, a problem that is quite costly and relatively common nowadays, and that we need to find a way to prevent prematurity. We need research that can give us additional tools that can intervene and can stop prematurity, and we need to do a better job of applying those few interventions that we already have available, such as smoking cessation and the progesterone therapy. Above all, we need to join in partnership—the able Federal representatives that you have heard from this morning, the volunteer sector which we represent with March of Dimes, and the research community and the academic community. We need to join together. We have joined together. We are a quite determined band of committed organizations and individuals to provide sustained support so we can solve this problem for our country together.

I think that what I will do very quickly is just remind you all and thank you on behalf of the 3 million volunteers of the March of Dimes, the 1,400 staff of our organization. Senate bill S. 1726 is extraordinarily important and meaningful to our volunteers.

We are an organization that is now 66 years old. We are devoted to various aspects of improving children's health. We kind of see our trajectory, if you will, as from polio to prematurity, with a lot of stops in between around important children's health issues that we believe we have been, as March of Dimes, important in solving these problems.

In 2003, we launched this National Prematurity Campaign. We based it on the best data and scientific evidence that we could compile. We know, and you have heard this morning, that this is a growing problem, a major contributor to infant mortality, and certainly it is the number one cause of mortality among black infants in this country, and although these infants account for about 12 percent of the births, nevertheless there is a disproportionate share of infant death in the African American community.

Our campaign, at least its first phase, is 5 years. We will devote \$75 million of March of Dimes money to this campaign. This will be raised by our volunteers across the country. We are pleased to be joined in partnership with the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the Association of Women's Health, Obstetric and Neonatal Nurses. These organizations form our steering committee and guide the Campaign. We have so far 35 other national organizations who have joined and have become part of the National Prematurity Campaign alliance.

Our goal in this Campaign is to reduce the rate of prematurity by at least 15 percent by 2007. I think that is a formidable goal. When you consider the fact that prematurity rates have been rising for the last 2 decades, I know you can appreciate that both to stop the rise as well as to achieve a decrease in rates of prematurity is a tall order.

I believe the Campaign is well-planned and well-ordered. We will invest our own March of Dimes dollars in more research, and we

will also seek to have additional Federal support for research. You heard very ably, I think, from Dr. Alexander about that. We seek to educate women as to the signs and symptoms of preterm labor so they can get connected with their health providers at an early stage when the problem is manifesting, and we will also be providing support for those 480,000 families every year who experience a baby born prematurely. You will be hearing more about that first-hand from Kelly Jordan.

We are also concerned about lack of access to health coverage for women, particularly in the early stages of thinking about starting a family and in early stages of pregnancy, so we will devote resources in the Campaign to that as well.

I mentioned prematurity as costly. I will summarize this very quickly. The cost of the average hospital stay for a healthy newborn without complications is \$1,300. For a baby born premature with a principal diagnosis of prematurity, it is \$75,000 for that hospital stay. So you can begin to appreciate the dramatic cost implications. For all infants born in the year 2001, their hospital stays amounted to \$29.3 billion, and about half of that amount, \$13.6 billion, is the hospital charges ascribed to infants with a diagnosis of prematurity. So half the hospital charges for the labor and delivery are associated with 12 percent of the births. Again, you begin to really appreciate the disproportionate costs associated with prematurity, and of course, the bill is paid by employers and by individuals, but most particularly by employers, private health plans, business, and the Medicaid program.

There are other costs as well. The consequences of prematurity are quite severe in terms of health problems—you have heard about that—cerebral palsy, developmental delay, blindness. There are data—for example, in the *Journal of the American Medical Association*, there is a very well-developed article published in 2002 that demonstrates the connection and the greater risk for babies born premature both for lower cognitive test scores as they go to school, as well as for behavioral problems such as suicide and emotional problems, particularly as they begin to reach their teen years. So this is a problem that does not stop when the baby graduates from neonatal intensive care; for many of the infants, it continues to be a matter of lifelong health consequences.

This legislation, S. 1726, is extraordinarily important to us. While there have been very important steps taken within the Federal agencies to begin to come together around the problem of prematurity and the associated condition, low birth weight, nevertheless this bill would provide a framework, would provide specific guidance, and frankly, it would codify the interest of the Congress in this problem of prematurity and would help us work together over a sustained period of time.

The bill would expand, intensify and coordinate research related to prematurity. You will be hearing more about that. It also contains some important provisions that attach to the children's health study, and you have heard that elaborated. In particular, there are three activities that I would like to draw to your attention.

First, the bill would establish a Surgeon General's Conference on Prematurity and Low Birth Weight. This would be very important and would really give an opportunity for many of us to come to-

gether, share what we know, and also outline what we need to learn in order to tackle the problem. It would develop a consensus research plan for HHS on prematurity and low birth weight, again, gathering the resources already in place to augment the effort. It would also allow for regular reporting to the HHS Secretary and to the appropriate committees of the Congress on these activities.

So we are very, very pleased that you all have taken interest in this problem and that this bill has been constructed. We hope that it will receive approval in the very, very near future.

Again, on behalf of all of our volunteers and our staff and the organizations that we work with in partnership, thank you very, very much for your interest in the problem.

Senator ALEXANDER. Thank you, Dr. Howse.

[The prepared statement of Dr. Howse follows:]

PREPARED STATEMENT OF JENNIFER L. HOWSE, PH.D.

Mr. Chairman, and Members of the Subcommittee, I am pleased to be here today to discuss with you the growing public health crisis of premature birth. On behalf of the 3 million volunteers and 1,400 staff members of the March of Dimes, I want to thank Chairman Alexander and Ranking Member Dodd for their interest and work on reducing the rates of preterm birth and particularly for introducing S. 1726, the PREEMIE Act.

As you know, the March of Dimes is a national voluntary health agency founded in 1938 by President Franklin D. Roosevelt to prevent polio. He took an unprecedented action believing in the power of the volunteer. It took 17 years, breakthroughs in research, and hundreds of volunteers before the Salk vaccine was developed, and the victory against a dread disease secured. Today, the Foundation works to improve the health of mothers, infants and children by preventing birth defects 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 54 chapters in every State, the District of Columbia and Puerto Rico.

Once the Salk vaccine was declared safe and effective, the March of Dimes turned its attention to preventing birth defects, supporting researchers who developed prenatal diagnostic tests and organizing and supporting a nationwide network of genetic service centers and regional neonatal intensive care units. Scientists funded by the March of Dimes were the first to report that drinking alcohol during pregnancy could cause fetal alcohol syndrome.

In the 1980s, March of Dimes research helped lead to the use of surfactant to treat respiratory distress syndrome in newborns a finding that has saved thousands of lives. In the 1990's the Foundation launched a \$10 million effort to fight spina bifida and other neural tube defects by working to obtain FDA approval to fortify the grain supply and teaching health professionals and women about the importance of taking folic acid. This national folic acid campaign is showing impressive results—the National Center for Health Statistics has reported that the rate of neural tube birth defects has decreased 26 percent between 1995 and 2001.

We have worked diligently to fulfill our mission—to improve the health of infants and children by preventing birth defects and infant mortality—in a number of ways. Our expense allocations are comprised of general operational, fund raising, and the largest percentage—75.8 percent—for program services. Those services are organized into three categories: Education, 47 percent; Community Services, 28.6 percent; and Research, 24.4 percent.

Over the last 68 years, we at the March of Dimes have learned important lessons about initiating and sustaining a national campaign that achieves positive measurable results for families and children. Using this experience, in January of 2003, we launched a campaign to address another issue of central importance to the Foundation's mission—preterm birth.

The March of Dimes Prematurity Campaign—a 5-year, \$75 million effort—is a very significant commitment for the Foundation. According to data from the Centers for Disease Control and Prevention (CDC), prematurity is the number one cause of neonatal mortality in the U.S. It is the number two cause of infant mortality, and the number one cause of mortality among black infants. And still the rate of prematurity is increasing. The American College of Obstetricians & Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Association of Wom-

en's Health, Obstetric and Neonatal Nurses (AWHONN) are working as partners with the March of Dimes to carry out this campaign. In addition, to these three partners, 37 other organizations representing government, maternal and child health education and research, and trade and industry associations have joined this campaign as members of the National Prematurity Campaign Alliance.

Recently, the CDC reported the first rise in infant mortality since 1958. The nation's infant mortality rate in 2002 was 7.0 per 1,000 births, which is up from 6.8 in 2001. Whether 2002 will be a blip or not, it is a wake-up call regarding a critical prenatal health issue. The infant mortality rate has not declined in a significant way for the past several years. And it is important to note that the 2002 increase is due to birth defects, prematurity/low birth weight, and complications during birth.

It is one of the goals of our Campaign to decrease the rate of preterm birth in the U.S. by at least 15 percent. This is going to be difficult as the national rate continues to rise. In 2002, 12.1 percent of babies were preterm—before 37 completed weeks of gestation. This is a very disturbing 29 percent increase since 1981. Premature birth takes a disproportionate toll on racial/ethnic minority populations. In 2002, the highest preterm birth rates are among Non-Hispanic Black infants where 17.7 percent were born preterm across the Nation.

An analysis of Agency for Healthcare Research and Quality data by the March of Dimes found that on average, 2001 hospital charges in the U.S. for newborns without complications were \$1,300. By contrast, charges for those infants with a principal diagnosis of prematurity averaged \$75,000. In 2001, hospital charges for all infants totaled \$29.3 billion. Nearly half of that total—\$13.6 billion—was for babies diagnosed as premature. In other words, nearly 50 percent of the total charges for infant hospital stays in 2001 were for babies who were born too soon or too small. Employers, along with private health plans, assume half the total hospital bill for prematurity. The Federal/State Medicaid program also bears a large share of the cost.

Other costs, however, are more difficult to quantify. Such as those incurred after a baby leaves the NICU. About 25 percent of the youngest and smallest babies live with long-term health problems, including cerebral palsy, developmental delay, blindness, and other chronic conditions. A study published in 2002 by the *Journal of the American Medical Association* found that children born prematurely are at greater risk for lower cognitive test scores and behavioral problems when compared to full-term children.

FEDERAL GOVERNMENT'S ROLE—S. 1726

As significant as we believe the March of Dimes Campaign will be, the Foundation is a non-profit organization with limited resources. Success in reducing the incidence of prematurity requires a commitment from the Federal Government as well. The Foundation was pleased to work with the Chairman and Ranking Member to develop S. 1726, the Prematurity Research Expansion and Education for Mothers who deliver Infants Early (PREEMIE Act) and hopes that the bill will be reported by the committee and approved by the Senate this year.

This legislation provides for much needed Federal support of research and education that will help reduce the rates of preterm labor and delivery. Specifically, the PREEMIE Act calls on the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to “expand, intensify and coordinate” research related to prematurity. It formally authorizes the Maternal Fetal Medicine Unit Network—which includes university-based clinical centers and a data coordination center—through which perinatal studies to improve maternal and fetal outcome are conducted. Also authorized is the Neonatal Research Network to improve the care and outcome of neonates, especially very-low birthweight infants. These NICHD supported networks address major problem areas with randomized controlled trials, studies, and outcomes research.

The bill also adds a section on assisted reproductive technologies to the National Children's Study, calls for an analysis of the relationship between prematurity and birth defects and developmental disabilities and requests an Institute of Medicine (IOM) report on the health and economic consequences of preterm birth.

To stimulate more consistent collaboration among HHS agencies and to better target promising research activities being conducted under the auspices of various Federal agencies, the PREEMIE Act codifies the Interagency Coordinating Council on Prematurity and Low Birthweight (LBW) and gives it specific activities. The Council would include representatives of Department of Health and Human Services agencies that conduct prematurity-related activities and outside organizations with an interest in prematurity. Proposed activities include:

- A Surgeon's General Conference on prematurity and LBW.
- Development of a consensus research plan for HHS on prematurity and LBW.
- Regular reporting to the HHS Secretary and appropriate committees of Congress on current HHS activities relating to prematurity and LBW (including the recommendations from a Surgeon General's Conference).

The PREEMIE Act also authorizes several demonstration projects to help disseminate information on prematurity to health professionals and other providers, as well as to the public. Projects would include development of information on the signs of preterm labor; screening for and treating infections; counseling on optimal weight and good nutrition (including folic acid); smoking cessation education and counseling; and stress management. In addition it calls for Federal agencies to conduct programs to improve treatment and outcomes for babies born prematurely. The bill also establishes grants for NICU family support programs—which respond to the needs of families with babies in the Neonatal Intensive Care Units (NICUs) during hospitalization, the transition home and in the event of a newborn's death.

The "PREEMIE Act" is needed to expand resources for research into the causes of prematurity. March of Dimes volunteers and staff look forward to working with the Senate and House sponsors, and our Prematurity Campaign Partners—the Academy of Pediatrics, the American College of Obstetrics and Gynecology, and the Association of Women's Health, Obstetric and Neonatal Nurses—to obtain swift approval of this measure.

