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EXAMINING PUBLIC HEALTH LEGISLATION:

H.R. 2820, H.R. 1344, AND H.R. 1462

THURSDAY, JUNE 25, 2015

House of Representatives,

Subcommittee on Health

Committee on Energy and Commerce

Washington, D.C.

The Subcommittee met, pursuant to call, at 10:10 a.m., in Room 2322 of the Rayburn House Office Building, Hon. Joe Pitts [Chairman of the Subcommittee] presiding.

Members present: Representatives Pitts, Guthrie, Barton, Murphy, Lance, Griffith, Bilirakis, Ellmers, Brooks, Collins, Green, Capps, Schakowsky, Butterfield, Castor,

Matsui, Schrader, Kennedy, and Pallone (ex officio).

Staff present: Clay Alspach, Chief Counsel, Health; Noelle Clemente, Press Secretary; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Chris Santini, Policy Coordinator, Oversight and Investigations; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Health Policy Coordinator; Traci Vitek, Detailee, Health; Greg Watson, Staff Assistant; Christine Brennan, Democratic Press Secretary; Jeff Carroll, Democratic Staff Director; Waverly Gordon, Democratic Professional Staff Member; Tiffany Guarascio, Democratic Deputy Staff Director and Chief Health Advisor; Ashley Jones, Democratic Director of Communications, Member Services and Outreach; Una Lee, Democratic Chief Oversight Counsel; and Samantha Satchall, Democratic Policy Analyst.

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Mr. {Pitts.} Our guests can take our seats. We are voting on the Floor right now, so we are going to try to expedite this a little bit, get through our opening statements on the panel. I would ask the Members to abbreviate their opening statements so that we can go to the Floor and came back after the votes to hear the testimony and do the Q&A.

I have a UC request. I would like to submit the following documents for the record: a statement from Representative David Jolly, Florida 13; a letter of support from American Academy of Pediatrics, American Congress of Obstetricians and Gynecologists, March of Dimes, and Society of Maternal-Fetal Medicine. Without objection, those will be entered into the record.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} The Chairman will now call the subcommittee to order and recognize himself for an opening statement.

Today's hearing will examine three bipartisan public health bills to improve health care for newborns, infants and children. As many of you know, one of this subcommittee's top priorities has been helping and protecting children and families. These bipartisan bills that are the subject of today's hearing represent our ongoing effort to work together to strengthen public health and solve problems in our Nation's health care system.

H.R. 2820, the Stem Cell Therapeutic and Research Reauthorization Act, introduced by Representative Chris Smith of New Jersey and Doris Matsui of California, reauthorizes the Stem Cell Therapeutic and Research Act of 2005, which provides federal support for cord blood donation and research essential to increasing patient access to transplant.

H.R. 1462, the Protecting Our Infants Act of 2015, authored by Representatives Katherine Clark of Massachusetts and Steve Stivers of Ohio, will combat the rise of prenatal opioid abuse and neonatal abstinence syndrome. The bill will address the growing problem of overdose deaths involving heroin and help protect newborns and infants. Additionally,

this bill has a Senate companion bill, S. 799 sponsored by the Senate Majority Leader Mitch McConnell.

Finally, H.R. 1344, the Early Hearing Detection and Intervention Act of 2015, authored by Health Subcommittee Vice Chairman, Brett Guthrie and Representative Lois Capps, amends the Public Health Service Act to reauthorize a program for early detection, diagnosis and treatment regarding deaf and hard-of-hearing newborns, infants, and young children.

I would like to welcome all of our witnesses here today. We look forward to your testimony.

[The prepared statement of Mr. Pitts follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} I now recognize the ranking member, Mr. Green, for his opening statement.

Mr. {Green.} Thank you, Mr. Chairman. I have a statement I would like to put in the record.

I want to welcome our panels.

These bills are all very bipartisan, and I appreciate the Chair and the Majority setting them for today, but I would like to ask unanimous consent to place my statement into the record and yield--

Mr. {Pitts.} Without objection, so ordered.

[The prepared statement of Mr. Green follows:]

********** COMMITTEE INSERT **********

Mr. {Green.} --my time to my colleague from California.

Mrs. {Capps.} Thank you, Mr. Chairman, and thank you, Mr. Green for yielding time, and I appreciate the hearing on these important bills.

I am particularly pleased that H.R. 1344, the Early Hearing Detection and Intervention Act, will be discussed here today. As a co-author of that bill along with my colleague, Representative Guthrie, I thank you for including this reauthorization in today's hearing.

Since the program received its authorization in 2000, we have seen how vital it is for babies and their families. As a school nurse, this hits home for me too. Back in 2000, only 44 percent of newborns were being screened for hearing loss. Now we are screening newborns at a rate of over 98 percent before they leave the hospital and linking them to follow-up care, which is the critical piece, and we know that early intervention is key in helping children with hearing loss achieve academically and developing in line with their peers.

Our work isn't done. As a school nurse, I had a lot of interaction with students who were already behind lagging from their classmates due to undiagnosed and/or untreated hearing loss. We can prevent more children from suffering in

the classroom through better investment in follow-up and intervention as part of a successful hearing screening program for newborns and infants. We need to ensure that every newborn is screened, every family has access to follow-up care. Early identification and intervention are key to a child's well-being, and that is what this bill would support.

I am hopeful we continue to work in a bipartisan way to move this and other bills that we are examining today and bring them all to the Floor this year.

So thank you, witnesses, for being here, and I yield back.

[The prepared statement of Mrs. Capps follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} The Chair thanks the gentlelady.

Chairman Upton has asked to yield his time to Representative Guthrie, so the Chair recognizes Representative Guthrie at this time.

Mr. {Guthrie.} Thank you very much. In the interests of time, Congresswoman Capps had a lot of statements that I was going to make, so I am pleased to be here to support 1344 that I am pleased to have co-authored with Congresswoman Capps. And I have been interested in this issue, early detection and screening, since I was in the State legislature. I did research when a bill was going through the legislature and learned if a newborn--at the early stages if you have hearing loss and you don't have the opportunity to hear correctly, you can never gain that back, even if you learn it as a young adult or a teenager or whatever. You can never gain it back.

The current law is set to expire September of 2015, a mere 3 months from now, and these services will go away and we will lose the opportunity to catch these early screenings. So I am pleased that Chairman Pitts has put this on the agenda for today. This bill appears to be moving forward, and I appreciate working with Congresswoman Capps, and I appreciate your time, Mr. Chairman, and I yield back.

[The prepared statement of Mr. Guthrie follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} The Chair thanks the gentleman. I thank him for expediting as well.

The Chair now recognizes the Ranking Member of the full committee, Mr. Pallone, for his opening statement.

Mr. {Pallone.} Thank you, Mr. Chairman.

Did you have a statement on the other side?

Mr. {Pitts.} Yes, we did.

Mr. {Pallone.} Okay. I know you are trying to get it done fast here.

Let me thank Chairman Pitts and Ranking Member Green for holding this hearing on important pieces of legislation that will surely improve the health of our Nation. I am pleased that all three bills have robust bipartisan support and continue this committee's tradition of a thoughtful, collaborative approach to public health legislation.

I am not going to read all the bills. I mean, obviously H.R. 2820, the Stem Cell Therapeutic and Research Reauthorization Act, it continues the highly successful Be The Match Registry for bone marrow, and this bill ensures that this critically important program continues to operate.

As far as H.R. 1344, the Early Hearing Detection and Intervention Act of 2015 introduced by Representatives Capps and Guthrie, obviously this is important for newborns who now

are regularly screened for hearing loss, and so this is something that we support.

And finally, H.R. 1462, the Protecting Our Infants Act of 2015, is a greatly needed piece of legislation to address a sad reality of our country's opioid epidemic. This bill rightly recognizes the immediate need for a comprehensive national strategy to address prenatal opioid abuse. So I also thank Representative Clark. She has talked to me about this in the past. I look forward to working with you and our colleagues on these important public health bills.

I yield the remainder of my time to Representative Capps--she already spoke.

I yield back. Thank you.

[The prepared statement of Mr. Pallone follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} The Chair thanks the gentleman, and the Chair recognizes Mr. Green for a UC request.

Mr. {Green.} Mr. Chairman, I ask unanimous consent to place into the record a statement by our colleague, Doris Matsui, in support of the bills.

Mr. {Pitts.} Without objection, so ordered.

[The prepared statement of Ms. Matsui follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} I have someone monitoring the Floor with the number of minutes and Members not voting, so I will keep you updated on that.

At this time I will introduce our panel. We have one panel today, and thank you all for coming. I will introduce you in the order of your presentations and ask if you can abbreviate them somewhat. At some point if we don't get through them, we will have to go to the Floor and return to hear the rest.

But first Dr. Jeff Chell, Chief Executive Officer, National Marrow Donor Program; Dr. Joanne Kurtzberg, President of the Cord Blood Association; Dr. Patti Freemyer Martin, Ph.D., Director of Audiology and Speech and Language Pathology, Arkansas Children's Hospital; Dr. Stephen Patrick, Assistant Professor of Pediatrics and Health Policy, Department of Pediatrics, Vanderbilt University School of Medicine; and finally, Dr. Mishka Terplan, Medical Director of Behavior Health Systems of Baltimore.

