

**National Children's Study
Stakeholder Telebriefing
October 3, 2008**

John McGrath: Thank you, Yolanda. And thank everyone for joining this call this afternoon, and in some places, perhaps, this morning. My name is John McGrath, and I'll be moderating this call. And first of all, welcome to this briefing of the National Children's Study.

Today has been a very exciting day for the National Children's Study. It began with a briefing on Capitol Hill for interested members and their staff. We then had a media briefing here at the National Institutes of Health, and you may notice that there are several stories on the wires—we have a Reuters story, an AP, and a couple of radio stories now. We are delighted to have the opportunity to have a discussion with you, many of the key members, people who have been participating in the Study.

We understand there are close to 100 people on this call this afternoon. On the call are new and existing Centers; members of the Interagency Coordinating Committee, including the U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), and the National Institute of Environmental Health Sciences (NIEHS); and many professional organizations that have been friends of the Study for years. So to everyone, welcome.

We'll begin by hearing background from two key people, Dr. Duane Alexander and Dr. Peter Scheidt. Dr. Alexander is the Director of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). Dr. Peter Scheidt is the Director of the National Children's Study. They will be followed by speakers who are participating from around the country.

I now turn this over to Dr. Alexander.

Duane Alexander: Thank you, John, and good afternoon everyone. And thank you for joining us.

As John says, this is our third of these briefings today; I think it's important for you to get an idea of the magnitude of interest in this study as indicated by the attendance at these briefings. We began this morning with a congressional briefing at 9:00 a.m. in the U.S. Capitol. This was arranged by Congresswoman Doris Matsui from California, who has been a lead congressional champion for this study and who co-chairs, with Congressman Chris Smith from New Jersey, the congressional caucus on the National Children's Study. In all my years in Washington, I have never

heard of a congressional caucus for a study, so I think this is a first, and it gives you an idea of the interest in this study.

The other thing that gives you an idea of the interest is the fact that we also had Congressman Robert Etheridge from North Carolina present and an overflow attendance that actually spilled out into the hallway. So there's a lot of interest from the congressional staff and members in this study.

At 11:00 a.m., we did a press briefing. There were more than 60 members of the media there. Many of them are from your hometown newspapers and radio stations that were informed about your entering this study, and they dialed in to get information about it and asked us questions about it. Again, that's a very large interest and participation. And now we're going to have our briefing for the stakeholders, and we have almost 100 of you all on the line. So thank you for joining us.

We're here today to give you an end-of-fiscal-year progress report on the National Children's Study and to announce 39 new locations and 27 Study Centers for the National Children's Study. Periodically we've been providing updates on the Study's progress. Many of you have been with us on these before for earlier announcements, and I'll provide a crash course for those of you who are new and a review for those who have been with us before.

The National Children's Study of Environmental Influences on Health and Development began with passage of the Children's Health Act of 2000, which mandated the NICHD and a consortium of federal agencies to design and conduct the National Children's Study. Partnering with NICHD in this effort are the NIH's NIEHS, CDC, and EPA.

Since preparation for the Study began in 2000, researchers affiliated with it have been devising the methods needed to conduct this study. They've been deciding what kinds of samples they'll need to collect; the means to analyze these samples; and how to devise ways to recruit a population of Study volunteers that's representative of the population of the United States in all its social, geographic, economic, and racial diversity.

The Study will begin by recruiting women before they give birth and in many instances before they conceive their children. The Study plans to follow these children that the women give birth to until they're 21 years of age, monitoring their environmental exposures and their health and development closely from early infancy on through childhood and into young adulthood. Eventually, 100,000 children will take part.

The National Children's Study will encompass a nationally representative sample designed to be a composite of the U.S. population. It will include children throughout the United States, from rural, urban, and suburban areas; from all income and educational levels; and from all racial groups.

In 2004, we identified 105 U.S. communities from which we would recruit the Study's participating families. Our first major announcement on the Study's progress was the awarding of contracts for seven Vanguard Centers in 2005. These were the initial Study Centers and will be the first Centers to recruit volunteers for the Study. The Vanguard Centers will also test the research methods we need to conduct the larger Study. In 2007, we added an additional 12 new Study Centers.

Each of the Study Centers will enroll volunteers from the Study locations they manage. The researchers at the Centers will collect biological samples from the mother and child, as well as samples from the women's and children's environment: air, water, even house dust. They will collect samples of the materials used to construct homes and schools to see whether these or other environmental factors influence the children's health.