Another important piece of legislation, S. 1734, the Prevent Prematurity and Improve Child Health Act proposes to increase access to health insurance for uninsured women, infants and children. Specifically it:

- Gives States the option to include pregnant women in the State Children's Health Insurance Program (SCHIP);
- Gives States the option to cover legal immigrant pregnant women in SCHIP and Medicaid;
- Removes the exemption for tobacco cessation coverage under Medicaid;
- Encourages States to include smoking cessation as a core performance measure in the Maternal and Child Health Block Grant;
- Gives States the option to extend beyond 60 days post partum the period during which family planning services are provided to women enrolled in Medicaid; and
- Gives States the option to use SCHIP funds to supplement benefits provided through private insurance to children with special health care needs.

Health insurance coverage and access to medical care are among the most important factors related to positive medical outcomes. Data from the Census Bureau show that for the aggregate years 2000–2002, nearly 19 percent of women of child-bearing age were uninsured in the U.S. Among children under age 19 in the U.S., more than 12 percent—or about 1 in 8 children—had no health insurance during the 2000–2002 period. The reasons are many, and they are complex, but the outcome is the same: life is not beginning on equal footing.

The IOM report issued in January of 2004 stated that the 43 million currently uninsured Americans don't get needed medical care, so, to quote the report, "they tend to be sicker and die sooner." This unconscionable situation cannot continue. Insurance is necessary not only to prevent preterm birth but to enhance maternal and child health generally.

Prematurity is a growing, devastating problem. We know the road ahead of us is long. And we also know we cannot travel it alone. That is why we especially appreciate the commitment of the Chairman and Ranking Member, Senators Alexander and Dodd to improving women and infants' health.

The March of Dimes and its partners can increase awareness of the problem of prematurity. We can reduce the tremendous costs generated by preterm birth through education, counseling, and access to health coverage. We can increase our knowledge and understanding of the causes of prematurity through research. And—ultimately—we can decrease the rate of preterm birth in the U.S.

But to do so requires a commitment from each of us. And I am confident that working together we will be successful.

Senator ALEXANDER. Dr. Lockwood.

Dr. LOCKWOOD. I would like to add my really profound thanks for the opportunity to talk about prematurity, both from the perspective of a physician and also as someone who has spent the last 15 years of his research career on the topic as well. So I want to thank Chairman Alexander and Ranking Member Dodd and Senator Bond and the other Members of the Subcommittee who are not

here. And I will unfortunately repeat a number of things that have been said, but maybe repetition is not so bad in this context.

Premature births, just for definitional sake, are those that occur before 37 weeks of pregnancy instead of the usual 40, and they are the leading cause of infant mortality as well as mental retardation, cerebral palsy, lung and gastrointestinal damage, and hearing and vision loss in children.

As you have just heard, the March of Dimes estimates that premature births result in nearly \$14 billion in annual health care costs. So clearly, premature birth is a major public health challenge.

Ironically, while much progress has been made over the past 20 years in understanding the causes of prematurity, there has been a 27 percent increase in premature births over the past decade. In fact, in 2002, 12.1 percent of births in the United States were premature.

As has also been alluded to, among the major risk factors for prematurity are, ironically, a prior premature birth, African American race, mothers who are very young and somewhat older, underweight or of short stature. Risk factors developing during pregnancy include vaginal infections, bleeding and discharge, as well as uterine contractions and pelvic pressure. But unfortunately, only 30 percent of patients destined to deliver preterm can be identified by those risk factors.

There are a number of biological pathways that are thought to be responsible for premature birth. The four that I and my colleagues at Yale have been studying include fetal and maternal stress, maternal and fetal inflammation, uterine bleeding, also known as placental abruption, and excess uterine stretch caused by multifetal pregnancies. I would like to briefly discuss each of these.

There is reliable and consistent scientific evidence that women with high levels of anxiety and depression have a two-fold elevated risk of premature birth. However, fetal stress caused by placental abnormalities is associated with an even stronger, four-fold risk of prematurity.

We think that maternal and fetal stress account for about one-third of all preterm births. Fortunately, most of those deliveries occur after 32 weeks, which is a less dangerous period. Yet-to-be-identified genetic factors are thought to be responsible for either an exaggerated response to stress or abnormal development of the placenta.

Inflammation of the uterus, fetal membranes, and the fetus itself has also been linked to prematurity. We believe that bacteria or allergens may trigger premature birth by activating the fetal and/or immune system, leading to contractions, fetal membrane rupture, and cervical dilation.

While 40 percent of all premature births may be caused by inflammation, it appears to be responsible for at least 60 percent of very early premature births—that is, those occurring before 32 weeks—and is more common among African American women, which may help account for their nearly twofold higher rate of prematurity.

Unfortunately, we do not know how or why inflammation develops in some pregnancies or whether it is caused by a true infection

or allergic reaction or simply an exaggerated, genetically-determined, immunological response to normal bacteria or otherwise trivial allergens. Again, genetic variations may account for these puzzling findings, and research is needed to identify the relevant biological mechanisms, determine which women really are at risk, and design prevention strategies.

Bleeding into the wall of the uterus, or placental abruption, also appears to trigger prematurity, and we think that these abruptions, as they are called, account for one-quarter of all premature births, but about 40 percent of very early ones. However, while we now appreciate the link between uterine bleeding and premature birth, we have only limited ideas about what causes such bleeding or how it triggers premature labor.

Multifetal pregnancies, including twins, triplets, and quadruplets, appear to cause excessive stretching of the uterus and cervix, triggering premature labor.

There has been a surge of multifetal pregnancies over the past 20 years, brought on by increased use of fertility treatments. While this increase has now plateaued, multifetal pregnancies account for 17 percent of all premature births, since 60 percent of twins, 90 percent of triplets, and over 95 percent of quadruplets deliver prematurely.

However, we do not understand why many women with twins and some with triplets deliver near term—and I have certainly seen that myself in my practice—while others deliver in their 4th month, which I have seen as well. Yet again, we think genetic factors may account for this variable response to uterine stretch.

Currently, our ability to identify women at risk from any of these four causes is limited. Historical risk factors, as I have just shown, and mother's symptoms identify too few women to be useful. Recently developed techniques, including detection of a short cervix by ultrasound and of a protein called fetal fibronectin in vaginal mucous, produce too many false positive results for their use as screening tests.

And while our diagnostic tools may seem inadequate, so are our treatments. As Duane has already pointed out, bed rest has been traditionally used in high-risk patients without any scientific validation of its efficacy. Anti-contraction medications, called tocolytics, prolong pregnancy for 48 hours, giving us time to administer steroids that may help mature the fetus' lungs, but they do not prevent prematurity. And, despite the suspected role played by infection in premature birth, antibiotics have also not been shown to prevent prematurity.

Most recently, several studies have suggested that progesterone therapy prolongs pregnancy in high-risk patients. Progesterone may work by opposing the effects of stress hormones, reducing inflammation, preventing uterine bleeding, and minimizing uterine stretch, affecting each of the potential causes of prematurity. However, a number of questions remain about its use, such as when in pregnancy it needs to be started, whether it can be used with multifetal pregnancies, and at what dose.

Clearly there is a pressing need for further research into this problem, yet the extent of current research is minimum.

There are multiple reasons for this paucity of research. First, the branch of the NIH with jurisdiction over this type of research has been chronically underfunded for years. The National Institute of Child Health and Human Development, or the NICHD, receives less than 5 percent of the total NIH budget, yet it is supposed to support almost all research into maternal, child and fetal health problems. If you want to think of it from this perspective, about 5 percent of the 5 percent is used for prematurity research.

The current Federal budget deficit has exacerbated this problem. The NICHD now plans to fund research grants receiving study section scores up to the 12.5 percentile, whereas in the past 5 years, they have funded research grants up to the 21st percentile. To put that into simpler terms, roughly 90 percent of the grant applications going to NICHD will not be funded in the current climate.

Second, there has been a virtual absence of industry-sponsored research because of concerns about liability, costs, and adverse publicity.

The final reason for this dearth of prematurity research is the precarious financial status of academic departments of obstetrics and gynecology. After seeing substantial reductions in clinical revenues and soaring malpractice insurance premiums over the past 10 years, many university-based departments of ob-gyn have no financial ability to support the preliminary research results needed to justify grant applications.

As an example, each professional liability insurance premium for an academic obstetrician at Yale next year will be over \$100,000.

Indeed, nearly half of university-based departments of ob-gyn have no NIH-funded research at all.

The Society for Gynecological Investigation, our primary ob-gyn research organization, the Society of Maternal-Fetal Medicine, the leading organization of high-risk obstetricians, the March of Dimes, and the American College of Obstetricians and Gynecologists all strongly support efforts to increase funding for prematurity research and my comments here today.

Based on my experience as a clinician, departmental chair, and both March of Dimes and NIH-funded investigator, I urge Congress to authorize new funding to be administered through the NICHD for research targeted to prematurity.

Specifically, I would urge new funding to create centers of excellence in prematurity research focusing on basic and translational, not just clinical, research into the fundamental genetic, biological, and environmental causes of prematurity, and second, new funding for research to address the underlying causes of the substantial disparity in rates of very early premature birth between African American women and those of other races.

I would also recommend that Congress provide financial incentives and liability protection to pharmaceutical companies to develop new drugs to prevent prematurity.

More than 460,000 babies are born premature each year, and 80,000 are born before 32 weeks. These latter babies are 70 times more likely to die in their first year of life, and as I noted previously, if they survive, they are far more likely to suffer handicaps. While the plan I have suggested admittedly requires a sub-

stantial investment, the yield on this investment will be extraordinary.

Thank you very much for this time.

Senator ALEXANDER. Thank you, Dr. Lockwood.

[The prepared statement of Dr. Lockwood follows:]

PREPARED STATEMENT OF CHARLES J. LOCKWOOD, M.D.

Premature births (PMBs) are deliveries that occur prior to 37 weeks of pregnancy instead of the usual 40. They are a leading cause of infant mortality, as well as mental retardation, cerebral palsy, lung and gastrointestinal damage, and hearing and vision loss in children.

The March of Dimes has estimated that PMBs result in nearly \$14 billion in annual health care costs. Thus, PMB is a major public health challenge.

Ironically, while much progress has been made over the past 20 years in understanding the causes of prematurity, there has been a 27 percent increase in PMBs over the past 2 decades and, in 2002, 12.1 percent of births in the United States were premature.

Among the major risk factors for prematurity are a prior PMB, African-American race, and mothers who are very young, underweight or of short stature. Risk factors developing during pregnancy include vaginal infections, bleeding and discharge, as well as uterine contractions and pelvic pressure. Unfortunately, only 30 percent of patients destined to deliver preterm can be identified using these risk factors.

A number of biological pathways are thought to be responsible for PMB. The four that I and my colleagues at Yale have been studying include:

- fetal and maternal stress;
- maternal and fetal inflammation;
- uterine bleeding, also known as placental abruption; and
- excess uterine stretch caused by multifetal pregnancies.

There is reliable and consistent scientific evidence that women with high levels of anxiety and depression have a two-fold elevated risk of PMB. However fetal stress, caused by placental abnormalities is associated with an even stronger, four-fold increased risk of PMB.

We think that maternal and fetal stress account for about a third of all PMBs. Fortunately most of these deliveries occur after 32 weeks, which is a less dangerous period. Yet to be identified genetic factors are thought to be responsible for either an exaggerated response to stress and/or abnormal development of the placenta.

Inflammation of the uterus, fetal membranes, and the fetus itself, has also been linked to PMB. We believe that bacteria or allergens may trigger PMB by activating the fetal and/or maternal immune system leading to contractions, fetal membrane rupture, and cervical dilation.

While 40 percent of all PMBs may be caused by inflammation, it appears responsible for at least 60 percent of PMBs occurring before 32 weeks, and is more common among African-American women, which may help account for their nearly two-fold higher rate of prematurity.

Unfortunately, we do not know how or why inflammation develops in some pregnancies or whether it is caused by a true infection or allergic reaction or simply an exaggerated immunologic response to normal bacteria or otherwise trivial allergens.

Again genetic variations may account for these puzzling findings and research is needed to identify the relevant biological mechanisms; to determine which women are at risk; and to design prevention strategies.

Bleeding into the wall of the uterus, or placental abruption, also appears to trigger PMB. We think that abruptions account for another quarter of all PMBs, including 40 percent of very early ones. However, while we now appreciate the link between uterine bleeding and PMB, we have only limited ideas about what causes such bleeding or how it triggers prematurity.

Multifetal pregnancies, including twins, triplets, and quadruplets appear to cause excessive stretching of the uterus and cervix triggering preterm labor.

There has been a surge of multifetal births in the past 20 years brought on by the increased use of fertility treatments. While this increase has now plateaued, multifetal pregnancies account for 17 percent of all PMBs, since 60 percent of twins, 80 percent of triplets and over 95 percent of quadruplets deliver prematurely.

However, we don't understand why many women with twins and some with triplets deliver near term while others deliver by their 4th month. Yet again we think that genetic factors account for this variable response.