Thank you for coming today. Your written opening statements will be made a part of the record as will all Members' written opening statements as usual. You will be given 5 minutes to make your summary. If you can abbreviate that, we would appreciate it.

So at this point, the Chair recognizes Dr. Chell for 5 minutes.

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^STATEMENTS OF JEFFREY W. CHELL, M.D., CHIEF EXECUTIVE OFFICER. NATIONAL MARROW DONOR PROGRAM; JOANNE KURTZBERG, M.D., PRESIDENT, CORD BLOOD ASSOCIATION; PATTI FREEMYER MARTIN, PH.D., DIRECTOR OF AUDIOLOGY AND SPEECH LANGUAGE PATHOLOGY, ARKANSAS CHILDREN'S HOSPITAL; STEPHEN W. PATRICK, M.D., M.P.H., M.S., ASSISTANT PROFESSOR OF PEDIATRICS AND HEALTH POLICY, DEPARTMENT OF PEDIATRICS, VANDERBILT UNIVERSITY SCHOOL OF MEDICINE; AND MISHKA TERPLAN, M.D., M.P.H., FACOG, MEDICAL DIRECTOR, BEHAVIOR HEALTH SYSTEM BALTIMORE

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^STATEMENT OF JEFFREY W. CHELL

} Dr. {Chell.} Good morning, Mr. Chairman and other distinguished Members of the Committee. Thank you so much for inviting us today.

As you have heard, I serve as the CEO of the National Marrow Donor Program and Be The Match. We have operated the C.W. Bill Young Cell Transplantation Program since its inception, and that includes a single point of access, the Office of Patient Advocacy, the Bone Marrow Coordinating Center, as well as the Cord Blood Coordinating Center, and with the Medical College of Wisconsin, we hold a contract for

the Stem Cell Therapeutics Outcome Database through our research entity, the CIBMTR. I serve as Executive Director of that entity.

I would like to thank you all and members of the subcommittee for inviting us to speak on behalf of our 565 network partners all over the world, and at the NMDP, we deeply appreciate your support of helping us fight blood cancers through transplantation, often, the only potential cure for these deadly diseases. I would also like to thank Representatives Chris Smith, Doris Matsui, David Jolly, and Chaka Fattah for their leadership in introducing H.R. 2820.

As I testify before you today, I am reminded of a hearing in 1987. On that day, the late Congressman Bill Young called on Congress to establish the national registry where children and adults with leukemia and other fatal blood disorders could find a donor. Congress heard that call at that point and established the national registry.

Congressman Young's vision was inspired by a child, 11-year-old Brandy Bly, who was fighting leukemia. No one in her family was a suitable match, and without access to a transplant, she would not survive. At that time there was no registry available, and it was the simple statement from her physician that really stimulated Congressman Young to take action, and he said ``Wouldn't it be great if there was a

registry of donors that we could tap in to help save a life like this this?'' and that really became the basis of our national registry.

Since that hearing in 1987, we have made great progress. The NMDP is now the global leader in providing cellular therapy, which is often the only treatment available that can cure some of these life-threatening blood disorders and other significant diseases like sickle cell disease. We also educate healthcare professionals, conduct research, and offer support and education in multiple languages to help patients lead healthy lives after transplant. Today, children like Brandy have a much better chance for a lifesaving transplant.

We have been honored to serve as the steward of this critical resource for the last 28 years. During that time, the growth of transplant has increased significantly, and even since 2005, transplants overall have grown 200 percent, and for minorities it has grown 250 percent. We now have over 12 million donors in our registry and over 200,000 cord blood units, but we partnered with 66 registries all over the world to provide a total of 25 million donors and over 600,000 units of cord blood, and it is as easy to find a donor and make that transplant happen if that donor was halfway across the world or across the street.

Outcomes for transplant for have also improved as well

as the number of transplants, so your survival has gone from 40 percent to over 70 percent in the last 10 years. But we are especially proud--if we could show the first slide--of our work fighting diseases afflicting children.

In 2014, we facilitated 1,200 unrelated transplants for patients 18 years and older, and the first slide shows how important the source not only bone marrow but also umbilical cord blood is in fighting transplants. Dr. Kurtzberg and other pioneers in this field introduced cord blood in the late 1990s, and those truly are helping patients that we would have otherwise not been able to help.

But your ongoing commitment has made these advances possible and turned the tragic loss of Brandy into hopes for tens of thousands of Americans. One of those is Hadley Mercer. She was just 6 months old when she was diagnosed with acute myeloid leukemia. After two rounds of chemotherapy, her parents and physicians agreed that a bone marrow transplant was likely her only chance as well as her best chance of survival. We found a perfect match for her, a young man in his 20s. Now almost 2 years old, she is going to have a normal and healthy life because of her donor angel. She is also alive because of your continued support for the C.W. Bill Young Cell Transplantation Program.

The NMDP has never forgotten the importance of that

physician's simple statement that inspired Congressman Young, and every day we are inspired by people who we meet, young and old, who are seeking to find that match. If we could show the next slide?

[Slide]

It shows us that even though we have made tremendous progress, we are meeting less than half the need of the pediatric population, and in this slide you can see the lighter-colored areas are areas where we are only meeting 25 percent or more of the total need, and as we get darker colors, you can see that there is more and more. So there is many, many more children we can help. So thank you very much for your time and attention.

[The prepared statement of Dr. Chell follows:]

********** INSERT A **********

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Mr. {Pitts.} The Chair thanks the gentleman, and we are out of time on votes for the Floor. At this point the Chair recognizes Dr. Kurtzberg.

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^STATEMENT OF JOANNE KURTZBERG

} Dr. {Kurtzberg.} Mr. Chairman, Ranking Member Green, and members of the subcommittee, thank you for inviting me to discuss H.R. 2820, the Stem Cell Therapeutics and Research Reauthorization Act of 2015. My name is Joanne Kurtzberg, and I am the President of the Cord Blood Association of Pediatric Transplant and I am the Founder and Director of the Carolinas Cord Blood Bank, which is a public cord blood bank at Duke.

I want to thank both Congressman Chris Smith and Congresswoman Doris Matsui for their leadership and the introduction of this legislation. I also want to acknowledge the subcommittee's bipartisan commitment to the creation and support of the NCBI, or National Cord Blood Inventory, a public cord blood banking network which began when this bill was introduced in 2005.

I am talking about a network of banks that save cord blood, which is the baby's blood remaining in the placenta, or afterbirth, after the baby is born. In the past, this cord blood was discarded as medical waste, so it has never been a controversial source of stem cells. Cord blood contains stem and progenitor cells of the blood and other

tissues, and it can be collected without harming the mother or the baby and banked for future use, and I put a picture up there of what the bag looks like that we save cord blood in. We save it in less than an ounce of fluid in two compartments with little pigtails so we can test it later and make sure it is appropriate for a patient for transplant.

[Slide]

If I could have the next slide, it shows you a picture of the very first recipient of cord blood transplant in the world, who is a little boy from North Carolina with a fatal disease called Fanconi anemia. His sister was a match and not affected, and when he was 5 years old he went to France for this transplant, and you can see him 27 years later doing well, a happy, healthy, working, married adult with me. He reached the benchmark of being taller than me, which is what many of my patients like to do post-transplant. But most importantly, he is fully engrafted with his baby sister's cells, and that proved that cord blood contains stem cells of the blood.

[Slide]

Next slide. Briefly, after that transplant, unrelated donor cord blood banks were established, first at the New York Blood Center, later through support from Congress to establish at NHLBI the COBLT program at Duke and two other

sites, and as you know, the first legislation was passed in 2005 establishing the National Cord Blood Inventory as part of the C.W. Bill Young Cell Transplantation program. This stem cell source is unique because FDA has issued guidance to license cord blood, and there are now five licensed cord blood banks in the United States. In 2014, we also created the Cord Blood Association to represent both public and private cord blood banks and the cord blood community.

[Slide]

Next slide, you can see just the milestones in cord blood transplantation. It has been pioneered in children with inherited metabolic diseases. It has been used with two cord blood or double cord blood transplantation at the University of Minnesota, and there have been over 35,000 cord blood transplants performed worldwide and 160 banks established worldwide since it started.

[Slide]

This just shows you--next slide--some of the research that is going on, so we now have ways to expand cord blood in the red line, so that the patient is in graft in 6 to 10 days instead of 20 to 30 days, and if you would go to the next slide, you will see some just facts about the NCBI. There are 13 members, five licensed banks, and not all the money appropriated has actually been--authorized has been

appropriated over the past 10 years, but with the funding we have had, 90,000 high-quality, diverse cord blood units have been stored.

[Slide]

The next slide shows you a kit that we can send out to moms who want to donate anywhere in the country so the cord blood can be stored in the national inventory.

[Slide]

The next slide shows you just an example of a little boy with Hurler syndrome. This is a fatal disease where children die by age 5. With a cord blood transplant, you can see on the right, this child is a healthy adolescent with normal intelligence, and many children with these kind of diseases have been helped.

[Slide]

The next slide lists some of the exciting regenerative medicine trials that are emerging for uses of cord blood beyond treating patients with leukemia and other diseases, and that includes autism, hearing loss, stroke, and cerebral palsy.