In its national scope and the number of children it will follow and its focus on development from infancy through adulthood, the National Children's Study is unique. There is no other American study quite like it. We look to it to provide new information that will help treat and perhaps even prevent any of a range of childhood conditions and adult conditions that have roots in childhood: asthma, autism, attention deficit disorder, learning disability, mental health problems, obesity, diabetes, high blood pressure, and heart disease.

We anticipate that in the long term, what we learn from the Study will result in a significant savings in the nation's health care costs. Let me give you an example. According to one estimate, just six of the conditions that the National Children's Study will look at—obesity, injury, asthma, diabetes, schizophrenia, and autism—cost the United States \$758 billion per year. Estimating conservatively, if what we've learned from the National Children's Study results in only a 1 percent reduction in the cost of these conditions, our nation will save about \$7.58 billion a year. That 1-year savings is more than double the entire \$3.2 billion the National Children's Study is expected to have cost by the time all the children who participate reach 21 years of age.

In explaining the promise of the National Children's Study, we often talk about its potential to provide information on conditions that manifest themselves in adult life. But we won't have to wait 21 years before we see results. Because the Study follows children from before birth through

adulthood, we expect it to yield information along each step of the developmental process from infancy to early childhood, to preteen and teen years, and again in early adulthood.

Today, we have reached a major milestone. For 2008, a total of 27 Study Centers have been funded. Some of these have been funded in previous years. We have posted a listing of the 2008 Centers and their corresponding locations in our news release on the NICHD Web site at www.nichd.nih.gov. Today's announcement brings the total number of new and previously funded Study Centers to 36, covering 72 of the eventual 105 locations. Contracts have been awarded to these Study Centers we are announcing today based on rigorous criteria. They have demonstrated a strong ability to collect information for the Study and the ability to inform their communities about this study, to recruit eligible women, and to devise plans to retain the women and their children until the children reach 21 years of age. They have also demonstrated a strong capacity to protect the privacy of the Study participants.

Progress of the National Children's Study will always be contingent upon funding, which is approved by Congress on a yearly basis. With that in mind, we anticipate that the Study will start recruiting the first volunteers in early 2009.

Having introduced the Study to those who are not familiar with it and having reviewed it for those who have attended our earlier briefings, I'll now announce the names of the newly awarded 2008 Study Centers and their locations. After that, the Director of the National Children's Study, Dr. Peter Scheidt, will talk about the Study's immediate future and its projected launch in 2009.

The Study Centers and the locations they will cover that are funded in 2008 are:

- Arkansas Children's Hospital, covering Benton County, AR
- Baylor College of Medicine, covering Harris County, TX
- Brown University, covering Bristol County, MA
- Case Western Reserve University, covering Lorain County and Cuyahoga County, OH
- Children's Hospital of Philadelphia, covering Burlington County, NJ
- Emory University, covering Bradley County, TN, and Baldwin County, GA
- Johns Hopkins University, covering Montgomery County, MD
- Maine Medical Center, covering Cumberland County, ME
- Michigan State University, covering Grand Traverse County and Lenawee County, MI
- Mt. Sinai School of Medicine, covering Montgomery County, NY, New York City (Manhattan), and Passaic County, NJ

- Northwestern University, covering DuPage County, IL
- Saint Louis University, covering Jefferson County, MO, and Johnson County, Union County, and Williamson County, IL
- Tulane University, covering New Orleans, LA
- University of Arizona, covering Apache County and Pinal County, AZ
- University of California, Irvine, covering Kern County and San Bernardino County, CA
- University of California, Los Angeles, covering Ventura County, CA
- University of Colorado, covering Douglas County, CO
- University of Iowa, covering Polk County, IA
- University of Louisville, covering Jefferson County, KY
- University of Miami, covering Baker County, Orange County, and Hillsborough County, FL
- University of North Carolina at Chapel Hill, covering Cumberland County, Durham County, and Burke County, NC
- University of Texas Health Science Center San Antonio, covering Hidalgo County, TX
- University of Texas Southwestern Medical Center at Dallas, covering Lamar County, TX
- University of Utah, covering Bear Lake County, ID, and Lincoln County and Uinta County, WY
- University of Washington, covering Grant County, WA
- Vanderbilt University Medical Center, covering Davidson County, TN
- Yale University, covering Litchfield County, CT.