Currently our ability to identify women at risk from any of these four causes is limited. Historical risk factors and a mother's symptoms identify too few women at risk to be useful. Recently developed techniques, including detection of a short cervix by ultrasound, and of a protein called fetal fibronectin in vaginal mucus, produce too many false positive results for their use as screening tests.

And while our diagnostic tools are inadequate, so are our treatments:

- Bed rest has been traditionally used in high risk patients without scientific validation of its efficacy;
- Anti-contraction medications, called tocolytics, prolong pregnancy for 48 hours, giving us time to administer steroids to help mature the fetus' lung, but they do not prevent prematurity; and
- Despite the suspected role played by infection in PMB, antibiotics have not been shown to prevent prematurity.

Most recently, several studies have suggested that progesterone therapy prolongs pregnancy in high-risk patients. Progesterone may work by opposing the effects of stress hormones, reducing inflammation, preventing uterine bleeding and minimizing uterine stretch. However, a number of questions remain about its use, such as when in pregnancy it needs to be started, and at what dose.

Clearly there is a PRESSING need for further research into this problem, yet the extent of current research is small.

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The current Federal budget deficit has exacerbated the problem. The NICHD now plans to fund research grants receiving study section scores up to the 12.5 percentile whereas in the past 5 years, they have funded research grants up to the 21st percentile.

Secondly, there has been a virtual absence of industry-sponsored research because of concerns about liability, costs and adverse publicity.

The final reason for the dearth of prematurity research is the precarious financial status of academic departments of OB/GYN. After seeing substantial reductions in clinical revenues and soaring malpractice insurance premiums over the past 10 years, many university-based departments of OB/GYN have no financial ability to support the preliminary research results needed to justify subsequent grant applications.

As an example our professional liability insurance premiums for an academic obstetrician at Yale next year will be over \$100,000.

Indeed, nearly half of university-based departments of OB/GYN have no NIH funded research.

The Society for Gynecologic Investigation, our primary OB/GYN research organization, the March of Dimes and the American College of Obstetricians and Gynecologists all strongly support efforts to increase funding for prematurity research.

Based on my experience as a clinician, departmental chair, and both March of Dimes and NIH-funded investigator, I urge Congress to authorize new funding, to be administered through the NICHD for research targeted to prematurity. Specifically I would urge:

(1) New funding to create centers of excellence in prematurity research focusing on basic and translational research into the fundamental genetic, biological and environmental causes of prematurity; and

(2) New funding for research to address the causes of the substantial disparity in rates of very, early PMB between African-American women and those of other races.

I would also recommend that Congress provide financial incentives and liability protection to pharmaceutical companies to develop new drugs to prevent prematurity.

More than 460,000 babies are born prematurely each year and 80,000 are born before 32 weeks. These latter babies are 70 times more likely to die in their first year of life, and as I noted previously, if they survive they are far more likely to suffer serious handicaps. While the plan I have suggested admittedly requires a substantial investment, the yield on this investment will be extraordinary.

Ms. Jordan, welcome.

Ms. JORDAN. Thank you for having me today. I want to thank you, Senator Alexander, the Senator from my home State of Ten-

nessee, and Senator Dodd. It is quite an honor that you have asked me here today to share my family's story.

I know that those who are here have been able to see my beautiful daughter, and she is one of the success stories.

In the year 2000, I was 35 years old and pregnant, and I was happy as can be. It was my lifelong dream. I did everything right. I did the pre-, pre-, pre-pregnancy care; I did prenatal care. I did not take an aspirin. I did not drink caffeine. I did not smoke. I did not drink. I did everything by the book.

At 25½-weeks, I had a very severe headache. I went to my doctor, thinking that maybe he was going to try to convince me to take some aspirin. Instead, he admitted me to the hospital. Within 24 hours, I was in labor and delivery, surrounded by my doctor, my family, my minister, and a few close family and friends. And I was faced with a very difficult decision. They told me that I had something called HELLP syndrome, which is kind of related to preeclampsia. Basically, there is no known cure for HELLP syndrome. The only cure is delivery of the child.

Well, I was just past 25 weeks' pregnancy, so we knew that there was very little likelihood that she would survive, and if she did, her life would not be what we had dreamed of.

They gave us a choice—I could induce labor, which would probably ensure that she would not make it and would ensure my immediate survival, or we were given a choice to take an ambulance to a regional trauma hospital, which is the choice that we made. We got in the ambulance and went to the trauma hospital. We were hoping to get me to 32 weeks of pregnancy. Well, that did not happen.

I did get three rounds of steroids, and it did help develop her lungs, as Dr. Lockwood mentioned, so we were grateful for that. But just shy of 26 weeks, they told me it was time to deliver. Basically, if I had died, they were also going to lose my child. I had hoped and dreamed that they could do like in the movies and hook me to all sorts of machines and sustain my life and help my child to go to 40 weeks of pregnancy. They explained to me that that is not how it happens.

So I was taken to the labor and delivery room at just shy of 26 weeks and forced into an emergency Cesarean section. For those of you who have not been a part of it, it is not very pleasant. They took one arm and strapped it to one side of the table, they took another arm and strapped it to the other side. They took my feet, put them together and strapped them down to the end of the table. I had very little clothes on; I was draped; and a gas mask was put over my face.

I will tell you at that moment you feel like you have failed your child in some way because I was not able to have a full-term pregnancy. When I closed my eyes, I knew that when I woke up, there was a tremendous likelihood that my daughter would not be there, and if she was there, there was a tremendous likelihood that she would have a very difficult life.

Well, I did wake up, and they told me that my daughter had been born, and they had determined that although she was only one pound and 10 ounces, she was a life worth fighting to save. So I was grateful. They told me that there was a 40 to 50 percent

chance that she would not survive. But we continued to pray and believe in medical science and the power of prayer that there was a chance that my daughter would make it.

We took it 1 day at a time. Her little head would actually fit right in the palm of my hand. Her skin was very thin and transparent. We could not really hold her; it was about a month before I was actually able to hold her. But I was able to stick my little pinky into the isolette that she was in, and her hands were so tiny that when she held it, they barely went around about 50 percent of my pinky. But that was my way of letting her know that I was there.

She had a little hole between her heart and her lungs, and fortunately, there was a medication that had been created that was able to close that hole instead of her having to face surgery. If the medication had not worked, she would have had to go under surgery at one pound, 10 ounces.

She was on a ventilator because she could not breathe. The ventilator was not working. They turned the ventilator setting up to the highest setting it could be on, and she blew a hole outside of her lungs. Basically, her lungs burst. Her chest cavity filled with air. They had to insert tubes in her chest—and you can see in the picture, it is one of the red tubes. They cut a hole in her chest wall and inserted the tube. They were not able to give her any anesthesia because she was too small, and they were more concerned that the anesthesia would kill her; but we knew that we had to get the tube in. She had more tubes and wires coming off her body than you could possibly imagine.

Her eyes had been fused shut maybe just a week before she was born, but she had two arms, two legs, ten fingers and ten toes, and she was the most beautiful thing I had ever seen in my whole life.

And day by day, minute by minute, she got stronger. At about 2 months of being in the hospital, they told me that it looked like she was going to make it. Now, that did not mean that she was going to have a normal life—it just meant that she was going to make it, and that was okay for me.

She got bigger and stronger, and at 4 pounds, 7 ounces, this most fabulous physician told me it was time to take her home. And I was petrified. She was still on oxygen, and she was on a heart monitor. I begged him to just keep her there until she was at least in first or second grade. I said if you could just keep her long enough for her to be able to sustain herself—but he encouraged me, and he told me we could do it.

So with a huge oxygen tank in hand and a heart monitor to make sure that her heart continued to beat and make sure she was getting enough oxygen, we took her home. It was not the normal homecoming that we had planned on, but we did it.

Six months after she arrived home, she was off oxygen; in 1 year, she was off the heart monitor. Whitney is now, as you can see from this picture, quite possibly the most beautiful 3-year-old little girl who has ever walked the face of this earth. She has absolutely no repercussions from her early birth—and when I say no repercussions, I mean none. That is a medical anomaly.

It is proof that the research efforts of these fabulous people that you have heard from are making a tremendous, tremendous dif-

ference. It is because of that I have the life that I had dreamed of, and I have this family. But it was kind of a bittersweet thing, because while Whitney made it home, the other two babies that were in her corner of the hospital did not have such a positive outcome.

So there is a lot more that needs to be done, and that is why I feel so honored to have been able to come and share my story, because I wanted you to see that the research does make a difference, but there is so much more that needs to be done. We need to help save these babies once they are born early, but far more important, we just need to prevent this from happening in the first place.

So on behalf of my wonderful husband Sam and my beautiful daughter Whitney and from the bottom of my heart, I thank you for what you are here to do today.

Thank you very much.

[The prepared statement of Ms. Jordan follows:]

PREPARED STATEMENT OF KELLY BOLTON JORDAN

I would like to start by thanking Senator Alexander, my Senator from the State of Tennessee, and Senator Dodd for holding this hearing and inviting me to share my family's experience.

I was a healthy 35-year-old when I became pregnant with my little girl, Whitney. I received prepregnancy care and when I became pregnant I started prenatal care immediately. I followed all the traditional pregnancy advice—healthy eating habits, regular visits to my obstetrician, no smoking, no drinking. Through my 6th month, I had a perfectly normal pregnancy.

At 6½ months of pregnancy (25½ weeks), I developed a syndrome related to Preeclampsia, called HELLP (a syndrome characterized by hemolysis, elevated liver enzyme levels and a low platelet count). The doctors had no information on the cause of my illness and there was no way to prevent it. This turned into a life-threatening illness and my husband and I had some very difficult decisions to make. The only way to improve my condition would have been to induce labor when I first entered the hospital, but we were told that our baby would have almost no chance of survival. I asked the doctors to fight with everything they had to save her and not to be as concerned with my survival, but they told me that if I were to die, my baby would as well. It was a delicate balancing act, trying to keep me alive and giving her more time to grow inside of me. I was given 3 rounds of steroids to speed up her lung development, but after 5 days, I took a turn for the worse and the doctors had to do an emergency cesarean section to save both of us. We knew that our baby could have major health problems and that I could have died, but we never wavered in putting her needs above mine. I was not looking for a perfect child—I just wanted to save the one inside of me.

Whitney was born on October 11, 2000—3½ months early. She weighed just 1 lb. 10 oz. My husband and I were warned that Whitney's medical prognosis was bleak. Initially, we were told that Whitney had a 40–50 percent chance of survival. If Whitney was to live, it was likely that she would have life-long repercussions from her early arrival.

Whitney was taken directly to the neonatal intensive care unit where her tiny fragile body was hooked up to more tubes and lines than our eyes could bear. Unable to breathe on her own and with terribly underdeveloped lungs, she received surfactant therapy and was on a ventilator for over a month. Whitney was pricked so many times that her little feet became human pincushions.

When I touched her for the first time a few days after she was born, it was very scary—she was so fragile and could not tolerate stimulation. Her skin was thin and transparent. We could only touch her for brief periods and sometimes not at all as she was sensitive to the touch. It was more than a month until I could first hold her and even then, it was only for minutes at a time so she wouldn't be overstimulated.

During Whitney's 3 months in the NICU, it seemed that we took one step back for every two steps forward. At birth, a small hole was found between her heart and lungs. She faced surgery that would be quite dangerous but, in the end, her condition was treated with medication. Then a ventilator blew a hole in one of her delicate lungs and they had to open her chest without the aid of anesthesia. You never feel your child is out of danger, but after 2 months, we felt she would survive.

We were at the NICU sometimes several times a day, into the wee hours of the night—these were very emotionally trying times. My husband and I are both in jobs with wonderful people and some flexibility. We did not resume our normal activity until Whitney came home from the hospital and even then, we were only operating at partial capacity. We were lucky to have understanding employers and incredible health insurance. The costs were astounding. Whitney's 3-month hospital stay cost about \$250,000.

The other families we encountered during Whitney's NICU experience were from all walks of life but all facing the same battle. Parents had different reactions to their child's situation. Some parents were attentive and doting and others never visited because they were afraid of bonding with their sick baby. Another family had limited visits because they couldn't afford money for gas or parking to come to the hospital. Some of the babies who passed through the NICU during those 3 months will have lifelong health problems and some, sadly, died.

Finally, Whitney began to gain weight, one by one the tubes and lines were removed, and she was moved to an open bed. The time was approaching for her dismissal from the hospital. With supplemental oxygen and a heart monitor, we were sent home to raise our beautiful little girl. We were overjoyed to bring Whitney home but had lingering fears about being sent home with an infant weighing just 4 lbs. 7 oz. What if she stopped breathing? What if she did not get enough oxygen? What if she had neurological damage? What if her vision was impaired? After 6 months, she came off oxygen and then, a year after leaving the hospital, she was taken off the heart monitor.

Whitney is now a healthy, happy 3-year-old and has no repercussions from her early birth. She laughs all the time and loves life—a life that would not have been possible without the type of medical research that others have testified about. Although Whitney's days are now spent medicine-and machine-free, other babies are not as lucky. That is why I commend the subcommittee for holding this hearing and urge continued expansion of research into why preterm birth happens and how to care for babies when they are born so small and fragile.