[Slide]

The next slide shows you some data showing that babies with birth asphyxia have had their outcomes improved when they receive a cord blood infusion in the first 2 days of

life.

[Slide]

The next slide shows you our data from Duke showing that a cord blood infusion can actually help children with cerebral palsy regain function and regain normal performance, and the next slide shows you just how the brain can, in the lower left, actually re-form connections after a cord blood infusion.

So I thank you for your attention and for your support, and we will be able to entertain questions later.

[The prepared statement of Dr. Kurtzberg follows:]

********** INSERT B **********

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Mr. {Pitts.} The Chair thanks the gentlelady, and I apologize for the interruption here but we must now go to the Floor to vote. We are going to vote for three bills and then we will recess for that and come back immediately for the rest of the hearing.

So without objection, the subcommittee stands in recess.

[Recess]

Mr. {Pitts.} The time for our recess having expired, we will reconvene the subcommittee, and we are now ready for Dr. Martin. You are recognized for 5 minutes for your opening statement.

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^STATEMENT OF PATTI FREEMYER MARTIN

} Ms. {Martin.} Good morning, Mr. Chairman and members of the committee. I want to express ACH's and my appreciation to Congressman Guthrie and Congresswoman Capps for their leadership in introducing H.R. 1344, the Reauthorization of the Early Hearing and Detection Intervention Act for Children.

This important bill provides assistance to States in identifying hearing loss in infants and young children and places an emphasis on ensuring that those identified with hearing loss receive appropriate intervention.

Hearing loss is the most commonly occurring condition that newborns are screened for. Three babies per thousand are born with hearing loss, and this number almost triples by the time children enter kindergarten.

When hearing loss is detected early, children can learn sign language, be fit with hearing aids for cochlear implants and/or receive early intervention services that enable them to achieve on par with their hearing peers. If it is not detected early, it can be devastating to children's academic and psychosexual development. There is now abundant scientific evidence that the brain develops in response to

early visual and/or auditory stimulation, which is critical for children with hearing loss. Almost 30 years ago, a report commissioned by Congress showed that the average deaf child at that time had a 4th-grade reading level when they were old enough to graduate from high school, in large part due to the fact that these children were not identified until they were 2-1/2 years to 3 years old. Since newborn hearing screening has been implemented, we have seen the average age of identification drop to 2 to 3 months. More importantly, deaf children who are diagnosed early and receive appropriate early intervention often achieve on the same level with their hearing peers by the time they reach 1st grade.

H.R. 1344 is the reauthorization of a very successful program, which has been in place for 15 years. Because of this initiative called EHDI, 98 percent of babies are now screened for hearing loss before they are discharged from the hospital. Most of these babies go home to families where it never even occurred to their parents to wonder if they could hear them sing or whisper or cool mommy loves you or daddy's big boy. Early screening allows those infants who do not need assistance to be connected with services--who need assistance to be connected with services, to learn to communicate with their families using sign language and/or hearing technology and start on the path to prepare them for

school readiness. Of babies who need follow-up, we know that 95 percent of those are born to hearing parents, often with little or no exposure to individuals who are deaf or hard of hearing. They find themselves in a situation that was unanticipated and for which their roadmap on parenting and all their how-to guides may not really apply. A great resource for many of these parents is having access to adults who are deaf or hard of hearing or other forms of parent-to-parent support and family-to-family support as stipulated in this bill.

There is much to be proud about this previous legislation that has captured in the reauthorization. The EHDI program has enabled unprecedented collaboration between public and private agencies and across all levels of government. The EHDI program is often cited as a model of how government at different levels and private and public entities should and can work together. The reauthorization continues to emphasize the partnerships among HRSA, CDC and the NIH, and includes language for those agencies for further collaboration.

I want to call your attention to a couple of sections in the bill. First, it focuses on continuing to provide limited federal support to programs already in place for infants. In the previous version of the bill, the focus was exclusively

on babies. This bill reauthorizes services for babies and extends it to young children. This is critical because now we know that by the time children are 5 years of age, we will almost triple the number of children who have hearing loss, and we need to intervene with this group early so that they are ready to learn when they hit school age.

Another important aspect is the focus on families being involved and empowered in the process for their children in a timely way. So engaging and enabling these families is not just desirable but critical. Family involvement is described as the tipping point for children having full access to language, whether it is visual, spoken or a combination of both, and involvement with families is described as family-to-family support and from a variety of professionals including deaf and hard-of-hearing consumers in this bill.

It is about more than just screening for hearing loss. We do screening really well but there is work to be done on getting appropriate services for many infants and young children. We have the basis in place but systems to ensure that infants with hearing loss receive the appropriate follow-up for diagnosis, for medical care, and early intervention services from providers that have the knowledge and skills to help them communicate with their families needs to be refined and improved.

Because of previous funding for the EHDI programs, loss to follow-up has been reduced by half over the last 10 years, but there is much more work to be done.

Thank you.

[The prepared statement of Ms. Martin follows:]

********** INSERT C **********

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Mr. {Pitts.} The chair thanks the gentlelady and now recognizes Dr. Patrick 5 minutes for your opening statement.

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^STATEMENT OF STEPHEN W. PATRICK

} Dr. {Patrick.} Chairman Pitts, Ranking Member Green, and honorable members of the committee, my name is Stephen Patrick. I am a Neonatologist and Researcher at Vanderbilt University School of Medicine.

It is a privilege to speak with you today about the rising number of infants being born diagnosed with drug withdrawal in the United States. The bill before you, H.R. 1462, the Protecting Our Infants Act of 2015, makes positive steps to improve the health of women and infants impacted by opioid use and misuse.

A few months ago, I was caring for a 2-day-old baby in the neonatal intensive care unit at Vanderbilt Children's Hospital. At just 48 hours of life, the infant became fussy and jittery. Over the next 24 hours, the infant continued to worsen with diarrhea, sneezing and increased fussiness. Each of these signs are classic for drug withdrawal. However, as mother denied use of any drugs that may cause withdrawal, until the baby's drug screen came back positive for prescription opioids. Once I informed the mother of the baby's drug screen, she reluctantly admitted that she had been using pain pills without a prescription. The baby

remained in the hospital for a bit undergoing treatment.

And as I reflected on this case, I began to wonder, what if the infant had been discharged to home at the typical 24 hours of life only to have drug withdrawal at home. Would he have been brought back to the hospital critically ill, and with systems may help his mother be more knowledgeable and forthcoming about her drug use, and how do we connect her with drug treatment, particularly during pregnancy. This situation unfortunately is increasingly common.

Neonatal abstinence syndrome is a drug withdrawal syndrome that infants exposed to opioids experience shortly after birth. Opioids pass from the mother through the placenta to the fetus. At the time of birth when the supply is stopped, the infant is at risk of developing drug withdrawal within the first few days of life. Infants with neonatal abstinence syndrome have difficulty feeding and are more likely to have breathing problems, tremors, increased muscle tone, fever, difficulty sleeping, and inconsolability. Severe neonatal abstinence syndrome requires treatment with an opioid like morphine or methadone and an average hospital stay of about 3 weeks. Watching an infant have drug withdrawal is distressing for doctors, nurses, and for parents.

According to the Centers for Disease Control and

Prevention, the number of prescription opioids used in the United States quadrupled over the last decade, and by 2012, there were 259 million prescriptions written for an opioid, more than one for every American adult. This rapid increase in opioid use and misuse impacted nearly every population in the United States including women of childbearing age and pregnant women, and a study our group published in May using data from the Tennessee Medicaid program, we found that of 110,000 pregnancies in a 3-year period, nearly 30 percent filled a prescription for an opioid pain reliever during pregnancy.

Throughout the country, as prescription opioid use grew, so did the incidence of neonatal abstinence syndrome. Using billing data from the Nation's hospitals, our research team conducted a series of studies to determine national rates of neonatal abstinence syndrome. From 2000 to 2012, the number of infants diagnosed with the syndrome grew nearly fivefold. By 2012, one infant was born every 25 minutes on average in the United States with neonatal abstinence syndrome, accounting for an estimated $1.5 billion in healthcare expenditures, 80 percent of which are paid for by Medicaid.

The scope of the problem is staggering in some communities. For example, some areas of my home State, Tennessee, reported one in 20 infants born in their community

have neonatal abstinence syndrome, and in some NICUs, nearly 50 percent of their total annual hospital days are dedicated to treating this one condition. This rapid increase has largely caught communities and providers off guard. Today there are no well-researched standard treatment protocols for infants with NAS, and as a result, treatment and clinical outcomes vary widely throughout hospitals in the United States.

Addressing the complexity of perinatal opioid use and neonatal abstinence syndrome requires a thoughtful public health approach. Our goal should be to promote healthy mothers and infants by supporting prevention and recovery, and this must begin with primary prevention--engaging public health measures to prevent opioid misuse even before pregnancy including bolstering prescription drugs monitoring programs, improving access to contraception, ensuring opioid prescribing is necessary and appropriate, especially among pregnant women; and secondary prevention--improving screening for drug use in pregnancy and ensuring that drug treatment is available when it is needed and that it includes medication-assisted treatment when appropriate; treatment should be comprehensive, gender-specific, and inclusive of obstetric care; and tertiary prevention--improving identification and treatment of infants suffering with neonatal abstinence

syndrome and working to improve post-discharge outcomes.