From this listing, you get an impression of the breadth and scope and diversity of this study. It includes very urban areas—New York, Los Angeles; it includes rural areas, industrial states, and counties that are primarily Indian reservations. All these are important for the Study, and all are included, and we are happy to have made these awards to these contract organizations and to the Centers and the sites that they will be covering.

It is now my pleasure to introduce Dr. Pete Scheidt, the Study Director, who will tell you more about the Study and its plans.

Dr. Peter Scheidt: Thank you very much, Duane, and thank all of you on the call for joining us today.

We now see the light at the end of the tunnel of preparation for actual data collection in the National Children’s Study. While adding Centers and locations to fill out the sample, we are scheduled for the National Children’s Study’s Vanguard Centers to begin recruiting for the pilot phase of the Study in January of 2009. That’s only a few months away.

The Vanguard Center at the University of North Carolina at Chapel Hill will begin recruiting in Duplin County, North Carolina, and the Vanguard Center at Mt. Sinai School of Medicine will begin recruiting in Queens, New York. I would like to emphasize that this initial recruitment will be for the pilot phase of the Study. That's the early phase of the Study in which we test the sampling methods, the recruitment methods, and the full core protocol that we developed to see if they'll work as well as we believe they will—to kick the tires and work out the bugs, so to speak.

Then, in April, the other five Vanguard Centers will begin enrollment at locations in California, in Pennsylvania, in a group of rural counties in South Dakota and Minnesota, in Utah, and in Wisconsin. I won't name all of the remaining Centers and locations here, but they're available on the Study's Web site, which most of you are familiar with, www.NationalChildrensStudy.gov.

Following the Vanguard pilot period, we expect to begin the 4-year recruitment for the full Study in three successive waves beginning in July 2010, again in July 2011, and finally in July of 2012. A minimum of 250 births are expected in each of the Study locations for each of the 4 years of recruitment. Currently, the Vanguard Centers are hiring and training staff, meeting with local community groups and healthcare professionals to inform them about the Study, and working with community advisory boards to provide ongoing guidance on a range of Study-related issues. The Centers for the Wave 1 locations will be cranking up these activities shortly, while we are bringing on Wave 2 Centers and locations that are announced today.

Of course, as always, and as Dr. Alexander pointed out, our funding is allocated by Congress each year, and all of the projections we're making today are contingent on yearly funding renewals.

In the past, I've talked about the Study following children through their 21st birthday, and in fact it may well continue into adults, informing about how exposures early in life affect adult disease. But, right now, I'd like to emphasize the Study's early outcomes and benefits. As we expand toward the full sample and enrollment for this 20-plus year study, it's important to emphasize that we expect the Study to yield information on a variety of pregnancy and birth-associated conditions early on, just a few years away.

Let me exemplify one important anticipated early outcome: paramount among the conditions we need to learn more about is that of preterm birth. According to findings from the Surgeon General's conference on preterm birth last summer, every year nearly 500,000 American babies are born prematurely. That's more than 12 percent of U.S. births that are preterm, and this rate has actually been rising in recent years.

Because of advances in research in health care, many preterm babies survive and do well; however, a sizable number of them experience serious complications, some of which are life-long. Preterm infants are at risk for early death from the direct complications of prematurity, and they're at increased risk of Sudden Infant Death Syndrome, which is a sudden and unexplained death in the first year of life, and at increased risk for a number of conditions including cerebral palsy, mental retardation, learning disabilities, visual disabilities, and hearing problems. The costs associated with prematurity are substantial. This is estimated, from the Surgeon General's conference, at \$26 billion per year.

So we look to the National Children's Study to provide information that will be helpful in reducing the proportion of preterm births and their considerable and personal costs. With 100,000 pregnancies, the Study will include genetic samples from women and their infants, information on their diets, possible exposure to chemicals in their environment, measures of emotional stress, and other types of measures.

So, in addition to the many long-term benefits of this study, we can expect some early and some very important benefits as well. We expect that what we learn from the National Children's Study will provide new information that we can use to begin solving the problems of preterm birth, and we anticipate that we will have this information in just a few years.

So with that to look forward to, and with the expansion of the Study, let me turn the Study over to our next speaker.

Duane Alexander: I'm happy to introduce our next speaker. As indicated earlier in my remarks, I said that the Study is being put together by a consortium of federal agencies. The lead agencies, in addition to NICHD, are NIEHS, CDC, and EPA.