Senator DODD. Very good; perfect job.

Senator ALEXANDER. Well, we ought to shoot fireworks up for that.

Senator DODD. I was just going to say we can thank you and go home; she kind of said it all.

[Laughter.]

Senator ALEXANDER. That was beautifully said. Thank you so much for telling that story and telling it so beautifully.

What hospital were you in?

Ms. JORDAN. The regional medical center.

Senator ALEXANDER. Is that right? And how long before you went home with the oxygen machine?

Ms. JORDAN. She was there for 3 months. They kept her about 2 weeks shy of her due date.

Senator ALEXANDER. You talked about the other two babies who did not have such a good outcome, and you have obviously thought about this a lot since then. You talked about how you did everything right that you knew to do.

Looking back, were there some things that you knew to do that other mothers do not do? I asked the first panel what were the things that a mother should do today, even though it might not always prevent prematurity. What is your answer to that question today?

Ms. JORDAN. It was prenatal care and pre-pregnancy care. If I did not have a physician that I could have picked up the phone and called and said, "I have this really bad headache—what should I do?" I would not have gone into the hospital; I would have died, and my child would have died if I had not sought medical attention.

So I think there is no replacement for having a good physician on your side and having the care of good doctors and nurses.

Senator ALEXANDER. I mentioned earlier that some years ago—actually, my wife did this, and Marguerite Sallee, who is the staff director of our subcommittee, created a Healthy Children's Initiative in our State, and one of the devices for that was to try to make sure that every pregnant mother was matched with a pediatrician. And the pediatricians in the Memphis area where you live volunteered to try to help make that happen.

Anything else besides having the prenatal health care that just sticks out to you as advice for pregnant mothers who want to try to avoid prematurity based on what you have learned?

Ms. JORDAN. From what I saw—and I was at a regional trauma hospital—I was the oldest mother who delivered, and I was 35 years of age at the time. There were children delivering children—12 years old, 13 years old. There were mothers who did not know that doing cocaine was going to affect their children, did not know smoking would. When I was at the hospital, I was horrified to see pregnant women standing outside, smoking cigarettes when they were at the trauma hospital waiting to deliver their children. I just wanted to scream because it seemed so obvious to me.

I think it is education. In my walk of life, we saw so many people from so many different socioeconomic backgrounds, it was just a given and assumed that you did not drink, you did not smoke; but I think that some people do not have that educational background, they do not have access to doctors, and they are not surrounded by people who were given the education. So I think the education has to come very early on, from keeping teenagers from getting pregnant to, if they do get pregnant, getting them the proper medical care and education so they can have a chance of having healthy births. When Whitney was in the hospital, there was a 2½-pound baby next to her that was addicted to cocaine and was having to be weaned from cocaine, not to mention all the other lifelong problems that she was going to have and be exposed to.

Senator ALEXANDER. Dr. Lockwood, we heard Ms. Jordan say that she did everything right as far as she could tell, yet she still had a premature birth, and you talked about research. Are there one or two areas—you are a distinguished researcher—what are the one or two areas of most promising research, in your opinion?

Dr. LOCKWOOD. Let me actually comment about the frustration that many of us have, similar to your frustration, in that it is not clear that prenatal care actually reduces prematurity, and there are studies to suggest that it does not.

Smoking certainly lowers birth weight, but it is not so clear that it actually promotes—I am not advocating smoking, I am not here for the tobacco companies—but it is not so clear that it actually reduces the occurrences of prematurity, and it actually does reduce the occurrence of preeclampsia and HELLP syndrome. But again, there are plenty of bad things associated with smoking—do not take this the wrong way.

And you can go down the list of all the things that Duane Alexander mentioned and point out that at best they would have a marginal effect on prematurity rates.

I think that if you do not understand the fundamental causes of a problem, it is very, very difficult to prevent it. It would be like asking me 150 years ago how do we prevent TB—well, put people out in the sunshine and give them fresh air. We just do not know in the vast majority of cases.

To answer your question, the two areas that I think are absolutely vital for study are the basic underlying biochemical mechanisms that lead to prematurity—each of those pathways, we know more and more about but not nearly enough—and the genetics. Much of what underpins the occurrence of prematurity is genetic, and if we can better understand that and the genetics of the disorders that are related to prematurity by having common placental abnormalities like preeclampsia, HELLP syndrome, and fetal growth restriction, we will be able, I think, to far better address the issue and have real substantive cures and preventive measures in the next few years.

I do not mean to be so vague, but there is not any answer to your question, and we really do not know—

Senator ALEXANDER. That is not vague. That is very precise—the answer is we do not know.

Dr. LOCKWOOD [CONTINUING]. We really do not know.

Senator ALEXANDER. There is a great deal we do not know.

I have one other question, and then I will let—we are going to have to wrap up in 5 or 10 minutes—I will let Senator Dodd finish the questioning. But let me ask you, Dr. Lockwood—you mentioned that your medical malpractice costs for academic obstetricians—that means those who are at the university and who occasionally deliver babies but not regularly—is that right—

Dr. LOCKWOOD. That is correct.

Senator ALEXANDER [CONTINUING]. —cost you \$100,000 a year.

Dr. LOCKWOOD. Will cost us; right.

Senator ALEXANDER. We have a difference of opinion in the U.S. Senate about how to fix that, but putting aside the solution for just a moment, do you want to say anything else about the severity of the problem and the consequences of the failure to fix the rising cost of medical malpractice?

Dr. LOCKWOOD. I will do it in the context of prematurity, in the spirit of bipartisanship here, rather than talk about—

Senator ALEXANDER. You can do it in a scientific way—just tell us the truth about it. We will handle the politics.

Dr. LOCKWOOD [CONTINUING]. The bottom line is that we need relief, frankly, and what we propose, the Society for Gynecological Investigation, is that the Federal Government support a proportion of a malpractice premium for an academician—for an ob, for example, in an academic setting—as a percent of their grant. So if they are 50 percent on an RO1 from the NICHD, 50 percent of their premium would be paid from additional money to support that research—because without doing that, we know for a fact that in 4 years, our malpractice premiums per obstetrician will be \$169,000, which means there is no way that a young physician scientist can in any way, shape, or form do anything but clinical care just to pay the price of his or her premium. So it is going to absolutely destroy the ability, particularly in obstetrics—not quite as bad in gynecology—to do good perinatal research, whether it is clinical, wheth-

er it is basic or translational. It is crippling academic departments, because we do not make that much money. Our patients are generally Medicaid patients, we do not get much reimbursement, and our patients are complicated—a lot of very complicated cases are seen by full-time, high-risk obstetricians in an academic setting—so they do not generate much clinical income, and if they are expected to spend 3 days in a lab and not generate any clinical income during that time, and since these premiums are not prorated to the amount of effort made, it will actually destroy academic obstetrics in this country.

Senator ALEXANDER. Thank you.

Senator Dodd, why don't you finish the questioning, and then we will try to wrap up?

Senator DODD. Thanks very much, and let me thank all three of you—and again, Ms. Jordan, you were terrific. And I have tremendous appreciation for Dr. Howse and my constituent, Dr. Lockwood, and their wonderful testimony. But as we all know, we all love a story. When we get through all the data and material and the scientific research and so on, it all comes down to you—and Whitney—and that is really what this is all about in many, many ways. So I am very grateful to you. It is not easy to come up here and go through stories like this, but the fact that you have really helps tremendously and brings home the point. So I am very grateful to you.

First of all, Dr. Howse—just a ball park—could you give us some idea—we have all been talking around this today—of the cost of prematurity. I do not know if there has been a broad macro answer that has ever come up from the March of Dimes—obviously the case of Whitney, we have a very good outcome, but as you point out, and Ms. Jordan does as well and Dr. Lockwood has, obviously, for I guess the majority of children who are born premature, the result that Whitney has had is not the norm. So there is a cost that goes beyond the child leaving the hospital and going back home.

Do you have any idea that you can put a number on what the estimate in cost is as a result of failing to come up with some answers on the causes of prematurity?

Ms. HOWSE. It is a tough number to get to. I think if you start from the base of \$13.6 billion just for the hospitalization, for the labor and delivery and that initial hospital stay, if you have that as a base—

Senator DODD. That is for the 480,000 premature births.

Ms. HOWSE [CONTINUING]. That is for the babies with the primary diagnosis of prematurity, for their hospital stay.

Senator DODD. And that cost on an annual basis is over \$13 billion.

Ms. HOWSE. Yes, \$13.6 billion for the hospital stay. Now, that is just for labor and delivery and the stay in the NICU. That recurs every year because this is a problem that so far we have not figured out how to start—

Senator DODD. Can I ask you a naive question? Just to put it in context, what would be the comparable cost of 480,000 babies coming to term, just to give us some sense? Do you know what that would be?

Ms. HOWSE [CONTINUING]. Well, roughly, the number for the hospital cost just total for all kids is about \$29 billion, so the 12 percent of the babies born premature accounts for half of the annual hospitalizations.

Senator ALEXANDER. And if I may interrupt, you said earlier, did you not, that \$1,300 is the average cost for a baby born at term.

Ms. HOWSE. Yes, per baby.

Senator ALEXANDER. Per baby. And \$75,000 is the cost associated with prematurity, which is—

Senator DODD. Breathtaking.

Ms. HOWSE. Right.

Senator ALEXANDER [CONTINUING]. Excuse me for interrupting.

Senator DODD. No, no. I am glad you made that point.

Ms. HOWSE. It is a staggering difference.

And then, Senator, there are a lot of different studies and metrics that are used to try to determine the lifetime cost of a disability. That is the kind of metric that we start getting into, so you have to add productivity and chronic health costs, special education costs, and so forth. I think many people would perhaps settle on a figure somewhere between \$250,000 and \$500,000 a year to support the most severe consequence of prematurity—lifelong cost.

Senator DODD. That is breathtaking in its scope, and I will come back, Dr. Lockwood, in a minute to the 5 percent of 5 percent, which I think was a pretty startling moment in your testimony.

But I was curious, Ms. Jordan—you are a well-educated women. I gather you and your husband do pretty well financially and so forth. I want to get to the support. I loved your statement that, after watching how well the doctors had taken care of Whitney in the hospital, you wanted her to stay until she was in the first or second grade.

Ms. JORDAN. Oh, yes.

Senator DODD. I can relate to that in many ways. But you did get home, and you went through several months, obviously, with the oxygen and the heart monitors and so forth. How much support did you get, outside what you and your family could obviously provide because of your own circumstances, but from the hospital itself or from others in the area? And I want to get to the point, Dr. Howse, about what would happen to a person not in Ms. Jordan's situation, and how much support given a similar situation, particularly the numbers that we are talking about and the people we are talking about and the profile shared with us earlier, how much support does an individual leaving get today who would not necessarily have the ability that Ms. Jordan and her husband have.

Ms. JORDAN. To answer your question, Whitney's stay was \$250,000, by the way, because she was one of the sickest of babies. We are fortunate to live in Tennessee, where we have a program called Tennessee Early Intervention, and it is a fabulous program. So that when Whitney came home, we had many resources that we could reach out to to help make sure she was developing like she should.

Our health insurance—I had a fabulous employer, Merrill Lynch—was Blue Cross, Blue Shield that provided nursing care to come to the home several times a day to make sure that she was getting oxygen and the heart monitor was working and that sort

of thing. Without health care coverage, I do not know where we would have been, without Tennessee Early Intervention.

As far as education upon leaving the hospital, there was really none other than that which you would beg to have. When you check out of a hospital with a 4-pound baby, they do not give you a pamphlet on how to raise her. There is no instruction manual that comes. So it required a lot of research and a lot of looking and a lot of asking. So there was very little education.

Senator DODD. So you had a good health care policy, on the \$250,000 hospital cost, that picked up most of that?

Ms. JORDAN. It did cover almost every dime of it other than a couple of hundred dollar deductible. Now, that does dip into her lifetime benefit—I never dreamed I would have a concern of tapping out in a lifetime benefit—but what if Whitney had had to stay on a ventilator, or what if she had had \$250,000 to \$500,000 in medical costs each year—we would have quickly run out of insurance, and I do not know where we would have turned.

Senator DODD. Yes, exactly. I am thinking, because obviously given the profile of the normal case, you are talking about an overwhelming majority who have no health insurance, and have to bear those costs. Obviously, people are paying higher premium costs and whatever else to pick up those costs.

Had Whitney been born to a poor mother with no health insurance, I presume the hospital in Tennessee would have provided her with the same kind of care. That is the great story in America, that you get that kind of care, that doctors do not sit there and make judgments about whether you have an insurance policy or not—but obviously someone pays that bill. The bill does not go unpaid. And that is one of the things we have not really come to terms with in the Congress of the United States about how to face that reality, and we had better face it soon, because obviously the costs are staggering.