Mothers and infants impacted by the prescription of opioid and heroin epidemics are in desperate need of a public health approach to address this problem. We cannot wait any longer to respond, and the status quo is simply unacceptable.

The Protecting Our Infants Act takes the necessary and important steps forward to improving research and service care delivery. For the patient I described in my introduction and for the thousands like him, we need the tools to learn how to treat him better, and perhaps even more importantly to prevent him from being there in the first place.

As a neonatologist and researcher, I applaud the bill's authors and the committee's interest in this critical public health problem and this issue that affects so many vulnerable mothers and infants in the United States today.

Mr. Chairman, I thank you for the opportunity to speak today and I look forward to your questions.

[The prepared statement of Dr. Patrick follows:]

********** INSERT D **********

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Mr. {Pitts.} The chair thanks the gentleman and now recognizes Dr. Terplan for 5 minutes for an opening statement.

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^STATEMENT OF MISHKA TERPLAN

} Dr. {Terplan.} Good morning, Chairman Pitts, Ranking Member Green, and distinguished members of the subcommittee, and thank you for having me here today.

My name is Mishka Terplan, and I am an OB/GYN and Addiction Medicine Specialist and the Medical Director of Behavioral Health System Baltimore. I am pleased to testify on behalf of the American Congress of Obstetricians and Gynecologists in support of H.R. 1462, the Protecting Our Infants Act. I would like to thank Representatives Katherine Clark and Steve Stivers for their leadership in introducing this legislation and the eight cosponsors on the Health Subcommittee, and I urge the committee to act swiftly in reporting out this bill.

H.R. 1462 represents a bipartisan, bicameral effort to address the critical problem of opioid addiction and neonatal abstinence syndrome facing pregnant women from all socioeconomic backgrounds. NAS refers to medical issues associated with drug withdrawal in newborns following prenatal opioid exposure and is expected and treatable with no long-term negative outcomes documented in the literature.

While I want to stress the importance of the mother-

infant dyad, my testimony will focus primarily on the woman and how passage and implementation of this bill would improve access to quality treatment and care for this population.

Specifically, the bill would commence three important initiatives that address the following: One, prevention and treatment of prenatal opioid use disorders. Preventing inappropriate opioid use among pregnant women and women of childbearing age is crucial. Quality preconception care and family planning optimize a woman's health and knowledge before conceiving a pregnancy, improving the likelihood of having a healthy pregnancy and a healthy baby. Among women with opioid addiction, almost 90 percent of their pregnancies are unplanned. All pregnant women are concerned for the health of their baby-to-be and are motivated to change unhealthy behaviors. Most pregnant women who use substances including opioids quit or cut back. Those who cannot stop using by definition meet criteria for having a substance use disorder. In other words, continued use in pregnancy is pathognomonic for addiction, which is a chronic relapsing brain disease.

When treating pregnant women with opioid addiction, withdrawal or detoxification are rarely clinically appropriate. Detox results in relapse, and any abrupt discontinuation of opioids can result in preterm labor, fetal

distress, or fetal demise. Safe prescribing during pregnancy includes opioid-based medications such as methadone or buprenorphine, which are standard of care for pregnant women with opioid addiction. However, pregnant women continue to face access issues and most do not receive opioid agonist therapy. Denying pregnant women evidence-based treatment in order to prevent NAS is discriminatory.

Additionally, opioid medication should be accurately labeled to ensure appropriate access to medication for women who are addicted and for whom the alternatives such as heroin or withdrawal during pregnancy are much more dangerous. Specifically, the FDA boxed warning related to pregnancy should be removed or updated to remove the inaccurate information linking opioid use during pregnancy with ``life-threatening neonatal opioid withdrawal syndrome,'' a claim with no scientific evidence.

Number two: Gaps in research and programming. Additional research is needed on effective and non-addictive pain treatment, and any such research should include women of childbearing age and pregnant women. However, it is important to note that medically appropriate opioid use in pregnancy is not uncommon, and opioids are often the safest and most appropriate treatment for a variety of medical conditions and severe pain during pregnancy. Pregnant women

with substance use disorders need access to comprehensive services including prenatal care, drug treatment, and social support. Punishing pregnant women with substance use disorders by targeting them for criminal prosecution or forced treatment is inappropriate and will drive women away from care. Innovative treatment models are needed and should be tailored to pregnant or parenting women and should provide priority access.

Number three: Improved data collection and surveillance. Opioid addiction has become more widespread geographically and demographically. In communities with high opioid prescription and addiction rates, there will be higher rates of pregnant women with opioid addiction and subsequent NAS. Access to national and State-specific NAS data would enable trend analysis and foster greater sharing of best practices and treatment strategies. Improved data collection would also help us better track and understand the long-term outcomes of infants with NAS. For those purposes, data endpoints need to be of both clinical and sociological significance.

Thank you for the opportunity to testify at today's hearing. The committee's attention to and interest in reducing maternal opioid addiction and NAS are crucial, and the Protecting Our Infants Act represents a positive step

forward in addressing this growing issue I welcome your questions. Thank you.

[The prepared statement of Dr. Terplan follows:]

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Mr. {Pitts.} The chair thanks the gentleman. That concludes the opening statements of our panel. We will now begin questioning. I will recognize myself for 5 minutes for that purpose.

Dr. Chell, we will start with you. In what patient population do you see the number of transplants rising the fastest, if you can give us sort of a--

Dr. {Chell.} Yes. The group that is rising the most quickly is the elderly population, the senior population, and that is growing by double digits every year, and the reason for that is, the medical conditions for which transplant is often the only cure tend to occur in older populations, diseases like acute myeloid leukemia, myelodysplastic syndrome, myelofibrosis, and others.

Mr. {Pitts.} Dr. Kurtzberg, while the cord blood and the bone marrow donor programs have enjoyed great success over the past 10 years, what, if any, are the barriers you face to realizing the full potential of these programs?

Dr. {Kurtzberg.} There are two major barriers I would cite. The first is that cord blood grows slower than bone marrow when you first give it for a transplant, and so there is a big need for more research to develop ways to expand cord blood in the laboratory before it is infused, and I

showed one slide showing that there is promising work being done in that area.

The second is that the cost of a cord blood transplant, and that is for procuring the donor and also taking care of the patient, is higher than some other types of transplantation, and part of that is due to the fact that with licensure of cord blood, the costs of manufacturing have gone up while the market-bearing price for reimbursement cannot change because really, it is already too expensive to have a transplant. So we are really struggling for cord blood to be able to be subsidized through programs like this so that the patient can afford to use the donor.

Mr. {Pitts.} Thank you.

Dr. Martin, can you elaborate on the importance of medical intervention for and follow-up with medical services for deaf individuals? Why is a public health-based approach important at this time?

Ms. {Martin.} Children with hearing loss need follow-up for medical intervention because sometimes hearing loss will be coexisting with other conditions. We want these children to be evaluated for what other coexisting morbidities might occur with hearing loss. What we do know is about a third of children with hearing loss also have another disability as well, and so that medical pace is really critical for them.

It makes it a very important public health program. The American Speech and Hearing Association, the National Center for Hearing Assessment and Management, the American Academy of Pediatrics, and American Academy of Otolaryngology have all worked really well on this to ensure that these children get the type of medical care that they need to assist them in having improved outcomes.

Mr. {Pitts.} Thank you.

Dr. Patrick, you have performed extensive research on neonatal abstinence syndrome. In your written testimony, you state that Medicaid spent $1.2 billion for NAS hospitalizations in 2012. In February of 2015, the GAO released a report that showed gaps in research funded by the Federal Government in this area. Where should future research focus to close those gaps?

Dr. {Patrick.} Well, we have research gaps throughout the continuum of neonatal abstinence syndrome. We need better measures to identify patients at risk of drug withdrawal. We need better systems to diagnose drug withdrawal. The current way we diagnose drug withdrawal is if we have an infant that we know has been exposed to an opioid, so we have to know that first, and then we score them on a system that can be pretty subjective. Basically it's an observation of the infant, and we go through a checklist of

what they look like. That was developed decades ago. We need better systems that are more objective and perhaps use technology to aid in that, and we also don't have great mechanisms to understand what is the most effective way to treat these infants, how can we be most efficient, how can we ensure that we can keep mom and baby together when we can. There is a lot that we have to learn, and I think there are gaps throughout the continuum of our treatment of infants.

Mr. {Pitts.} Thank you.

Dr. Terplan, can you provide more background on the statement in your testimony that the FDA boxed warning related to pregnancy is incorrect and is not validated with scientific evidence? What problems has this caused? To your knowledge, is the FDA in the process of addressing this?

Dr. {Terplan.} So the statement on the box is that use of methadone can cause life-threatening neonatal opioid withdrawal syndrome. The likelihood of death from NAS is no different from the likelihood of death for other infants born at matched gestational age. So it does not contribute in excess mortality risk to newborns, neonatal abstinence syndrome. So that is scientifically inaccurate.

The FDA has convened a panel to discuss the labeling of this medication that both ACOG and the American Society of Addiction Medication testified at a couple weeks ago, so they

are working towards that.