The next speaker represents the Interagency Coordinating Committee (ICC). She's Elizabeth Blackburn from the Office of Children's Health Protection in Environmental Education at EPA. Liz?

Elizabeth Blackburn: Good afternoon. I am delighted to join my colleagues in making this momentous announcement regarding the largest study of environmental influences on children's health and development in the United States. It is quite appropriate that for the second year in a row, we share this important news during Children's Health Month, the purpose of which is to focus national attention on children's health.

Eleven years ago, concerns about children's health led to an executive order that directed federal agencies to address disproportionate environmental health and safety risks to children. This action gave birth to

the National Children's Study and to the Interagency Coordinating Committee, of which I am a member. As Dr. Alexander mentioned, the Interagency Coordinating Committee is made up of four lead agencies—NICHHD, NIEHS, CDC, and EPA.

The ICC provides broad scientific and administrative oversight of the National Children's Study and helps to ensure that the Study stays true to the Children's Health Act of 2000. ICC members represent their agencies' interests in planning for and implementation of the National Children's Study. This is important because data generated by 100,000 children and their families participating in the National Children's Study will be of great value to the mission of each lead agency as well as to our nation's children and their children.

Let me give you some examples: the size and scope of the Study will allow us to answer critical questions in children's environmental health that have been difficult or impossible to address through our other research approaches. The evaluation of combined impact of multiple environmental factors, including chemical, physical, social, and cultural factors, becomes possible with the promise of the Study's rich database. Study data will help us to understand the nature and the extent of health problems facing infants, children, and adolescents, including the very important issues of health disparities. We will learn new information about the impact of environmental and genetic factors and gene/environment interactions on child health and development.

The longitudinal design will strengthen our ability to assess the effects of environmental exposures on children's growth, development, and disease, such as the effects of pesticide exposures on neurological, developmental, and cognitive deficits. We hope to be able to identify and reduce sources of hazardous pollutants that affect children where they live, learn, and play.

Especially important to my agency will be the data produced to help evaluate the consequences and/or the effectiveness of our regulatory decision. The Study will help us assess the effectiveness of public health efforts to decrease children's exposure to specific chemicals.

The National Children's Study is truly an unprecedented collaboration, and we welcome the new Study Centers and the locations they will oversee into the National Children's Study family. We look forward to working together to identify influences on children's health, their interconnectivity, and thus ways to potentially improve the well-being of generations to come. Thank you.

Duane Alexander: Thank you very much. The next two speakers represent principal investigators (PIs) from the Study. The first is Dr. Jennifer Culhane, a PI at the Vanguard Center at Children's Hospital of Philadelphia (CHOP). Jen traveled to Washington this morning to join us in our congressional briefing at 9:00 a.m., presenting a view from the front lines of this study as a PI at a Vanguard Center, and did a terrific job. Jen?

Jennifer Culhane: Hi, Duane. I'd like to start by saying thank you very much to Dr. Alexander and Dr. Scheidt for inviting me to the congressional briefing as well as to participate in this phone call. I'd also like to say a big thanks to NICHD under the direction of Dr. Alexander and to the Program Office of Dr. Scheidt because without their continued efforts, I don't think we would be at this stage.

I'm just going to talk very briefly about the CHOP Study Center, as it has a relatively unique position in that we've been involved in all waves of procurement. We're a Vanguard Center with Montgomery County, Pennsylvania; we have all seven counties also referred to at times as Wave 1 counties; and we have recently just received the contract to undertake the data collection in Burlington County, New Jersey, which is a 2008 county.

So we've been involved from the beginning. And I'd like to just briefly tell you about the activities that are ongoing because at times I think people get the feeling that there's lots of planning and not a lot of activity, and the truth is that there's a lot of activity going on at the Vanguard Centers and lots of movement to launching a recruitment in January for two of the Vanguard Centers and in April for the remaining five.

At our Vanguard Center, we have fully completed our segment selection and the descriptions of our communities from which Study participants will be drawn. We've completed our listing activity, which is really our first field activity, which is developing a systematic listing of all dwellings that are within our catchment areas, and we have done lots of outreach and engagement to stakeholders in the community. Specifically, we've developed a community advisory board; we spent a large amount of time educating and engaging providers, obstetric and pediatric; we've had lots of interaction with hospital administrators and hospital institutional review boards; and we're now just beginning very aggressive outreach and engagement to potential participants.