Ms. HOWSE. One of the provisions in this bill that we are examining today would really get at that question of parent education and parent support to go through the neonatal intensive care unit experience, and then also address that question of transition from hospital to home, because I think this is a situation where we probably have resources out there that can support and can facilitate parents' journey in this terrible circumstance, but it is really a matter of pulling things together and having some statements of best practice and having some expectations around what kinds of supports parents will need. So that is one of the areas that is addressed in your bill as well.

Senator DODD. Yes, exactly, and I want to raise the point, because I think it is a very important piece of this.

Dr. Lockwood, very quickly—you may have addressed this in your testimony, and if you did, I apologize for not picking up on it—we have all obviously heard here about the disproportionate incidence of prematurity occurring in the minority community, particularly the African American community. What have your studies shown about it, and why is that the case? Can you add anything more than what we have heard?

Dr. LOCKWOOD. Yes. I think some of this has been touched upon, but the rate is about twice the rate in white populations. Cur-

rently, around 17 percent of all live births to African American mothers are preterm. It is an enormous problem, and it is a particular problem in very premature babies, before 32 weeks, where they have an even more disproportionate rate. If they are twofold higher overall, they are threefold higher among these very, very premature babies, and of course, very often they are less affluent, and it is a greater hit, as you have already pointed out.

If you correct for all socioeconomic factors, if you correct for cultural factors, new immigrants and so forth, the rate is still substantially higher—at least one-and-a-half, almost three-quarters higher. So there clearly are probably some biological phenomena. We have a lot of ideas about what might be triggering; we may have some new research to suggest that there might be a genetic predisposition to overreact to sort of benign bacteria that are in the reproductive tract, and in that inflammatory reaction, you trigger premature delivery.

So they are really sort of overreacting, if you will, to relatively benign bacteria that are in the wrong place, and I think this is an incredibly fertile area—pardon the pun—of research, because really, we do have the tools already today to block those pathways, and it would make a huge difference if we really understood clearly what that pathway was.

Senator DODD. Are there clinical trials and studies being done? Are there any products that are particularly focused on the African American community?

Dr. LOCKWOOD. I think most of the focus has been on stress, and I think it is a mistake, to be honest with you, because I think that stress tends to cause late preterm deliveries that are not so critical, that do not result in long-term health problems. It is the infection and inflammatory pathways that seem so critical in that population and that I think we should really be focusing like a laser beam on to discern and then to begin clinical trials.

Senator DODD. Yes. I was quite taken with your 5 percent of the 5 percent and the whole issue. Just let me tell you here today that I will do what I can talking to our colleagues and others to see if we cannot do a better job in that area. Obviously, we are promoting this piece of legislation, but getting some more resources into this area—it has been historically a difficult area because children, particularly poor children, are not necessarily great advocates, and we rely on people like yourself and the March of Dimes and others to make the case—people like Ms. Jordan I suspect might become a stronger advocate today having been through what she did on behalf of these families.

But clearly we need to be doing a better job. If you are not impressed with anything else, just the economics of this are pretty staggering. So I cannot promise you what we are likely to get out of this, but I am going to be talking, as I am confident that my colleague from Tennessee will—we will have some conversations with people about how we might move along here and do a little bit better.

Let me address, as I know you did in your testimony, and I have certainly heard a lot from my folks in Connecticut about the issue of the malpractice insurance problems. I hear you. This is a huge problem, obviously, particularly in an area of medicine which is, of

all the practices, the least lucrative when you start talking about obstetrics and gynecology and pediatrics and so forth. In fact, I would not have passed anywhere near the legislation we have over 24 years dealing with children—never would have passed the Family and Medical Leave Act—had it not been for the Academy of Pediatrics—never. We never would have gotten the child care legislation or any major piece of legislation affecting children. The major source of support I have had has come from the medical professions dealing with children. So I am very sympathetic to the work they do.

Also, coming from the State that is known as “the insurance capital of the world,” I just find it hard to understand why it is, when you look at States that either have caps on these costs or ones that do not, the premiums still seem to go up. The one difference is in a place like California, they not only have a cap on the non-economic damages, but they have a cap on premiums. And it is a big enough State that they can get away with it because it is so important, but nonetheless, there, they have been able to really hold down premiums.

And again, the insurance industry does not want to hear this, but how do you explain why one doctor who may have had a questionable record and practice and someone who is working primarily as a researcher are charged the same rates? We do not do that in the automobile industry, we do not do it in any other area of insurance. So clearly, there is an answer to this, and if we can get together on it, we have really got to find a way to do it, because we are driving people out of these very important areas.

We have got to sit down and work through these things, and it requires some time and effort, but my hope is that we can do that—we should do it, and we need to do it rather quickly as well, in my view. But I appreciate you raising it, because it is an important point.

Mr. Chairman, thank you immensely.

Senator ALEXANDER. Thank you, Senator Dodd.

This has been a very good hearing. We have been talking about a bill that Senator Dodd and I are cosponsoring, S. 1726, the PREEMIE bill. Our goal is to expand research so that we understand why some babies come early, and then, second, that we help transmit that information to mothers. We have been involved with the March of Dimes effort which is going to put a high priority on this for the next 5 years; we have heard a lot about that. We have heard that there are some things that mothers who are pregnant should do—plan their pregnancy if they can, take folic acid—these come from Dr. Alexander—have a physical exam, do not smoke, get prenatal health care. Progesterone seems to help, but then, we hear also that we really do not know why most babies come early and that many of the things that we thought helped, such as bed rest, may not have any effect at all.

That shows the importance of the research. We have heard from Dr. Lockwood that there is not enough research and that the costs of medical malpractice insurance are making it more difficult for there to be enough start-up research to get NIH grants. Ms. Howse pointed out that the average cost of a baby born to term is \$1,300 for the hospital stay but about \$75,000 for a baby born premature

with all the associated costs, which is a staggering difference, and both Senator Dodd and I think that.

So I think we are on the right track, and this is a very important piece of legislation. I am glad, as Chris said, that in the House, it has strong sponsorship. Maybe we can get on with it, and it will make us a lot more effective as a country if, when we go out to our community health centers to pass out information about how to avoid prematurity, we know why babies are born premature.

And Ms. Jordan, let me especially thank you for coming. That was a beautiful story, and I would love to meet Whitney someday, and I have an idea that I will have that chance sooner or later.

Thank you all very much for coming.

The hearing is adjourned.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF PEDIATRIX MEDICAL GROUP, INC.

Pediatrix Medical Group, Inc. is pleased to submit this testimony for the record in support of S. 1726, the Prematurity Research Expansion and Education for Mothers who Deliver Infants Early (the PREEMIE Act). Because of Pediatrix's focus on premature and other critically sick infants, its size and scope of outreach across the United States and Caribbean, and the extensive research conducted by the company in the area of preterm births, we believe we are in a unique position to comment on the merits of this worthwhile legislation as it relates to the issue of prematurity and to encourage swift congressional action.

Pediatrix is the largest neonatal and perinatal physician group in the U.S., with over 700 physicians and 325 advanced nurse specialists providing direct medical care in over 200 hospitals across the country to both premature and critically sick newborns, as well as women with high risk pregnancies. Last year, Pediatrix physicians cared for an average of 3,000 newborns each day in hospitals in 30 States and Puerto Rico.

Our maternal-fetal medicine specialists care for expectant mothers with medical and other surgical complications of pregnancy, while Pediatrix's neonatologists provide life-sustaining medical care for premature babies or those with serious complications. Pediatrix also provides pediatric intensive care, pediatric cardiology, and pediatric hospitalist services to sick and critically injured babies and children. Finally, in addition to the direct life-sustaining care provided by Pediatrix physicians and nurse practitioners in a NICU (Neonatal Intensive Care Unit) setting, we also provide both newborn hearing screening services and the most advanced and comprehensive program for screening metabolic and genetic disorders available for newborns. Through these screening programs, we identify problems that can occur as frequently as 2/1000 births, and for which early identification and treatment can prevent serious health consequences such as developmental delay, or even death.

As an example of the severity of cases handled by our doctors, 18 percent of newborns treated by Pediatrix in a NICU (Neonatal Intensive Care Unit) weigh less than 3 pounds at birth. We know that premature babies are significantly more likely to face serious health problems following delivery, and our goal is to have all children leave the NICU for their homes with the best possible start on life. Pediatrix physicians—as well as all neonatologists and maternal fetal medicine specialists—understand the terrible toll that having a preterm or other critically sick newborn can have on parents and other family members.

Because Pediatrix is in the unique position of treating so many premature and other extremely critical ill newborns, as well as pregnant women who are most at risk of giving birth to a premature baby, it is a leader in the private sector in developing Best Practice standards, conducting clinical trials, and engaging in other collaborative research efforts to improve health outcomes for premature infants. It has tracked the outcomes of more than 180,000 neonatal cases in a centralized database using an electronic medical record, thereby identifying ways to improve clinical care. Pediatrix research has included nutritional needs of very low birth weight babies, causes of respiratory failure, and causes of death among near-term newborns.

The results of this work directly benefit all pregnant women and newborns. We deliver applied, evidence-based solutions to health care providers to decrease morbidity and mortality of the patients we treat through our research. Through newborn screening, we decrease costs associated with treatable birth defects.

To share this knowledge across the broader community of newborn care providers, Pediatrix developed an active educational outreach program that includes "Pediatrix University," an interactive educational website, that now maintains more than 3,800+ registrants from 71 countries. Pediatrix is accredited to provide continuing education for physicians and nurses. Finally, new knowledge is regularly shared with the medical community through presentation and publication at peer reviewed medical forums.

The PREEMIE Act would provide a needed Federal impetus to help reach the common goal of reducing the rates of preterm labor and delivery. As well, it would promote the use of evidence-based care for pregnant women at risk of preterm labor and for those infants born preterm.

Pediatrix has prepared and regularly disseminates parental education materials to help prepare parents to understand the workings of a NICU. Many of these materials are also available as educational content on its the company's website. Understanding how traumatic a NICU experience can be for many new parents unfamiliar with a NICU's operation, these materials contain easy to understand information on various medical tests and procedures, common terms used in a NICU, frequently

asked questions, and even descriptions of the various health care professionals that new parents will likely encounter during their newborn's stay in the hospital.

In addition, Pediatrix is a leading partner in the March of Dimes NICU Family Support program, actively working to ensure that parents are better equipped to handle the additional emotional stress of having their newborn cared for in a NICU and at home. We recognize how frightening and confusing the NICU can be for families, and we help sponsor the March of Dimes effort to provide emotional and informational support to those with a newborn in the NICU. Support for ante-partum and high-risk women, parent-to-parent support, sibling education and support, and sensitive educational materials address the challenges that NICU families may face. We are working with the March of Dimes to make the experience more manageable for families in the hospital, during the transition home, and in the event of a newborn's death, and to make this support more widely available to the many children and families in need.

While Pediatrix is extremely proud of its record in improving health outcomes for premature babies, developing practice standards, and educating parents and family members to better understand and cope with their baby's treatment, we also recognize that much more needs to be done. Passage of the PREEMIE Act would foster continued research opportunities to address this critical and growing problem in our society. As medical advances make life-sustaining treatment a greater possibility for more preterm and low birth weight babies, we as physicians must continue our efforts to ensure that the health care we provide offers our tiniest and most vulnerable patients the best possible start on a healthy life.

Just as important, we need additional research in order to prevent preterm births in the first place, and to continue to find new and better ways to treat women at risk of giving birth to a premature baby, or facing other serious life-threatening medical complications.

Finally, we know first hand how much pregnant women, new parents, and family members need education and support services related to prematurity.

The PREEMIE Act is an important step in our united fight against prematurity. Pediatrix is proud to join with other providers, researchers and parents in urging swift congressional action of this bill.

PREPARED STATEMENT OF JOY V. BROWNE, PH.D.

Mr. Chairman and Members of the Subcommittee: I am pleased to submit the following testimony on premature babies on behalf of ZERO TO THREE. My name is Joy Browne and I am an Associate Professor at the University of Colorado Health Sciences Center, Department of Pediatrics in Denver Colorado. I am an Infant Development Psychologist working with premature infants in neonatal intensive care units (NICUs) and as they transition into their communities. I am also a Graduate Fellow of the Leadership Development Initiative at ZERO TO THREE. ZERO TO THREE is a national non-profit organization that has worked to advance the healthy development of America's babies and toddlers for over 25 years. I am here to talk to you today about premature infants—the developmental risks they face, prevention efforts, and early intervention services that may have a positive impact on their developmental outcomes. I would like to start by thanking the subcommittee for all of their work on behalf of our Nation's premature infants and their families.

Developmental Risks for Premature Infants

Infants born too early are at higher risk than full-term babies for medical and developmental complications, which can affect the growing baby and family well into childhood. The earlier the birth, the more risk of complications. The effects may be not only physical and cognitive, ranging from chronic lung disease to feeding problems to speech and language difficulties, but may also include socio-emotional challenges such as a difficulty responding to caregivers and an inability to regulate emotions. Children born prematurely may have additional long-term significant physical, cognitive and socio-emotional challenges that contribute to difficulties in school such as reading, doing arithmetic, or sitting still and paying attention to the teacher. Parents and professionals also report regulatory disorders, anxiety, and problems with peer relationships among prematurely born children.