Mr. {Pitts.} All right. Thank you. My time is expired.

The Chair recognizes the Ranking Member, Mr. Green, 5 minutes for his questions.

Mr. {Green.} Thank you, Mr. Chairman. Again, I would like to thank our witnesses for being here today and also for your understanding of our unusual schedules to run and vote on the Floor.

I would like to ask about the treatment that is available to women with opioid use disorders during pregnancy. The GAO report released earlier this year cited numerous gaps in the treatment of NAS as well as into the treatment of women with opioid use disorders. One of the major barriers the GAO identified was the stigma and criminalization of pregnant women who struggle with substance use during pregnancy. For instance, some State laws require healthcare providers to report substance use during pregnancy to State or local law enforcement officials. One State, Tennessee, defines drug use during pregnancy as criminal assault. According to Guttmacher Institute, 18 other States treat substance abuse during pregnancy as child abuse under civil child welfare statutes.

Dr. Terplan, what is the impact of such laws on the

incentive for pregnant women to seek treatment for addiction as well as prenatal care?

Dr. {Terplan.} Thank you very much for asking that question. Criminalizing or punishing pregnant women for substance use during pregnancy is a disincentive for them to seek prenatal care or seek substance treatment services or to continue with them. I know anecdotally from colleagues of mine who practice in Tennessee, which is the only State that has explicitly criminalized substance use during pregnancy that they are seeing women who are entering prenatal care late, going across State lines to deliver, delivering at home. One colleague of mine had a patient who delivered at home out of concern for being reported. She started bleeding, and the infant had something going on. They went to the emergency room, and that point in time she was arrested, so her concern, her actual concern with avoiding healthcare because of a fear of being caught up in the criminal system was realized.

Mr. {Green.} How do these--Dr. Patrick, how do these laws impact the diagnosis of treatment of NAS?

Dr. {Patrick.} Well, I think in part, beginning with women avoid care, they are more likely to not seek care in a hospital, and that alone is a disincentive. It creates a barrier to improving infant outcomes. The other piece is

that we have to know about the exposure. If there aren't systems that allow women to be forthcoming about their drug use and seek treatment, then we don't know about the exposure. So the infant that I described in my introduction, if we didn't know about it and that infant didn't have a rapid weight loss within the first 2 days of life, that infant would have been discharged home because we wouldn't have known about it, having to withdraw at home and potentially having complications at home including severe dehydration.

So I think that is why these systems, public health systems and public health approach, is much preferred to a criminal justice approach.

Mr. {Green.} Well, and I understand the legislature and people are being shocked by a mother having a child that is a user. What would you recommend as effective alternatives to address the issue of the prenatal drug use and improve health outcomes for both the mother and the child?

Dr. {Patrick.} Well, I think it begins with a lot of what the bill is doing, to begin to get people at the table, to understand what are the knowledge gaps, how do we coordinate things better. It begins with a public health approach to improving access to treatments and to understanding how we curb opioid use and misuse overall, even

before pregnancy. I think the easiest way to prevent an infant having drug withdrawal in my unit is to prevent opioid misuse even before pregnancy. So I think those public health measures are critical.

Mr. {Green.} Dr. Terplan, you had identified a number of additional treatment gaps for pregnant women with substance use disorders. You mentioned, for instance, a lack of access to medication-assisted therapy for pregnant women.

Dr. Terplan, is medication-assisted treatment the standard of care for pregnant women with opioid use disorders?

Dr. {Terplan.} Yes, and not just for pregnant women. It would be for men and non-pregnant women. Medication-assisted treatment would be the standard of care for opioid use disorders.

Mr. {Green.} What are the barriers to women accessing medication-assisted therapy and what can the Federal Government do to address these barriers?

Dr. {Terplan.} There seems to be--we did some research on this. Only 40 percent of pregnant women who are admitted into drug treatment for an opioid use disorder receive medication-assisted treatment in the United States. Some of that has to do with context of treatment. There are many abstinence-only treatment modalities and treatment programs

so they are not getting access to it in the treatment context. I know in my State of Maryland, I hear a lot of questions from providers throughout the State. There are large counties in Maryland where there is not a single buprenorphine provider who will take pregnant women. So I am in the process of going around the State and educating the substance treatment providers on how to care for the pregnant women, and one of the concerns that people have is that misperception and perhaps a medical legal liability, lack of knowledge in how to care for the pregnant woman, and oftentimes a lack of good, integrated care between the prenatal care providers and the addiction treatment providers.

Mr. {Green.} Okay. Thank you, Mr. Chairman. I know I am out of time.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the Vice Chairman of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. {Guthrie.} Thank you very much

Before I get to my questions, Dr. Patrick, I am from Bowling Green, Kentucky, so a lot of people have been to the NICU at Vanderbilt, and it has been a blessing to have such a world-class facility that close. We do have a NICU in my area, and my cousin, Scott Guthrie--I am not sure if you have

ever practiced with him--he is from Jackson, Tennessee, but does cover the NICU in Bowling Green.

Dr. {Patrick.} Yes.

Mr. {Guthrie.} So thanks for what you do.

So I want to talk to Dr. Martin. I am the sponsor of the early detection hearing bill, so I want to focus on that. Universal newborn screenings work very well, the newborn side. Could you help the committee understand why it is important to expand to early childhood screening? You know, I can see where a parent would not understand if their newborn wasn't listening, particularly if it is your first one and you are not sure exactly what they are supposed to communicate, but wouldn't a parent know if a child was 3 or 4 and they couldn't hear?

Ms. {Martin.} Well, one of the things that we see is that children who have what is called light-onset hearing loss like that that were born with normal hearing and acquired hearing loss in the first 3 to 5 years of life, that really they are pretty good at hiding out from their parents. So they read lots of visual cues that go on in their environment. There is lots of redundancy in how we tell kids to do things at that age, and parents want their kids to be typically developing, so it really flies under the radar a lot with that age child. We know from the statistics that we

will almost triple the number of kids who are identified. So if it is three per thousand at birth, we are going to have two to three times that number of kids who enter kindergarten, and even a mild, moderate to severe hearing loss in a child can be missed until they enter school age, and we want to intervene with them early. We have got great programs in place that can help them be ready to learn when they enter school. So it is important to expand it.

Mr. {Guthrie.} Okay. Thank you. Also, there seems to be a sense of urgency about deciding how to communicate with your child once they are diagnosed with a hearing issue and some strong opinions about whether families should use American Sign Language or spoken language. How does the early detection bill address this issue?

Ms. {Martin.} One of the important decisions that families have to make when their child is diagnosed with hearing loss is how they want to communicate with them, so they are making decisions about technology use, they are making decisions about the best way to communicate with their child or not. One of the stipulations in this bill is that families be given all the information about all the options that are available to them. So we want for families is for them to have the opportunity of informed choice, so we want to give them the information and help them weigh that in

their family situation with their family dynamics, what their desired outcomes long term are for their child, with their culture and traditions and beliefs and their family and make a decision about what sort of communication mode they choose. So it might be ASL, American Sign Language. It might be listening and spoken language. It might be some combination of both.

The good news is that there is not a right choice. The right choice is the choice that a family makes for their child, and we know that the EHDI bill has provisions in it that help us engage and equip families to make those decisions and to follow through with whatever decision that the make.

Mr. {Guthrie.} Well, thanks, and I was involved in creating and expanding the Governor's initiative involved in getting it passed when I was in the State legislature, and so a lot of States are doing this. What is the role of the Federal Government in this?

Ms. {Martin.} Well, the federal funding really primes the pump for this. It is a great example of the Federal Government seeing something that could take place and really be beneficial to families and to children, and stepping in and setting that program up, and so basically it is money that primes the pump for States to do what needs to be done

to identify these children and get them enrolled in services and helps them continue that process. So the States are all implementing it in different ways, in lots of different successful ways. The federal money helps us be able to share information back and forth and to be able to move towards best practice and evidence-based practice as we move forward in helping these kids attain their full potential.

Mr. {Guthrie.} Well, thank you very much. When I was involved, I did research on the bill, and I remember talking to a researcher at Vanderbilt--that is where I went down to really understand what was moving forward and whether to move forward or not, how much government do you get involved in--and they told me that if a newborn child, even if it is healthy, put them in a room where they couldn't hear, by the time they were 3, they would never be able to develop the proper speech patterns. So what if a child could get corrected or get on the right path in the earliest stages?

The other thing they did was eye screening, and the only reason I bring that up is because they said the normal pediatric screening would catch you going into kindergarten almost all the time except for about 1 or 2 percent, and so do you increase this program for 1 or 2 percent? Well, if you are one of those parents, you do, and it turned out when we passed the bill, my child had to go to an optometrist

before kindergarten at 5, and he was one of the 1 or 2 percent. So these are important programs, and I am pleased to be involved and pleased to work with Congresswoman Capps on this, and thank you for coming from Arkansas.

Ms. {Martin.} Thank you very much.

Mr. {Guthrie.} I yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentlemen from Oregon, Mr. Schrader, 5 minutes for questions.

Mr. {Schrader.} No questions, Mr. Chairman.

Mr. {Pitts.} All right. We will go to Mr. Kennedy.