So we've really done a lot of work on the ground. We've developed our field office, which is currently being renovated, and we've begun to solidify the exact mechanisms by which we will collect all of the Study data.

During our processes in developing our Vanguard Center, we've learned lessons about flexibility and about timing of outreach and engagement. I think it's really important for new Centers to understand that there are multiple stakeholders, and across your planning time, you don't have to do your education outreach to all the stakeholders at the same time and at the same speed.

So given that what I've described thus far, kind of our logistics around the data collection aspect of the Study, I'd like to briefly touch upon another aspect of the Study that I find particularly important and rewarding, and that is engaging the scientific community within my institution and all of the participating institutions across all of our five counties.

I think that this is something that has really been quite rewarding because the depth and breadth of the National Children's Study data, which in my opinion is clearly the biggest and most important study of child health to ever be undertaken in the United States, really entices scientists who haven't really studied child health or child morbidities in the past to bring their intellectual input to the table. And so within my own university, I have met with experts in genetics and epigenetics and autism, and with some pulmonology and endocrine experts, and they didn't really know about the National Children's Study. And through my outreach to them, they have really become energized to engage in helping to consider ancillary projects and how to use the data.

In a brief concrete example of this, another Study Center PI, Dr. Jim Swanson, has engaged world experts, I think both from within and outside the National Children's Study, to respond to the NIH road map request for applications to look at epigenetic contributions to certain birth outcomes. I think it's an excellent example of how the scientific community can rally around the data that are collected as part of the Study to really do cutting-edge science.

In conclusion, I think my messages are that there is a lot of work going on, on the ground, in the Vanguard Centers, so there's probably a lot more activity that people actually can see. Recruitment is beginning very, very shortly. Important scientific contributions will be made early, and I think that possible epigenetic application is an excellent example. Thank you.

Duane Alexander: Jen, thank you very much and thanks again for joining us this morning.

So we move now from a veteran PI who has been present from the beginning at the Vanguard Center at CHOP, to a new Wave 2 investigator, just funded. That's Dr. Jeff Murray, who is the PI at the University of Iowa, and Jeff, we welcome you. If I were a reporter, I would ask you, "Jeff, how does it feel to be a new investigator in this study?" But I won't

do that to you. Why don't you just give us your remarks and comments, please.

Jeff Murray:

We're terrifically honored to be a new part of the Study, and a terrific study that it is as well. At first, I'd also like to thank both Dr. Alexander and Dr. Scheidt and what I know are really hundreds of other people who have worked very hard over the last many years to make this study possible and have it be able to continue, and all of us who are newly joining the Study are incredibly grateful to those of you who have really stayed the course and made this possible.

Polk County, Iowa, we think, has a particularly unique blend of factors to bring to the Study. It's the home of our state capital, Des Moines, and so it has both urban and suburban regions associated with it, and then what I'm sure many of you associate with Iowa—the more traditional Iowa venues of large farms with lots of corn and soybeans. And so we're very excited to be able to bring this component into the National Children's Study.

Iowa has had a really long history of providing, we think, terrific care for our children and terrific educational opportunities for them as well. We have wonderful public health and wonderful point-of-care medicine here. And so we think it's a real honor for us to be able to be a part of a study that's really going to continue that ethic at a national level and bring a new generation of physicians and healthcare workers the kind of information that they're going to need to improve the health and outcomes of kids.

As we've already heard from a couple of the speakers today, we've had some wonderful advances in our ability to characterize environmental exposures and to quantify genetic and epigenetic variation. We can really look at these things with unprecedented levels of resolution now. This is really going to enable this study to provide terrific opportunities to look at gene/environment interactions as contributors to common childhood diseases. For someone like myself who is a pediatrician and a geneticist, it's an incredibly exciting time, and again, as you just heard from Dr. Culhane, there are lots of opportunities to energize and bring into the tent a whole new generation of investigators and existing investigators who haven't previously done this kind of work. So it's a really wonderful opportunity to capture new people as well.

The Study itself, with its sort of large, representative, prospective cohort, is also going to enable us to understand the causes and outcomes of these common pediatric disorders in a way that just hasn't been possible up until now. The combination of the technologies and the epidemiology is unique. It's also wonderful in that the Study is going to be capturing information in real time, and as we've already heard alluded to, there are some new epidemics that are occurring, things like childhood obesity and increasing

rates of prematurity. So those unanticipated epidemics that are probably already beginning, but we don't know yet what they're going to be, will be able to be studied much more quickly and addressed much more quickly because of this project's ability to be capturing information in very real time.