Preventing Prematurity

Experts used to believe that prevention and intervention before and during pregnancy could dramatically reduce prematurity. However, despite increased prevention and intervention efforts, the incidence of preterm births in the United States actually increased by 14 percent between 1990 and 2002. Further, the low birth weight rate is at the highest level it has been in 3 decades. More than 485,000 low

birth weight (less than 5.5 pounds), premature (less than 37 weeks' gestation) babies are born each year in the United States. Approximately one out of every eight babies (12 percent) is born prematurely. African Americans have the highest rate of preterm birth in the United States, are two times more likely to have babies with low birth weight, and are three times more likely to have very low birth weight babies as are Non-Hispanic White mothers.

The American College of Obstetrics and Gynecology attributes the increase in prematurity over the last decade in part to an increase in the number of women in the U.S. who are postponing pregnancy and to increased use of fertility therapies. Poor nutrition during pregnancy, smoking, multiple-birth pregnancies, and infections are also associated with prematurity.

Importance of Mental Health and Other Services Beginning in the NICU

The PREEMIE Act would fund Neonatal Intensive Care Unit (NICU) Family Support Programs which would respond to the emotional and informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death. I want to underscore how important it is that early intervention and support services begin as early as possible after the baby's birth.

Nurturing, supportive and consistent relationships that develop between parents and their newborns provide the foundation for the development of social competence, readiness to learn, and emotional security. Time spent in the NICU disrupts the normal interaction between parents and their baby. The developing parent/infant relationship is typically qualitatively different than if the baby had been born at full term. These altered interactions may in turn affect the baby's mental health and overall development in all domains. We need approaches that help build appropriate, supportive early relationships and address the stress created by having a fragile baby in an intensive care unit. Appropriate supports include mental health services, connecting families with parent-to-parent support groups, training staff on supporting parent-infant relationships, and helping parents create meaningful moments with their fragile infants.

Early Intervention Services for Premature Infants

Although the prevention of premature births is a widely held goal, the incidence of preterm births continues to rise. Mr. Chairman, I applaud the subcommittee's efforts to focus attention on preventing prematurity through this hearing and the PREEMIE Act that you and Senator Dodd have introduced. This is an important effort. However, we still have to promote better outcomes for children and families who we know will continue to have to face the consequences of premature birth. And here, the news is somewhat better.

Early intervention services for premature infants, even those that begin in the newborn intensive care unit, have shown positive effects on both physical and developmental outcomes. Early intervention, in the form of assessment, prevention and appropriate intervention is extremely important. Many premature infants are not currently eligible for early intervention services because developmental difficulties may not be evident until school age. Providing monitoring and information for families on appropriate development are essential so that the earliest intervention services may be initiated and potentially prevent emerging cognitive and socio-emotional problems.

All families with premature infants should receive education and support, whether from early intervention or from follow-up clinics. Parents of preemies may not only be dealing with the stress of caring for a high-risk baby, but they may also already be stressed from the high-risk pregnancy as well as the unexpected and/or traumatic birth. Parents of preemies require skilled, sensitive assistance from medical and mental health professionals to help them access information and resources; reduce emotional distress; alleviate fears; sort out financial implications and the cost of NICU care; and to help them help their children master the challenges that will confront them in the NICU and throughout their child's life. All services offered to families should demonstrate continuity and carry on long after the date of discharge from the hospital.

I am going to briefly highlight several prevention and early intervention programs for premature infants and their families.

Early Head Start

Congress created Early Head Start in 1994 with strong bipartisan support. It is the only Federal program specifically designed to improve the early education experiences of low-income babies and toddlers. By making pregnant women eligible for the program, Early Head Start explicitly recognizes that to reach this goal, services must start *before* birth. The mission of Early Head Start is clear: to support healthy

prenatal outcomes and enhance intellectual, social and emotional development of infants and toddlers to promote later success in school and life. One of the most important steps to preventing prematurity is to begin prenatal care as early as possible and to continue prenatal care throughout pregnancy. Statistics show that early and good prenatal care reduces the chance of a premature birth, having a small baby, and related deaths during delivery and the neonatal period.

Special Supplemental Nutritional Program for Women, Infants, and Children (WIC)

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC), was created to help alleviate the effects of poverty on the health of infants, children and pregnant or new mothers. Benefits provided to WIC participants are: supplemental nutritious foods; nutrition education and counseling at WIC clinics; and screening and referrals to other health, welfare, and social services. To receive WIC services, participants must be eligible by income (185 percent of the Federal poverty level), nutritional risk, and category (either a pregnant, breast-feeding, or postpartum woman); an infant under 1 year old; or a child under 5 years old. Pregnant women enrolled in WIC have fewer premature births, fewer low birth-weight babies, and fewer fetal and infant deaths. They also seek prenatal care earlier in their pregnancy and consume more of key nutrients such as iron, protein, calcium and vitamin C.

Part C of IDEA

Part C of the Individuals with Disabilities Education Act (IDEA) authorizes the Federal support for early intervention programs for babies and toddlers with disabilities, and provides Federal assistance for States to maintain and implement state-wide systems of services for eligible children, age birth through 2 years, and their families. Under Part C, all participating States and jurisdictions must provide early intervention services to any child below age 3 who is experiencing developmental delays or has a diagnosed physical or mental condition that has a high probability of resulting in a developmental delay. In addition, States may choose to provide services for babies and toddlers who are “at-risk” for serious developmental problems, defined as circumstances (including biological or environmental conditions or both) that will seriously affect the child’s development unless interventions are provided. Many States now have systems to identify premature infants who are automatically eligible for Part C services while they are still in the NICU. Similarly, some States have developed an Individualized Family Service Plan (IFSP) specifically for the developmental needs of newborns in the NICU, therefore providing seamless assessment, referral and intervention services.

Colorado’s NICU Liaison Project

The Colorado NICU Liaison project began as a result of statewide collaboration among NICU staff, Part C, the Colorado Department of Health’s Health Care Programs for Children with Special Needs, graduate parents and the Center for Family and Infant Interaction. Infants admitted to any of the 29 Colorado NICUs are identified and referred to community services. The infants are identified as “at risk” based on an Interagency Coordinating Council eligibility list of conditions that presumed the infant potentially will experience developmental delays. The Colorado Consortium of Intensive Care Units was committed to providing developmentally appropriate early intervention to infants under their care, and to support parents during the stressful time that their newborn was in the NICU. Through collaborative work between team members consisting of Part C, the Department of Health, hospital staff and graduate parents, an IFSP specifically for newborns was developed and is now used with all eligible infants. Currently, infants who meet the criteria for referral to community supports are referred to a community liaison, who assists the parents with identifying appropriate strengths and needs of the infant, identifying available community supports and resources, and with completing the IFSP. Upon discharge, the infant and family are followed by a service coordinator from their community. This statewide system has identified and referred over 3,500 infants since its inception in 1999.

Conclusion

We must continue to ensure that the prevention of premature births is a national priority. During the first years of life, children rapidly develop foundational capabilities—cognitive, social and emotional—on which subsequent development builds. These years are even more important for at-risk infants. Despite increased prenatal care, improved nutrition and other efforts aimed at preventing premature births, we know that we will continue to have early-born infants, with all of the complexities that prematurity brings to their medical and developmental outcomes, as well as to the continuing impact on the families. We also know that the vulnerability of these

babies consists of much more than the physiological challenges they experience in the NICU; prematurity can affect their cognitive and socio-emotional development well into the school years. Therefore, up-to-date medical care, early individualized developmental intervention such as the Newborn Individualized Care and Assessment Program, and support for developing infant-parent relationships can and must begin in the NICU and continue into preemies' early years in order for them to experience the best outcomes possible. Early Intervention programs such as Early Head Start, WIC, Part C and Colorado's NICU Liaison Project can serve as protective buffers against the multiple adverse influences that may hinder their development in all domains.

With the subcommittee's help, we have made some gains over the past few years in increasing funding for prevention and early intervention services for at-risk infants and their families. It is unacceptable that our overall policy and funding emphasis requires families and providers to wait until children are already behind developmentally before significant investments are made to address their needs. I urge the subcommittee to change this pattern and invest in at-risk infants and toddlers early on, when that investment can have the biggest payoff—preventing problems or delays that become more costly to ameliorate as the children grow older. We cannot wait until premature infants have fallen behind at age 4 and then provide special education and intensive prekindergarten services to help them catch up. We know how to provide prevention and early intervention to at-risk infants and their families that works. Policies and funding must be directed to preventing premature births, and supporting the development of those babies who do arrive too early. Their families also need programs that provide information and support so that they can provide optimal cognitive and socio-emotional development for their fragile infant. I hope the subcommittee will make that initial investment to ensure that premature infants have the services and supports they need so they do not fall behind.

Thank you for your time and for your commitment to our Nation's premature infants and their families.

PREPARED STATEMENT OF THE ASSOCIATION OF WOMEN'S HEALTH, OBSTETRIC AND NEONATAL NURSES

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) appreciates the opportunity to comment on the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act (PREEMIE ACT), as well as the problem of premature birth and low birth weight in the United States. AWHONN is a membership organization of 22,000 nurses whose mission is to promote the health of women and newborns. AWHONN members are registered nurses, nurse practitioners, certified nurse-midwives, and clinical nurse specialists who work in hospitals, physicians' offices, universities and community clinics across North America as well as in the Armed Forces around the world.

AWHONN is a committed partner in the campaign to increase public awareness of the problems of prematurity and to reach the Healthy People 2010 goal of decreasing the preterm birth rate by at least 15 percent. A partner in the March of Dimes' Prematurity Campaign, AWHONN launched a Prematurity Resource Center on its website; supported legislative efforts to reduce the rate of premature birth, and published numerous research and clinical articles in AWHONN's research and clinical practice management journals to assist providers in meeting the challenge of prematurity.

Premature Birth

Prematurity, defined by the World Health Organization as a newborn with a gestational age of less than 37 weeks, represents a serious and growing problem in the United States. Traditionally, prematurity was defined as having a low birth weight, or less than 2,500 grams, regardless of gestational age. Babies who are born prematurely have not yet reached a developmental stage where they are able to function independently, usually have immature lungs, and are very prone to infection because their immune systems are not developed. According to the National Center for Health Statistics (NCHS), during a period of 21 years, from 1981 to 2002, the rate of preterm birth has increased by 29 percent. In 2002, the number of babies born prematurely reached a record high 480,812, or 1 in 8 newborns.¹

Preterm birth takes a toll on families and the health care providers who work to save these fragile children. Preterm birth accounts for 23 percent of neonatal deaths in the 1st month of life. Premature babies who survive usually suffer lifelong con-

¹*Births: Final Data for 2002*. National Vital Statistics Reports. Centers for Disease Control and Prevention. Vol. 52, No. 10. December 17, 2003.

sequences, including cerebral palsy, mental retardation, chronic lung disease and vision and hearing loss. When born before 34 weeks of pregnancy, babies are particularly at-risk to develop respiratory distress syndrome (RDS) and experience bleeding in the brain, which can cause pressure in the brain and ultimately, brain damage. In addition to the physiologic consequences of prematurity, the undue stress and suffering of the family whose newborn is isolated in the Neonatal Intensive Care Unit (NICU), fighting for its life, cannot be underestimated. Prematurity and low birth weight birth also creates a significant financial burden in the healthcare delivery system. The March of Dimes estimates that charges for hospital stays for infants with any diagnosis of prematurity/low birth weight were \$11.9 billion in 2000. The average lifetime medical costs of a premature baby are conservatively estimated at \$500,000.

Who is at Risk—Causes of Prematurity

While the cause of approximately half of all premature birth is unknown, we know three groups of women are at greatest risk of preterm labor and birth: women who are pregnant with twins, triplets or more; women who have had a previous preterm birth; and women with certain uterine or cervical abnormalities. According to the March of Dimes, certain lifestyle factors put women at greater risks of preterm labor, including smoking, late or no preterm care, alcohol consumption, use of illegal drugs, domestic violence, lack of social support, high stress levels, long working hours with long periods of standing, and low income. Certain medical conditions that may increase the risk of preterm labor include premature rupture of the membranes (the sac inside the uterus that holds the baby breaks too soon), urinary tract infections, vaginal infections, sexually transmitted diseases, high blood pressure, diabetes, clotting disorders, obesity, being underweight before pregnancy, short time period between pregnancies (less than 6–9 months between birth and beginning of the next pregnancy), and bleeding from the vagina.

It is also significant to highlight how rates of premature birth vary by race/ethnicity. The Centers for Disease Control and Prevention (CDC) report that the percentage of premature births among African American women, 17.7 percent, is significantly higher than that of all other races, with the average at 12.1 percent.² Prematurity/low birth weight is the leading cause of death for African American infants.