Mr. {Kennedy.} Thank you, Mr. Chairman. I want to thank the witnesses for attending today and your testimony, and I really want to recognize the Chairman for calling a very important hearing.

I am going to focus my comments a bit on the opioid epidemic, which has been devastating for parts of Massachusetts and for expanding communities across our country. One thing that I know the entire group can agree on is with regards to the opioid crisis that is devastating in its reach, as we have heard from your testimony so far this morning. It does not discriminate, not by race, gender, age, demographics, income, or any other metric. The breadth and depth of this epidemic is particularly painful when it comes

to its youngest victims--newborns--and the rise of neonatal abstinence syndrome, NAS.

In the United States, the rate of opiate-dependent births has nearly tripled since 2009. In my home State of Massachusetts, the Department of Children and Families received 2,376 reports of substance use-exposed newborns between March of 2014 and March of 2015. In Tennessee, a recent study of the State's Medicaid program found that over a quarter of all women in the program were prescribed opioid pain relievers during pregnancy. Of the infant born there with NAS, 65 percent were born to mothers who were legally prescribed opioids. These statistics make it clear: We are falling far short in our efforts to protect the youngest among us from an epidemic and we are failing to provide reliable, appropriate care to pregnant women. We need to start researching today to protect our children tomorrow.

I want to recognize and congratulate and celebrate the efforts of our Congress, Congresswoman Katherine Clark from Massachusetts, and Congressman Steve Stivers, whose efforts will help address this dangerous failure to grasp the reach of NAS, and I thank them both for their leadership on this critical issue.

With that said, I wanted to focus my first question to both Dr. Patrick and Dr. Terplan. Can you expand on the gaps

in research in NAS, particularly around prevention and treatment, and what evidence-based medical guidance is currently available to doctors and nurses who treat mothers and newborns? I know you both touched on it a little bit in some of the questions but I would like to flesh it out a little bit more.

Dr. {Patrick.} Well, I think the gaps--we talked a little bit about some of the issues with diagnosis. We can go on throughout the spectrum in understanding how we send these kids home safely. We have--infants with neonatal abstinence syndrome are about two and a half times as likely to be readmitted to the hospital within 30 days after discharge. We really need systems, both service care delivery as well as research into the best mechanisms to ease that transition home. It is a complicated time for families, and you can think about an infant who is already a bit more fussy than usual and how this can be a challenging time for families. And so part of it is supporting families in that transition, perhaps using things that we know work well with the evidence that exists for childhood like home visitation programs. There really needs to be more targeted evidence towards this population and perhaps using evidence that we have garnered from other places.

And as far as prevention, I think the committee's work

that the committee has been working on more broadly on the heroin and prescription drugs epidemics, I think bolstering programs like prescription drugs monitoring programs and targeting special populations is really important, and ensuring that they are well funded at the State level and perhaps even targeted towards special populations such as women of childbearing age.

Mr. {Kennedy.} Thank you.

Doctor?

Dr. {Terplan.} So I am going to focus my comments more on women. Identifying women with substance use disorders at the time of labor and delivery is 9 months too late. So we need to be doing universal screening for substance use during prenatal care, and that should be done not just with toxicology testing, which is the most common way we test for things with a urine test, which is not a test for a behavioral disorder that addiction is but with an instrument, a validated instrument, and we actually need to have more good comparison between what is the right set of questions to ask. There is a CDC-funded study that just--I don't know if it started yet but it just got approved--to compare different screening instruments during pregnancy. So we will have better data for that in the future.

Really, for me, the research question is one about

implementation. We know what treatment modalities work. The issue is that women aren't getting access to them, and so it becomes not a hypothesis question of what is, you know, best practice per se but how to deliver what we know to a population.

Mr. {Kennedy.} I have got 25 seconds, Doctor. I want to push a little bit. What are the barriers to access? What can we do to alleviate those?

Dr. {Terplan.} I think there is a knowledge deficit. I think that also criminalizing of pregnant women for substance use disorders discourages adherence with treatment or access and care, and so they are showing up on labor and delivery rather than during treatment or during pregnancy, and I think there is also some federal barriers in terms of dissemination of methadone and also we don't have enough prescribers for buprenorphine in the United States.

Mr. {Kennedy.} Thank you both. I yield back. I thank the Chairman.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. {Murphy.} Thank you. I will try and rush through these.

First, Dr. Kurtzberg, as an experienced cord blood

banker and cord blood transplanter, what is your definition of a high-quality cord blood unit?

Dr. {Kurtzberg.} That is a great question. So a high-quality cord blood unit needs to be sterile. It needs to be checked incapable of transmitting genetic or infectious diseases, and most importantly, it needs to be potent, and potency can be measured by the number of cells that are in the unit, and we know now that we need a certain dose of cells to transplant individual patients and that many of the units that are collected are too small and don't contain that number of cells.

Mr. {Murphy.} So do you think the current HRSA contracting policies optimize the collection of high-quality cord blood units?

Dr. {Kurtzberg.} No, I think HRSA needs to help the banks to be incentivized to collect bigger units with more cells, and right now their policy does not do that.

Mr. {Murphy.} And you mentioned that among the potential uses for cord blood are in regenerative medicine. You have initiated trials using cord blood to treat brain disorders including autism. Could you please explain for the committee the current status of that project and insight you have about the future of that research?

Dr. {Kurtzberg.} Sure. So we think this research has

enormous potential in autism, cerebral palsy and other brain disorders in children that are probably acquired and not genetic, and in these cases, we have initiated studies predominantly funded through the Marcus Foundation or the Robertson Foundation where we are looking at the role of cord blood infusions in those children.

In autism, we have completed a 25-patient study for children ages 2 to 6 where we are looking at endpoints at 6 months and changes in symptoms of ASD, and we have shown that children who get a higher dose of cord blood cells similar to the dose we would give a patient with leukemia or another malignant diagnosis benefit and have improvement in the symptoms with decrease in autistic symptoms. We think and we have evidence on MRI that this is due to a normalization of the connectivity in the brain that is coming from signaling of the cord blood cells to cells in the child's brain, which helps repair these conduction pathways.

Mr. {Murphy.} That is fascinating. I want to follow up with you in the future.

But let me ask Dr. Terplan and Dr. Patrick, I used to work in an NICU as a psychologist and would follow up children with developmental disorders, and I would be correct in saying that maternal opiate use has increased risk for developmental problems in a child either directly or also

related to such things as low birthweight, prematurity, decreased head circumference? Am I correct in that continuing to be a concern?

Dr. {Patrick.} I am happy to address that. I think the literature is difficult. There have been several studies demonstrating some issues with behavior, particularly some other issues, lazy eye, strabismus has also been described. But one of the things that we need is more research to follow these infants long term.

Mr. {Murphy.} Well, let me ask this too, and also concern for increased risk for mortality if a physician is not aware of some of these problems during pregnancy and increased risk for fetal demise. Am I correct with those?

I am going to ask this question. I believe, Dr. Terplan, you mentioned one of the issues is information. I also chair the Oversight and Investigation Subcommittee here, and many of my colleagues have been part of that. We have looked at the issue of the concern for if someone is in treatment, those medical records are not there, so you can't find out, an OB/GYN cannot find out because it is not in the record, and we have tried to address it, should it be wholly within the record, should it be under the patient's approval. This was based on 1970s law and regulations. Should the patient say, well, put a 1-year waiver in to allow that

information in there? We had testimony just a week ago where one of our former colleagues had said, you know, it is in the chart if he has an allergy to penicillin, why can't it be in the chart that he has a reaction to opiates, please don't prescribe it, or if I am on there, to know those things. I wonder if you can comment on this 42 C.F.R. part 2, the thing that we tried to deal with. Do you want access to those records?

Dr. {Terplan.} So the reason for that legislation was just because individuals with substance use disorders are prejudiced against in our society and to protect them--

Mr. {Murphy.} But I understand, but we have already established it is the neonates that suffer.

Mr. {Terplan.} Yes, and so I think that the law which had a reason in the past actually does serve as a barrier to effective communication between parties. What I stressed when I talk about this is that there needs to be close collaboration between prenatal care providers and drug treatment providers and that consent forms need to be signed to get around that so that information can be easily shared.

Mr. {Murphy.} I just want to make sure we are not making behavioral medicine and physical medicine separate but equal.

Dr. {Terplan.} Correct.

Mr. {Murphy.} And if these are--you can have toxic and higher mortality rates. We know the mortality rate has skyrocketed to 42,000 deaths from drug overdose last year. We know there is a huge problem with neonatal abstinence syndrome. I hope you will respond more to this committee with your insights. I am fascinated by them and I want to hear more, because we want to make sure that you as providers have the information you need to know when you are dealing with a baby so you can deal with it effectively.

I thank you very much. I yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the Ranking Member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. {Pallone.} Thank you, Mr. Chairman.

I think it is important to understand neonatal abstinence syndrome, or NAS, in the context of the public health challenge of the overprescribing of opioid painkillers in the United States. Between 2000 and 2010, there was a fourfold increase in the use of prescribed opioids for the treatment of pain. In 2012, healthcare providers wrote 259 million prescriptions for opioid painkillers, enough for every adult American to have a bottle of pills.