Also, as you have heard from Dr. Alexander, although it is the National Children's Study, part of the children's environment is their whole family. It's their siblings, their parents, their grandparents, and other relatives as well, and so it really will become a study of adults as well as children. And these fetal origins of adult disease, again alluded to by several of the speakers, where things that affect the fetus *in utero*, the kind of epigenomic changes that can occur that Dr. Culhane talked about, will enable us to begin to identify those factors that are going to be a part of the whole lifetime of an individual, not just as a child, but as an adult as well.

I think we're also especially grateful for the very many families and professional organizations. I think we'll hear from Dr. Howse from the March of Dimes, which has played an amazing leadership role in studies of prematurity and bringing that to the attention of the U.S. population. I think it's been all of these people who have enabled the long-term support for the project to come about.

As I said earlier, I'm a pediatrician and a geneticist, and our group here has a terrific interest in prematurity and in birth defects, and this project's going to be just a wonderful way in which we can investigate these things in very real time, as Peter Scheidt said. It will be among the first observable outcomes that we'll have available to us, and I genuinely believe that the care of infants and children is going to improve dramatically in the next 5 to 10 years because of the work of the Study.

For me, it's also particularly poignant in that I'm speaking to you from a hotel room, getting ready for the rehearsal for my son's wedding, which is taking place tomorrow. And so as I'm reflecting on family and family values right now, and particularly on future grandchildren for myself someday, I realize at a very personal level how important this is. And again our very specific interest in prematurity, preterm birth, the consequences of prematurity and all of its complications—the ability of the Study to bring the wonderfully powerful technologies of genetics and environmental sciences to bear on an incredibly important problem is going to provide investigators like ourselves and many others around the country with just wonderful opportunities to find the causes, to understand the outcomes, and to really change the care of these kinds of children.

Iowa, again, has terrific perinatal health programs and lots of experience in epidemiology and birth defects, and we feel incredibly fortunate to have

been selected to be a part of the Study and to bring our own unique blend of children and their families to bear on the Study as well as what we hope will be some of our own investigative capabilities to try and improve it.

So we'd just like to thank everybody for this opportunity to congratulate the Vanguard Centers and the other participating Study Centers and especially all of the leadership for making this possible.

Duane Alexander: Jeff, thanks very much. And congratulations. And welcome to you and the other Wave 2 investigators to the National Children's Study. You have a special interest here; maybe if you can get your son and his wife to settle in Polk County and have a baby in the next 5 years, they can be participants of this.

Jeff Murray: We'll offer them that possibility.

Duane Alexander: Wonderful though the science of this study may be, and important and necessary as it may be, we wouldn't be where we are with this study without the incredible efforts of the advocacy community, both the advocacy organizations and the professional societies.

Leading these groups has been a partnership between the March of Dimes and the American Academy of Pediatrics. But many other advocacy organizations have participated. In fact, under the leadership of these two organizations, they have put together a coalition that regularly puts together a letter urging congressional support for the National Children's Study with over 100 people and organizations signed on. So they have done an incredible job, and we certainly would not be where we are with the funding of this study without them.

Leading the effort with the March of Dimes is its president, Dr. Jennifer Howse. Jennifer, welcome, and we welcome your remarks.

Jennifer Howse: Thank you very much, Duane, and again, congratulations to you and to Peter on your remarkable leadership of the Study. And it's just coming along wonderfully. It's such a wonderful occurrence for the advocacy community when programs really move forward in such a commendable way.

The March of Dimes is very pleased to be part of supporting this effort. And as you all know, I think, the mission of our organization is to improve the health of babies by preventing birth defects, premature birth, and infant mortality. And we're really very certain that the National Children's Study will make vital contributions to our mission in a number of important ways.

As you have been listening, of course, one of the targeted areas of the Study is pregnancy-related outcomes, and you've heard from the other speakers that even though our nation has certainly made great progress over the last several decades in improving maternal and infant health, nevertheless the reality is that the United States still lags behind more than two dozen industrialized countries in infant mortality. And of course, the problem that we've all been speaking about, preterm birth, has continued to get more and more serious. It's increased by 30 percent since the mid-1980s and now affects over 530,000 babies each year.

You heard Peter cite the Institute of Medicine study that this problem is costing our nation \$26 billion a year on an annual basis because of the consequences of preterm birth both in development and in chronic negative health conditions.