Current Research/Prevention Activities

The current prematurity research portfolio has yielded critical information that has helped health care providers deliver better treatment for women suffering preterm birth and their critically ill newborns. For example, in 2003 the National Institutes of Health (NIH) reported in the *New England Journal of Medicine* that weekly injections of 17-hydroxy-progesterone can reduce preterm birth by one-third among women at increased risk of preterm delivery because they had previously had a preterm delivery. CDC research activities include study of new methods that can be used for mass screening and early detection, pharmacological treatments for preterm birth prevention, and narrowing the high risk of preterm delivery among African American women. CDC's *Pregnancy Risk Assessment Monitoring Survey* (PRAMS) initiative collects information on self-reported maternal behaviors and experiences that occur before, during, and shortly after pregnancy. The goal of the project is to reduce adverse outcomes including premature birth and low birth weight.

While our ability to identify women who are at-risk for premature birth has improved dramatically through research and risk assessment, there remains no therapeutic regimen that has proven effective in prolonging pregnancy for more than a few days or improving neonatal outcomes. In fact, as reported by the CDC, the exact biologic mechanism for normal labor at term is not yet known and the mechanisms for preterm delivery are even more elusive. Current research shows promise, but both inadequate research funding and disjointed research efforts remain very real barriers to making the necessary scientific advancements that will result in fewer premature babies. An expanded and coordinated targeted research effort is needed to achieve the goal of preventing premature birth. The escalating numbers of premature births and the associated health care and emotional costs clearly demonstrate the need for a more significant investment into research to stop the growing epidemic of prematurity.

²The National Center for Health Statistics' National Vital Statistics Report on Births 2003.

The PREEMIE Act

In light of the severity of the problem, the rising frequency and the inadequacy of existing data and research, AWHONN urges the Congress to pass S. 1726, the PREEMIE Act. This legislation could drastically reduce the number of babies who are born too early and improve the health care community's ability to care for those who are. The PREEMIE Act would: investigate the causes of premature birth; identify the factors that make premature birth more prevalent in the African American community; educate the public and health care providers about premature birth; and promote standards of care to reduce pre-term labor and premature births.

The bill also calls upon the Director of the CDC to conduct a review of the PRAMS survey to ensure that it "includes information relative to medical care and intervention received, in order to track pregnancy outcomes and reduce instances of preterm birth." This survey is vital for collecting the data necessary to understanding preterm birth and neonatal outcomes, as well as for helping health professionals incorporate the latest research findings into their standards of practice. The CDC has indicated that there are currently gaps in its research, including the need to expand PRAMS from 31 States to all or nearly all 50 States, which would enable the program to give national estimates. AWHONN nurse members deliver care in a wide range of clinical sites that care for women and their families, or almost the entire breadth of the PRAMS data collection period. The knowledge gleaned through the expansion of the PRAMS survey will be directly beneficial to these nurses working with these special patients. We must invest the necessary funding to expand the PRAMS initiative and improve the cache of data available on preterm birth.

We are also pleased to see that this legislation calls for an Institute of Medicine (IOM) study on the health and economic consequences of preterm birth. The IOM would be directed to "assess the direct and indirect costs associated with premature birth, including morbidity, disability, and mortality." The study's focus on cost is significant in a time when health care delivery costs may indirectly affect health outcomes. Every day that a premature birth can be delayed saves money, and nursing research studies published in the *Journal of Obstetric, Gynecologic & Neonatal Nursing* bear this out.

Changes in perinatal care practices such as antibiotic treatment, surfactant therapy, and use of ventilation in the delivery room, have been influential in reducing neonatal mortality rates.³ The use of prenatal interventions such as antenatal steroids, tocolytic therapy, and antibiotics for ruptured membranes can delay premature birth by hours, days and even weeks, and can have a marked impact on neonatal survivability. Prenatal interventions that delay premature birth can also result in significant savings for the care of premature/low birth weight newborns, when measured in health care dollars. According to the *Journal of Obstetric, Gynecologic & Neonatal Nursing*, prenatal interventions that delay premature birth and affect a shift upward in birth weight of 250g for newborns weighing more than 750g result in an average savings from \$12,000 to \$16,000.

AWHONN is also pleased that the IOM study would provide recommendations on the best practices as well as the most promising areas of research to further prevention efforts. This represents an exciting area where nursing research has already made significant contributions. In the last decade, AWHONN has intensified its commitment to evidence-based practice through research utilization projects, research based protocols, and evidence based guidelines. These projects and research initiatives have helped nurses make a significant contribution to practice by basing practice protocols on scientific data. Nurses have developed interventions to reduce preterm birth rates. The effects of bed rest on pregnant women and their families have been frequently studied by nurses, and breastfeeding issues in relation to preterm birth have long been a topic of study for nurse researchers.⁴

The study's provisions relating to public and health care provider education and support services are of particular interest to AWHONN. Programs that provide information and education to health professionals are always welcomed and sorely needed. This legislation takes aim at one of our Nation's greatest health problems and what is known to be a major contributor to preterm labor and delivery: smoking. AWHONN recently launched a wide-ranging research program aimed at improving clinical practice delivered by nurses—the goal is to increase the likelihood of successful tobacco smoking cessation among childbearing women. The Setting Universal Cessation Counseling, Education, and Screening Standards (SUCCESS) project is an initiative that addresses improving clinical excellence to ensure the future health of newborns. Initially funded through a planning grant from the March

³(JOGNN 683).

⁴(JOHNN 661-662).

of Dimes, the SUCCESS project is nearing completion and the results will be released at the AWHONN Convention in June of 2004. AWHONN built an evidence-based guideline for pregnant women by using the Surgeon General's five A's of smoking cessation (Ask, Advise, Assess, Assist and Arrange) and modeled them to educate nurses about smoking and pregnancy and about the efficacy of the brief smoking cessation intervention. As part of the Advise process, nurses inform pregnant women about the risks of smoking in general and in relation to their pregnancy, including the increased instance of preterm labor and birth associated with smoking. AWHONN also participates in the National Partnership to Help Smokers Quit and is part of the group focused on offering help through the healthcare system. We are pleased with the inclusion of emphasis on smoking cessation and counseling program establishment in the PREEMIE Act. Passage of this legislation will support more research to decrease the rate of smoking in pregnant women.

Despite the limited funding the National Institute of Nursing Research (NINR) obtains annually, significant strides have been made to increase care for premature infants and their families. Nurse researchers supported by the NINR have examined many aspects of prematurity and the delivery of care in the NICU. This research has directly improved the care and outcomes of preterm infants. It is our hope that NIH funding opportunities for the PREEMIE legislation will include and intensify the excellent work that the NINR has done to date. The following are results published by NINR-funded investigators within the last 3 years:

- Karen A. Thomas, Ph.D., RN, found that preterm infants are sensitive to changes in their thermal environment, and caregiving activities may cause unintentional thermal alterations. Nursing care has changed in order to guard these infants from environmental factors and procedures that might result in drops in body temperature and contribute to newborn morbidity.

- A nurse researcher, Debra Brandon, Ph.D., RN, CCNS, found that maintaining cycled light patterns in the NICU benefits preterm infant growth, and may facilitate retinal development.

- Sandra Weiss, Ph.D., DNSc, RN, FAAN, found that low birth weight infants are susceptible to over-stimulation from parental touch, making them at-risk for long-term attachment problems.

- Gail McCain, RN, Ph.D. used a semi-demand, *ad lib* feeding protocol to help establish earlier full oral feedings in premature infants. This feeding method has helped these very small NICU babies experience normal oral feeding earlier and more successfully. In the long run, this helps these infants gain and maintain their weight.

- Suzanne Thoyre, RN, Ph.D. showed that, even nearing discharge, preterm infants can experience breathing difficulties while feeding. This important research has helped prepare nurses and parents to assess newborns and use different strategies to decrease risks and consequences associated with breathing difficulties.

- By observing NICU staff, Elaine Larson, RN, Ph.D., FAAN, CIC, found that many NICU nurses and physicians demonstrate suboptimal adherence to hand hygiene protocols. This has led to an increase in attention to hand washing in order to decrease hospital acquired infection.

The results of these studies provide neonatal nurses, practitioners, and other caretakers with new knowledge to address the care of the infant and the family, improve the health and development of preterm and other sick infants, and provide optimal discharge planning and follow-up care to at-risk infants and their families.

Finally, also included within the study would be the establishment of Neonatal Intensive Care Unit (NICU) family support programs with an emphasis on staff professional development and the promotion of family-centered care. It is in the NICU that families with a preterm infant often experience their darkest hours, and nurses are there with these families throughout the process. It is important, as shown in the preceding section, that families receive the support they desperately need while their infant is cared for in the NICU. AWHONN believes that the promotion of parenting and family-centered care is a critical part of comprehensive services to preterm infants and their families in the NICU. Nurses play an essential role in enhancing parenting and family-centered care in the NICU. This legislation will help foster a relationship where parents partner with health care providers to care for preterm infants, provide support for families and professionals responsible for caring for NICU patients, and ultimately improve the outcome for these children.

As an organization representing thousands of nurses who are on the frontline caring for pregnant women and newborns, AWHONN is pleased to lend its support to this crucial legislation. AWHONN's nurse members have long played a critical role in helping new mothers avoid pre-term labor, and provide emotional support and caring for premature babies. We look forward to playing a key role in the reduction of premature births and to bring healthier, full-term babies into the world. Because

half of all preterm births have no identifiable underlying etiology, and many of the known contributors to preterm labor and birth risk have only an indirect-causal relationship, the need for more research to better understand this problem is critical.

The Congress must act now and act quickly to pass the PREEMIE Act and reduce the number of children and parents who suffer not only physically, but also emotionally, because of premature birth.

Thank you for the opportunity to submit testimony on this crucial area of maternal-child health.

PREPARED STATEMENT OF THE AMERICAN HOSPITAL ASSOCIATION

Today, one in eight babies are born prematurely in the U.S. This is a statistic many hospital caregivers know all too well. Day in and day out, hospitals and their dedicated neonatal intensive care unit (NICU) staff face the medical and emotional challenges of caring for these babies fighting to survive.

The number of premature babies has been rising for more than 20 years making it essential we find answers as to the cause of premature birth. In nearly half the cases of premature birth, the causes are unknown. If we are to turn the tide, researchers and medical staff must be focused and be adequately funded.

That's why the American Hospital Association strongly supports this legislation. It will go a long way to expand, intensify and coordinate research related to premature births—all with the goal of healthier babies and families.

PREPARED STATEMENT OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

The American College of Obstetricians and Gynecologists (ACOG), on behalf of its 46,000 partners in women's health care, is pleased to offer this statement to the Senate Committee on Health, Education, Labor, and Pensions, Subcommittee on Children and Families. We thank Chairman Alexander, Ranking Member Dodd, and the entire subcommittee for their leadership to support increased research, education and prevention efforts to decrease prematurity.

ACOG Fellows care for and treat women of all ages. We believe improving maternal and child health is a vital investment, particularly in a woman's childbearing years. A mother's health is a strong predictor of child's life-long health and well-being.

ACOG Partner in Prematurity Campaign

ACOG is one of three major partners in the March of Dimes Prematurity Campaign, a 5-year effort to raise awareness about and reduce the rate of pre-term delivery. The Campaign aims to both increase awareness of the severity of prematurity, and decrease the rate of pre-term birth by 15 percent. Along with the American Academy of Pediatrics (AAP), and the Association of Women's Health Obstetric and Neonatal Nurses (AWHONN), ACOG will work to ensure that providers have the latest information available on the known risks of pre-term birth.

The cause of approximately half of all premature births is unknown. Studies have cited a history of tobacco use, maternal psychological stress, and periodontal disease as possible causes of prematurity, and studies have contradicted the commonly held belief that home uterine activity monitoring reduces the frequency of pre-term birth. ACOG policy now supports the use of progesterone as a possible treatment for women who have a history of pre-term labor.

Although the causes are largely unknown, pre-term labor and delivery have lasting health effects on both the mother and child, and disproportionately affect high-risk ethnic groups. Premature babies who survive may suffer lifelong consequences, including chronic lung disease, and vision and hearing loss. African-American mothers show the highest rate of pre-term labor at 17 percent, and low birth weight is the leading cause of death for African-American infants.

ACOG supports the Prematurity Research Expansion and Education for Mothers who deliver Infants Early Act, or PREEMIE Act, introduced by Senators Lamar Alexander (R-TN) and Christopher Dodd (D-CT), which builds upon and supports the significant research and outreach currently conducted by the National Institute of Child Health and Human Development (NICHD) and the Centers for Disease Control and Prevention (CDC). The bill focuses on pre-term labor and delivery research, provider education and support, and the health and economic costs of prematurity.

The NICHD's Maternal Fetal Medicine Unit Network (MFMU) focuses on clinical questions in maternal fetal medicine and obstetrics, particularly with respect to pre-term birth. The current Network is comprised of 14 university-based clinical centers and a data-coordinating center where more than 24 clinical trials, cohort studies and registries have been completed or are in progress. The NICHD has been instru-

mental in identifying progesterone as a possible method of reducing the incidence of pre-term labor.