So my questions. Dr. Patrick, first, can you describe what has happened with the incidence of NAS in the past

decade? In your opinion, is this phenomenon tied to the issue of the overprescribing of opioid painkillers for pain?

Dr. {Patrick.} Well, over the last decade, we know that neonatal abstinence syndrome has grown fivefold, and by 2012, one infant was born every 25 minutes on average with the syndrome. When we look at specific studies, there have been several studies looking at what is happening in generally prescribing, as you described, it has increased, but it has also increased among women of childbearing age as well as pregnant women over time. In a recent study we conducted in Tennessee, we looked specifically at opioid prescribing in pregnancy, and we found that nearly a third of pregnant woman had an opioid pain reliever prescribed in pregnancy, and most of those, 96 percent, were short-acting opioids. So yes, I think there is compelling evidence that what we have seen in our neonatal intensive care units and in labor and delivery is a result of the broader prescription opioid epidemic and it is the downstream effect that we are seeing negatively impact both women and infants.

Mr. {Pallone.} I think I was going to ask some questions about the Tennessee Medicaid program but I think you just answered them, so let me move on.

I was surprised by the prevalence of opioid prescribing in pregnant woman. It is eye-opening, to say the least, and

I think most of us associate NAS with illicit opioid use including heroin. While it is certainly important to ensure that pregnant women have access to treatment for pain, it is also important for patients and providers to understand that medical use of opioids during pregnancy presents a risk of NAS.

So do you think there needs to be more research conducted to inform us on when it is indicated to prescribe opioid painkillers during pregnancy?

Dr. {Patrick.} So from my perspective as a neonatologist, yes, I think guidelines would be helpful. I think the nuance here is that we have in one population perhaps overprescribing but we also have difficulty accessing medication-assisted treatment. So one thing that is important to know is that neonatal abstinence syndrome is not the worst complication of pregnancy; preterm birth is. And in some women with substance use disorder, accessing medication-assisted treatment is vital.

So we have this group of patients who have difficulty accessing medication-assisted treatment and we have another group of patients who are likely being overprescribed opioid pain relievers and another group of patients who are now using heroin, and so we need more research to understand this diverse population and how we improve outcomes based upon all

of them, and I think that is why the goal needs to be overall to improve health for moms and babies because they are tied so closely together.

Mr. {Pallone.} Thanks. In your paper, you conclude, and I quote, ``Prescription opioid use in pregnancy is common and strongly associated with neonatal complications.'' Could you just elaborate on that statement? In other words, what are the neonatal complications associate with NAS and how are they linked to prescription opioid use during pregnancy?

Dr. {Patrick.} Well, in that study, we looked at two different groups of people. We looked at--or three, actually--where there were no opioids prescribed, where there were opioids prescribed but neonatal abstinence syndrome did not occur, and when neonatal abstinence syndrome occurred. For infants that were exposed to opioids and for infants with neonatal abstinence syndrome, they are more likely to be born preterm and low birthweight, more likely to have respiratory complications, have things like jaundice and feeding difficulty. That was much more common among those infants, and I think, again, that is why primary prevention aimed at both moms and babies is really where we should target.

Mr. {Pallone.} All right. I want to thank you for your good work on this issue and for bringing much-needed public attention to the issue of NAS. I also want to thank

Representatives Clark and Stivers for their work on Protecting Our Infants Act of 2015, which will hopefully focus our efforts to address NAS at the federal level.

You were pretty fast in answering those questions so we can get it within our 5 minutes. Thanks again.

Dr. {Patrick.} I am a fast talker. Thank you.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentleman from New Jersey, Mr. Lance, 5 minutes for questions.

Mr. {Lance.} Thank you very much, Mr. Chairman, and good morning to the distinguished panel.

To Dr. Patrick, opiate abuse is a growing problem across the country obviously including in New Jersey. As a result, about 5 years ago, the Children's Specialized Hospital in New Jersey developed a neonatal withdrawal and rehabilitation program. When a baby is admitted, the hospital evaluates the child's symptoms using a 21-point checklist to determine how much medicine needs to be administered as the baby is weaned from its opiate, and a course of therapies designed to address many of the symptoms associated with neonatal abstinence syndrome, NAS, which has been discussed here this morning.

For example, the hospital uses a special stimulation device on the baby's throat to teach the infant how to

swallow, and the hospital also teaches the mother massage and calming techniques. Can you discuss the role that these types of rehabilitative therapies play in a child's recovery and how will H.R. 1462 help to ensure that more children receive the comprehensive care that they receive at a wonderful hospital in New Jersey, the Children's Specialized Hospital?

Dr. {Patrick.} Well, one of the things that we need to learn are more innovation such as the things that you have described where the literature may not be as robust, and so I think that is one thing that this bill provides. It outlines potential gaps. You know, I think that is one of the targets and one of the potential ways that this bill helps. What was the second part of your question?

Mr. {Lance.} I think you have answered it. We want to make sure that the bill is effective in developing techniques that will save the child's life.

Are there similar programs--I am sure that our program in New Jersey is not the only program that is trying to develop techniques in this area. Are there other programs across the Nation, and what are some of the methods used in other programs?

Dr. {Patrick.} Well, one of the most important things that we have seen grown up over the last several years are

States building perinatal collaboratives focused on improving care to moms and babies, and nationally, a group called the Vermont Oxford Network that we have been involved in that--

Mr. {Lance.} The Vermont Oxford--

Dr. {Patrick.} Network, yes, sir.

Mr. {Lance.} That is Oxford in England or--

Dr. {Patrick.} It initially started that way. But this program involves at the start 200 NICUs, mostly in the United States but in a couple other countries, focused on improving the care to infants with neonatal abstinence syndrome. One of the first things that we needed to do was just standardize the care that occurred because there's great variability from place to place, and hospitals like the hospital that you described where they have a standard approach, were focused on this one population and we know that we treat this population the same way every time, that alone is associated with improved outcomes. And so that is part of where we have been working over the last several years. There are a few hospitals that have popped up specifically focused--West Virginia is one specifically called Lily's Place just to treat infants with neonatal abstinence syndrome, and those innovations, to be able to allow rooming in where moms and babies stay together--because the NICU environment can be a chaotic environment where we have ventilators and all kinds

of machinery, places where there can be a dark, quiet environment where healing can occur as you have described.

Mr. {Lance.} Thank you. Is there anyone else on the panel who would like to comment?

Very good. Mr. Chairman, I yield back 1-1/2 minutes.

Mr. {Pitts.} Excellent. Thank you, Mr. Lance.

The Chair now recognizes Mr. Butterfield 5 minutes for questions.

Mr. {Butterfield.} Thank you very much, Mr. Chairman, and I thank all of the panelists for their willingness to testify today.

I will start off by apologizing for being late for the hearing. I have been trying to watch some of it on television while I have been trying to read the Supreme Court decision in the Burwell case a few moments ago, the 6-3 decision that for the second time affirms the Affordable Care Act, which was the historic law that we debated in this committee some years ago, and I was part of that debate, and our committee passed it, it passed the Congress, and now it is the law of the land and it is working, and I just wanted to make that statement for the record. I realize that is not the subject of today's hearing but I could not go back to my office without saying it. I am not gloating, Mr. Chairman. I am not gloating. I am not. I am not. I am not gloating.

I just wanted to reach across the aisle and say to my colleagues that the law is working and let us make it work and let us get healthcare to all Americans because they deserve it.

I welcome the witnesses and I am happy to recognize Dr. Joanne Kurtzberg, who is testifying today in her capacity as President of the Cord Blood Association. She is a Professor of Pediatrics and Pathology at Duke University School of Medicine. Duke is one of the world's premier healthcare providers. That is undisputed. It educates and employs the world's top doctors and nurses and researchers, and I am proud to represent Duke Med here in the Congress.

Mr. Chairman, I support these three bills that we are discussing today. I encourage their expeditious consideration. As Chairman of the Congressional Black Caucus, I know that many of the conditions which can be treated using cells from cord blood like sickle cell anemia disproportionately impact African Americans, and also as a member of Gallaudet University Board of Trustees, I care deeply about preventing hearing loss and supporting the deaf and hard-of-hearing community.

Equally concerning is the marked increase in prescription opiate abuse among pregnant women and its impact on infants.

Mr. Chairman, H.R. 1462 addresses this important issue and will identify ways to reduce neonatal abstinence syndrome, and so I appreciate the opportunity to discuss these very important topics.

Now, Dr. Kurtzberg, it is no surprise that I am going to go to you first with the time that I have. What are some of the diseases which impact African Americans disproportionately and are treatable by using cells from cord blood?

Dr. {Kurtzberg.} So the first disease we all think of is sickle cell anemia, which can be cured with hematopoietic stem cell transplant, and children and adults with sickle cell often have a hard time finding a match donor in their family or in the registry. Cord blood has the advantage of not having to be completely matched and therefore it has become one of the optimal donor sources for patients with sickle cell disease.

Mr. {Butterfield.} Can you elaborate on the need for racially diverse units in the NCBI?