So the March of Dimes, as many of you know, did launch a campaign in January of 2003, a national prematurity prevention campaign to both raise public awareness about the seriousness of this problem and to engage in research and partnerships and outreach and projects that could have an impact on the rate of preterm birth. And in fact I really invite all of your participation—next month, we'll be issuing a state-by-state report card on preterm birth rates, calling on the government and hospitals and employers and health professionals to focus on solutions.

But at the center of all of these efforts, even in better applying what we already know, translating information for consumers and health professionals—at the core of all of these efforts, and really at the core of this National Children's Study is the incredible importance of research to help us understand the fundamental factors, particularly genetic and environmental, that contribute to the problem of preterm birth. The research can really lead us to the answers and solutions that we need in order to intervene and to reduce the rate of early deliveries. And our organization, we have absolutely no doubt that the Study in fairly short order will be able to provide invaluable data on the causes of birth defects and premature births and the role that infection and inflammation may play in causing preterm birth and related birth defects. There are many, many important areas of discovery that are now under way.

So I think by following 100,000 children from diverse backgrounds, from gestation through infancy, childhood, and adolescence and young adulthood, this study—our National Children's Study—is going to provide a much-needed, detailed health portrait for our nation.

I'm sure many of you have been following the financial situation, the crisis, the meltdown, as we have here at March of Dimes, and there's no doubt that we have a time of great fiscal constraint before us. And I think

that it is so important for us to recognize that this is not the time to cut back on our nation's commitment to our future, which is improving the health and well-being of our children. So I really wanted to express on this call the redoubled effort and commitment of the March of Dimes and, I know, many others in the advocacy community to support the Study—to support its conduct, its expansion, and the dissemination of its results. I really will be looking forward to continuing to reach out to stakeholders, which include all of you on this call, in this important study for us to continue to work vigilantly and diligently with the Congress and with the new administration to continue full funding for this very, very important project.

So with these thoughts in mind, Duane, let me turn it back to you.

Duane Alexander: Jennifer, thank you very much. And thanks for your continued help and support for this study.

The advocacy partnership, leadership from the professional society side, has been provided by the American Academy of Pediatrics. And the point person there, as chair of the Committee on Federal Government Affairs has been Dr. Mike Genel, Professor Emeritus of Pediatrics at Yale. Mike, we welcome you and your comments and thank you for all you've been doing.

Mike Genel: Well, thank you, Duane, and thank you for your leadership.

As you stated, I am representing the American Academy of Pediatrics and its more than 60,000 member pediatricians and pediatric specialists. I have served as a liaison member of the Academy's Committee on Federal Government Affairs for almost 25 years, and I have also been privileged to serve on the National Children's Study Federal Advisory Committee since April 2005.

By way of background, I am a pediatric endocrinologist and clinical investigator who has been in an active clinician for almost 40 years and has been engaged in research to better understand disorders of growth and development in childhood, as well as to provide better treatments for children with chronic illness such as diabetes. The insulin pump was developed by my pediatric endocrine unit almost 30 years ago.

Now the Academy was an early advocate for the development of a longitudinal study of children and has remained a strong advocate for full implementation of the National Children's Study since it was authorized in the Children's Health Act of 2000. As Duane mentioned, more than 100 other professional organizations, including all of the major organizations that represent academic pediatricians, that is, pediatric investigators,

teachers, and administrators, actively support implementation of the National Children's Study.

I had intended to summarize the potential accomplishments of the National Children's Study, but my colleagues who preceded me have done this quite well. In fact, thinking that this is the time of the Major League Baseball playoffs, I suppose I'm last in the batting order rather than being the clean-up hitter.

As a pediatric endocrinologist, I have observed at close hand and with considerable dismay the epidemic of childhood obesity and its consequences, including early type 2 diabetes, which until recently we seldom saw, if ever, in children; premature cardiovascular disease and hypertension; and liver failure. By the time many of these youngsters come to our attention, it is difficult to reverse the process.

There's also a rising incidence of type 1 diabetes, or so-called juvenile diabetes, at least as seen in our pediatric endocrinology centers, which is thought to reflect the intersection of genetic vulnerability with environmental factors. This is also the case with other endocrine disorders such as hypothyroidism.

It is unquestioned, as my predecessors have mentioned, that many disorders of adult life have their origins in childhood: hypertension, coronary heart disease, certainly obesity. Better understanding of the multifactorial origins of these disorders and the interactions of biologic factors including genetics with the environment offers an immense opportunity for preserving a better quality of life while effectively reducing our health care costs.