These efforts are complimented by the Centers for Disease Control and Prevention (CDC) prematurity reduction efforts, which target surveillance, epidemiological research and State capacity building. The Centers collect vital data such as the mother's education and health, and history of tobacco use, but need more flexible technology systems to monitor this data. The CDC also partners with 31 State health agencies to promote healthy pregnancies, but due to lack of funds, has not been able to provide assistance to 13 additional States.

In addition to the research conducted through the NICHD and the CDC, physician education and access to care are essential components to reducing pre-term labor. By educating women's health care providers on the latest prematurity research findings, providers can offer timely and appropriate care to women. Increasing women's access to mental health and smoking cessation counseling, two suspected risk factors for pre-term labor, can also help providers reduce prematurity by improving maternal health.

The economic and health-related burden prematurity places on the health care system is immeasurable. A key provision in the PREEMIE Act calls for a joint CDC and NIH report on the effectiveness of outreach programs. The report will seek to examine short and long-term disabilities associated with premature births and the impact on maternal health, health care and quality of life. It will also offer recommendations on best practices and interventions to prevent premature birth, as well as the most promising areas of research to further prevention efforts.

Ob-Gyn Representation on NICHD Advisory Council

The important role that NICHD plays in understanding and finding solutions to prematurity raises a serious related concern that we'd like to bring to the committee's attention.

NICHD has overseen tremendous advancements for women including improving pregnancy and childbirth outcomes, and identifying cures for diseases and conditions affecting women of all ages and at all stages in life. NICHD is, in fact, the Institute where the vast majority of ob-gyn related research takes place and the only Institute where ob-gyns have a prominent role. It's critical, then, to require that the NICHD Advisory Council include an adequate number of individuals who have distinguished themselves in ob-gyn clinical practice and research.

Currently, this important Council, which guides the Institute's research funding decisions, is composed of 17 appointed members, including pediatricians, ob-gyns, sociologists, biologists, media consultants, and nurses. Currently, the Council includes 3 distinguished ob-gyns, who bring to the Council years of expertise and knowledge of women's health care needs, research priorities, and the impact of research discoveries on women's lives. One of these individual's terms expires in November 2004, giving NICHD the opportunity to appoint another individual to fill this slot.

ACOG worked actively with the NICHD to advocate the appointment of another ob-gyn to this position, and we are deeply troubled by indications that NICHD plans to fill this position with an attorney, rather than with another ob-gyn. Research conducted at NICHD helps shape the future of women's health care. Women across America and the world suffer from issues of maternal morbidity, uterine fibroids, vulvodynia and numerous other health care issues that are far from being understood and cured. The world faces global challenges, too, of the spread of sexually transmitted diseases, which have barely been acknowledged, much less challenged and defeated.

The NICHD Advisory Council must include an adequate number of ob-gyns who are experts in these clinical and research areas. We object strongly to any attempt to reduce the ability of our specialty to contribute to the research direction of this Institute which is obviously so critical to the area that we know better than any other group or medical specialty—women's health.

We look to Congress to amend the NICHD statute to require that its Advisory Council include no fewer than three experts in the field of ob-gyn. This action is necessary to ensure that decisions that will affect the future of women's health care are made by individuals with expertise and a deep level of commitment to the field. We hope to work actively with this committee and the Congress to restructure the Council representation requirements.

Medical Liability Crisis Puts Moms and Babies At Risk

The dwindling numbers of practicing obstetrician-gynecologists further jeopardizes the high rates of pre term labor. Across the country, liability insurance for obstetrician-gynecologists has become prohibitively expensive. Premiums have tripled and

quadrupled practically overnight. In some areas, ob-gyns can no longer obtain liability insurance at all, as insurance companies fold or abruptly stop insuring doctors.

When ob-gyns cannot find or afford liability insurance, they are forced to stop delivering babies, curtail surgical services, or close their doors. The shortage of care affects hospitals, public health clinics, and medical facilities in rural areas, inner cities, and communities across the country. The medical liability crisis affects every aspect of our Nation's ability to deliver health care services, harming our patients most, who lose access to care they deserve.

When confronted with substantially higher costs for liability coverage or the reality of not being able to find coverage at any price, ob-gyns and other women's health care professionals stop delivering babies, reduce the number they do deliver, and further cut back—or eliminate—care for high-risk mothers. With fewer women's health care professionals, access to early prenatal care is reduced, depriving women of the proven benefits of early intervention.

Women in underserved rural areas have historically been particularly hard hit by the loss of physicians and other women's health care professionals, as increases in liability insurance costs are forcing rural providers to stop delivering babies and pregnant women to drive long distances for prenatal and delivery care.

This crisis also means that community clinics must cutback services, jeopardizing the Nation's 39 million uninsured patients—the majority of them women and children—who rely on community clinics for health care. Unable to shift higher insurance costs to their patients, these clinics have no alternative but to care for fewer people. Low-income pregnant women lose critical prenatal care as a result.

It is clear that Congress must end the medical liability crisis or women will be at greater risk for losing care.

We thank the committee for addressing this important issue of prematurity. Both the NICHD and the CDC have made significant strides in reducing prematurity, but there is still no cure. We look forward to working with the committee and the Congress to guarantee adequate ob-gyn leadership at NICHD and to enact meaningful medical liability reform. And we will work with Congress and the Administration to support prematurity reduction and elimination through education, prevention and research.

PREPARED STATEMENT OF THE SOCIETY FOR MATERNAL-FETAL MEDICINE

Mr. Chairman and Members of the Committee, I am James Ferguson, President of the Society for Maternal-Fetal Medicine and Professor and Chair, in the Department of Obstetrics and Gynecology at the University of Kentucky College of Medicine. The Society for Maternal-Fetal Medicine appreciates the opportunity to submit testimony in support of S. 1726, the "Prematurity Research Expansion and Education for Mothers who Deliver Infants Early Act" or the "PREEMIE Act". We believe this bill provides meaningful steps in educating pregnant women about the problems of prematurity; expanding research to identify the causes of preterm labor and prematurity; and promoting the delivery of improved perinatal care.

The primary objectives of the Society for Maternal-Fetal Medicine is to promote and expand education in maternal-fetal medicine and to encourage the exchange of new ideas and research concerning the most recent approaches and treatments for obstetrical problems. Our Society has a very strong interest in improving pregnancy outcome through basic, translational and clinical research and through education leading to improvements in patient care.

Maternal-Fetal Medicine subspecialists pursue an additional 2 to 3 years of fellowship training following completion of their 4-year residency program in Obstetrics and Gynecology. Maternal-Fetal Medicine subspecialists provide consultative services to obstetricians and other healthcare providers, while in other cases we assume direct care responsibility for the special problems that high-risk mothers and high-risk unborn children face. The special problems faced by these mothers may lead to death, short-term or in some cases, life-long problems for themselves and/or their babies.

Preterm birth stands out as a major obstetrical challenge in the U.S. Fetal death occurs in nearly 1 percent and neonatal mortality in 0.5 percent of all U.S. pregnancies, and is up to 10 times greater in many developing countries. Yet, to date there has been little success in reducing the incidence of preterm births.

S. 1726 would authorize the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to expand research related to preterm labor and delivery and the care and treatment, and outcomes of preterm and low birthweight infants. For example:

Expansion of research in this area within the National Institutes of Health would allow the National Institute of Child Health and Human Development (NICHD) to

undertake major initiatives to hasten a better understanding of the pathophysiology of premature birth, discover novel diagnostic biomarkers, and ultimately aid in formulating more effective intervention strategies to prevent premature birth. We believe that the next major advance in elucidating the etiology of preterm delivery involves understanding the mechanism through the evaluation of protein and gene expression. These techniques are widely used in other medical fields and it is imperative they are used to understand prematurity.

In addition, the NICHD Maternal-Fetal Medicine Unit (MFMU) Network conducts large prospective clinical trials to address issues such as preterm birth. Since its establishment in 1986, this 14-center body has proven itself to be the most effective and cost efficient means to conduct the types of large-scale clinical trials needed for maternal-fetal research. Recently, the MFMU Network announced the results of the Progesterone Trial, a clinical research study that showed that treatment with progesterone could substantially reduce the incidence of preterm birth in high-risk pregnancies. This is one of the first advances in this area, despite extensive efforts over decades.

Research by the MFMU Network has helped women and their babies by finding the best courses of treatment and prevention for high-risk pregnancies. S. 1726 would provide a secure source of funding that would enable the MFMU Network to continue to launch new studies and to build on existing studies.

The Centers for Disease Control and Prevention (CDC) and State health departments currently use a pregnancy risk assessment monitoring system (PRAMS) to collect state-specific, population-based data on maternal attitudes and experiences before, during and immediately after pregnancy. The data can be used to identify groups of women at high risk for pregnancy complications, to monitor changes in the health status of the mother and baby, and to measure progress in improving the health of mothers and infants.

An intensified effort within the CDC could provide for expansion of the PRAMS to include establishing a uniform State and national reporting system of pregnancy related complications to track interventions and patterns of care received, and to conduct research into the causes of and interventions for pregnancy complications, especially complications relating to outcome disparities in different racial and ethnic populations.

The bill also provides for public and provider education and support services. It is crucial that the scientific knowledge that has been obtained be disseminated to health professionals and providers, as well as to the public so that the best treatment and preventive strategies are available to the mother and infant.

Our Society is also supportive of an interagency committee focusing on prematurity and low birthweight that will provide a forum for sharing information and will facilitate the development of collaborative research activities.

Mr. Chairman, we applaud your commitment to reduce the incidence of prematurity. It is a problem that merits research emphasis and increased resources. The Society for Maternal Fetal Medicine is honored to lend its support to S. 1726.

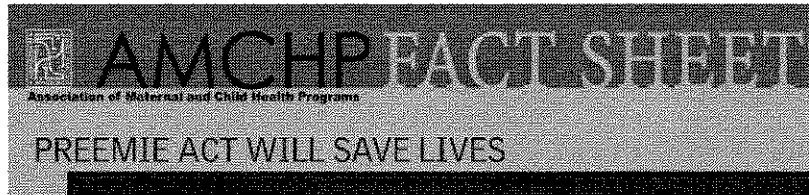
QUESTIONS OF SENATOR JEFFORDS

A recent brief by the Children's Dental Health Project stated that "A growing body of research supports an association between periodontal disease (inflammatory gum disease) and unfavorable birth outcomes associated with PLBW."

Question 1. How is the NIH working to determine if this association is causal?

Question 2. How is NICHD working with NIDCR to improve the evidence base on this possible link?

Question 3. How is the CDC utilizing its Pregnancy Risk Assessment Monitoring System (PRAMS) to determine the extent of this association and the oral health status of all pregnant women?



AMCHP Calls on Congress to Pass this Important Legislation

Almost half-a-million babies born in the United States are premature; that's a shocking 12 percent of all newborns. Preterm births are twice as high among African-American women. Over 300,000 newborns have a low birth weight.¹ One-quarter of the smallest babies, those with a very low birth weight, will die before their first birthday. Those who survive face the possibility of long-term disability and impaired development.²

The PREEMIE Act takes the first steps to address this national health issue. The Association of Maternal and Child Health Programs (AMCHP) supports this important legislation, introduced by Senators Christopher Dodd (D-Conn.) and Lamar Alexander (R-Tenn.) and Representatives Fred Upton (R-Mich.) and Anna Eshoo (D-Calif.). We are pleased to join our partners, including the March of Dimes, in support of the PREEMIE Act.

In particular, AMCHP strongly supports the bill's proposal to the Department of Health and Human Services to use the Title V Maternal and Child Health Block Grant—administered by our members—to measure some of the known causes of prematurity, such as the number of women who

smoke during pregnancy. We also support expanding federal research on preterm delivery, treatment, and the health of preterm and low birth weight infants.

AMCHP represents state public health leaders in maternal and child health. Together, these professionals serve 27 million women, children and families across the country, including over two million pregnant women and almost four million infants. As those responsible for ensuring the health of women and children in their states, our members play a pivotal role increasing prenatal care for pregnant women and their families. Thanks to their efforts, the infant mortality rate has decreased by 32 percent since 1990. That means three more babies are alive out of every 1,000 born today.

However there are still real challenges to save the lives of America's newborns. The number of babies with a low birth weight has increased 7.8 percent since 1980, despite the fact that it had been declining.

The PREEMIE bill would improve the treatment and health of premature babies and create programs to support the emotional and informational needs of their families. By reducing the number of babies who are born below normal birth weight, the legislation will help reduce healthcare costs for states, Medicaid and private doctors. More importantly, the bill will help ensure that all American families are healthier and happier.

¹ March of Dimes

² Child Trends Databank, www.childtrendsdatabank.org/indicators/57LowBirthweight.cfm

Association of Maternal and Child Health Programs
1220 19th Street, NW, Suite 801
Washington, DC 20036
Phone: (202) 775-0436 / Fax: (202) 775-0061
www.amchp.org

[Whereupon, at 12:02 p.m., the subcommittee was adjourned.]