Now the Academy's membership has been engaged through the Academy's advocacy network in contacting members of Congress to both educate them about the National Children's Study and to seek support in continued support for the Study. This advocacy will continue, and we are certain that the Study will receive the sustained and robust federal support it needs during the duration of the Study.

As noted, the Academy and the March of Dimes have worked closely with the congressional offices, including the Children's Study Working Group, where you had the briefing earlier today.

I think rather than repeat what everybody has said so well, I will close at that point. Thank you.

Duane Alexander: Thank you for your comments and for your continued strong leadership role in advocacy for the National Children's Study.

That concludes the formal presentations. At this time, we're going to open the microphone and the telephone lines for questions from any of the participants. We were scheduled to close at 4:00 p.m., but since it's almost 4:00 p.m. already, we will continue to be available as long you have questions. The operator will tell you how to ask the questions.

Operator: Thank you. Ladies and gentlemen, if you'd like to ask a question, we ask that you please press the 1 key on your touchtone telephone. If you feel that your question has been answered or you wish to remove yourself from the queue, please press the pound key. Once again, ladies and gentlemen, if you have a question, please press the 1 key at this time.

I'm showing no questions at this time. Once again, ladies and gentlemen, if you'd like to ask a question, please press the 1 key on your touchtone telephone. We do ask that you state your organization prior to asking your question.

Our first question comes from Melanie Marty. Please state your organization.

Melanie Marty: Hi, I'm with the California EPA Office of Environmental Health Hazard Assessment. And I just had a question about the environmental chemical exposures that are being measured. Are the individual Study Centers going to measure things, chemicals that they think are more important in their communities, or is there a list of chemicals that will be measured across the board, or is it both?

Peter Scheidt: This is Peter Scheidt. All the individual Study Centers will carry out the rigorous core protocol the same. And most of the chemical measures—the samples that they will be collecting—will not be analyzed immediately, but will be stored in a large repository. Especially the biologic markers that are stable will be stored in order to do analyses later and to preserve the maximum flexibility for those samples and to be able to do embedded case controls on a smaller number of samples that will allow us to carry out many more analyses than if we had to do all 100,000.

For some chemicals, it will be necessary, especially on the environmental samples, such as air and water especially, and dust—some chemical analyses will need to be done prospectively, up front. And some of those such as volatile hydrocarbons are not stable and must be done initially. But the majority will be done later.

In that way, there is a much greater flexibility about the many different kinds of analyses that can be accomplished.

Melanie Marty: Thanks.

Operator: Thank you. Once again, ladies and gentlemen, if you'd like to ask a question, please press the 1 key at this time.

Our next question comes from Donna Dabelea. Please state your organization. Miss Dabelea? Your line is open.

Donna Dabelea: Thank you. This is Donna Dabelea at the University of Colorado Denver, Colorado School of Public Health. My question is about whether Centers and investigators participating in the National Children's Study will be able to design ancillary studies to make use of the population participating in the Study and/or the samples collected as part of the National Children's Study.

Peter Scheidt: This is Dr. Scheidt, again. And the answer to that is "Yes." The investigators at the involved Centers are encouraged to take advantage of this platform of research and develop ancillary or adjunct studies on portions of the sample in greater depth than the core protocol for all 100,000 would permit.

But it's not limited to investigators at the funded Centers. Investigators from outside of those groups are also encouraged to creatively propose studies that take advantage of this remarkable opportunity as well.

Let me add, much additional information about adjunct studies and other components of the National Children's Study is available on the National Children's Study Web site, NationalChildrensStudy.gov, all one word, no apostrophe, and even the application procedures and Web-based forms are already there and ready for use.

Operator: Thank you.

Once again, ladies and gentlemen, if you'd like to ask a question, please press the 1 key at this time.

I am showing no further questions at this time.

Duane Alexander: If there are no further questions, we will consider this session closed. We thank all of you for participating; special thanks to the speakers for sharing their time and thoughts with us. We welcome the doubling of the number of the participants in this study with the addition of these Wave 2 sites that have just been funded, and we look forward to working with you in the days ahead.

Thank you very much. We stand adjourned.

Operator: Ladies and gentlemen, that does conclude today's conference. Thank you for your participation, and have a wonderful day. You may all disconnect.