Dr. {Kurtzberg.} Yes. So, you know, it is kind of a debate because we need big units, and biologically, patients with sickle cell--I am sorry--patients who are African American have sticky cells and their cells stick to the walls of their blood vessels. So when you do a blood test or a

cord blood collection, you actually get a fewer number of cells per volume of blood than you would from a Caucasian, and so it makes it more challenging to collect high-quality units from African American patients because you have to collect more to get big enough ones.

Having said that, the match, which is somewhat related to ancestry, will be better often if a patient receives a unit from someone of their own race. So really, the program is challenged to collect probably twice as many units from African American patients and donors in order to have a high-quality inventory for those patients.

All in all, we need more African American donations and collections, and they will provide better matches to African American patients, but they have to also be targeted to be big enough to serve those patients well.

Mr. {Butterfield.} I am also interested in the potential for new applications using cord blood and some of the cutting-edge breakthroughs that are being made in your field. Can you describe how your discovery of using unrelated cord blood for transplant benefits patients and how it could lead to future breakthroughs?

Dr. {Kurtzberg.} So we have specifically studied at Duke the use of unrelated cord blood in children with certain genetic diseases that affect the brain. These are

leukodystrophies like adrenal leukodystrophy, Krabbe disease, and diseases like Hurler syndrome and many others, and from that work, we have also learned that cord blood cells go to the brain and facilitate repair of various abnormalities in the brain like demyelination or abnormal connections, and we are now using that observation to treat children with birth asphyxia, cerebral palsy, autism, and then adults with stroke, and I think we are just at the beginning of seeing the opportunity for cord blood to also treat patients with adult demyelinating diseases like M.S. or others.

Mr. {Butterfield.} Thank you very much. I yield back.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. {Ellmers.} Thank you, Mr. Chairman, and thank you to our panel for being here today discussing this very important issue.

Dr. Martin, I am going to start with you. Can you talk about the early hearing detection and intervention program that has led to unprecedented collaboration between the public and private agencies across all levels of government and what has made this model so successful?

Ms. {Martin.} I think that the previous legislation--and this is carried on in the reauthorization--really

outlines the role of HRSA, the role of CDC, the role of NIH, and we have just had great success in working together to improve outcomes for children. We have also partnered at the State level across departments of health, departments of education. We have accessed resources in the private sector as well, and this seems to be an issue that people have been able to come together around and really show how that has been done, so that has been an excellent outcome for us.

Mrs. {Ellmers.} That is great. That is a great model for us to use into the future.

And Dr. Terplan, I know this question was posed to Dr. Patrick a little earlier in the subcommittee hearing, but I would like to get your take on the type of innovative treatment models that are needed to close the gaps in research and programming for pregnant women who are addicted to opioids.

Dr. {Terplan.} So I think we know a lot of the pieces that work: medication-assisted treatment for opioid-dependent women, which is methadone or buprenorphine. We need to think about there is a third medication that exists. Vivitrol is the brand name, and that has not really been studied in the United States in pregnant women, and having options is key. I think we get a little hung up one versus the other as if having a choice is an impediment rather than

actually something that is great and liberating clinically and allows us to actually be able to individualize therapies.

I think we also have to work on, it is not just the medication, it is also the other associated services. Pregnant women with substance use disorders are a unique population in addiction medicine and come with a whole host of needs--psychosocial needs, transportation needs, childcare needs and things like that--and we have to find ways to integrate those into treatment and find ways to reimburse for some of those things, which aren't traditional medical services.

Mrs. {Ellmers.} Thank you, Dr. Terplan.

And Dr. Kurtzberg, again, thank you for being here representing Duke Medicine and the Core Blood Bank. Now, with the Cord Blood Bank at Duke and the Carolina Cord Blood Bank and the licensing that the FDA put forward in 2012, can you tell us what the impact of that licensure has made on the Cord Blood Bank?

Dr. {Kurtzberg.} Yes. The licensure process has been challenging, in large part because this is the first hematopoietic stem cell source that has been licensed, and it has been a learning process on both sides of the fence. But the bottom line is that licensure has increased costs of running a bank, and because of that, banks are using more of

their limited resources to comply with some of these regulations as opposed to put more cord blood units in the bank and collect more units from donors. So we are hoping there could be some conversation with the FDA to help optimize the guidelines to apply to cells since most of these guidelines are really written for drugs, and to both keep the high quality of cord blood units but enable more resources to go into collection and storage.

Mrs. {Ellmers.} And again, you know, I just truly appreciate you being here testifying with our subcommittee here today on H.R. 2820, and there again, can you just talk a little bit about the difference between the cord blood stem cells and the embryonic stem cells and what that means to the future of research and the role that you are playing?

Dr. {Kurtzberg.} Well, cord blood cells are not embryonic cells. That is the first important thing to say. And cord blood cells can be collected without any risk to the mother or the baby, and in fact, they used to be discarded as medical waste. So we are literally recycling something that used to be thrown in the trash to save lives, so there is no real common or similarity between the two cells. Cord blood cells cannot give rise to every cell in the body. Cord blood cells are blood stem cells and progenitors, and they help reconstitute bone marrow after a transplant.

Mrs. {Ellmers.} Well, thank you very much, and I yield back the remainder of my time.

Mr. {Pitts.} The Chair thanks the gentlelady and now recognizes the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. {Capps.} Thank you, Mr. Chairman, and thank you to each of our witnesses for your testimony. I appreciate this opportunity that we have to come together to talk about these important public health bills. I want to especially focus, as I did earlier in my remarks, on a program near and dear to my heart, the Early Detection Hearing and Intervention Act, to reauthorize this important program. It is one as a school nurse I have worked on for over 15 years.

Each year, more than 12,000 infants are born with a hearing loss, and since the first authorization of this bill in 2000, we have seen a tremendous increase in the number of newborns who are now being screened for hearing loss. Back in 2000, only 44 percent of newborns were being screened for hearing loss and now it is over 89 percent before they leave the hospital. That is pretty astounding.

We have also seen an increase in the surveillance and tracking of hearing screens and examination. The reauthorization bill I have introduced with Representative Guthrie would not only ensure this program is there for the

children who need it in the future but it would also strengthen the program based on lessons we have learned over this time.

Once such area where reauthorization would improve the program is the way in which it clarifies CDC's role in conducting surveillance on early hearing detection and interventions. I want to focus three questions on our audiologist on the panel, Dr. Martin. You are the Audiologist at Arkansas Children's Hospital, and I am going to ask you three questions, and if you could be fairly brief so we can hopefully get these in.

What is an example of the surveillance conducted by CDC in which we have now seen gaps in addressing hearing loss? What has come out that reveals areas that we need to work on?

Ms. {Martin.} So one of the things that the CDC is helps us set benchmarks of what we want to try to track among States and then compare those, and so one of the most important numbers that we have seen come out of that work has been the loss to follow-up rates, and we have made really tremendous strides in the last few years because there has been funding available to help States look at loss to follow-up. We have reduced that number by 50 percent. There are still babies who are lost to follow-up and we are continuing to work on that.

Some of those lost-to-follow-up babies are not actually lost to follow-up. The EHDI program coordinators know those babies. They know where they are and their families have opted not to follow up for some reason, either financial or access.

Mrs. {Capps.} Let me push that a little further just to entice you to talk a bit more about it. While we are screening babies at a higher rate and we are doing better at follow-up, there still is a challenge, as you say, so follow-up care for newborns diagnosed with a hearing loss, this is such a critical time to get that intervention. How does this bill increase the likelihood that they are going to receive the appropriate follow-up care?

Ms. {Martin.} One of the things that it does is, it expands the way that we can share information among States and among providers, and it guarantees that we--ensures that we really make access for families easier to find. We have had some programs put in place that have been collaborative between American Speech and Hearing Association, the American Academy of Pediatrics that helps primary care physicians and parents find audiologists so that they can get good follow-up and be connected to services more quickly.

Mrs. {Capps.} And maybe you said this sufficiently, but if you could, there is a minute and a half left to elaborate

on the importance of these programs, focusing now on the parents, because many of the parents are hearing parents and so this is all totally new territory to them.

Ms. {Martin.} Absolutely brand-new territory to theme. Ninety-five percent of children who are born with hearing loss are born to hearing parents, and so they have really little or no contact prior to that time with anyone who has been deaf or hard of hearing, and so the great thing about the reauthorization is, it really recognizes the role of the family. So we figure that the family is the expert about their child. It puts the family in the driver's seat to make decisions. It sets up programs and systems where we provide information to these families so that they can make informed choice, and it helps engage them in the process. So it helps them be their child's first teacher, the expert on their child, and really help them partner with the different agencies in ensuring that their desired outcome for their child is the one that they get.

Mrs. {Capps.} Well, if that isn't reason enough for us all to support this legislation and the reauthorization. I appreciate your answering these questions.

I do, Mr. Chairman, wish to submit for the record a letter from the American Academy of Pediatrics supporting the reauthorization of the Early Hearing Detection and

Intervention Act. I will submit that for the record.

And I will yield back my time.

Mr. {Pitts.} Without objection, so ordered.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} The Chair now recognizes the gentlelady from Indiana, Mrs. Brooks, 5 minutes for questions.

Mrs. {Brooks.} Thank you, Mr. Chairman, and thank you for calling this important hearing on public health issues.

The Indianapolis Star--and I represent Indianapolis and to the north--a columnist by the name of Matt Tully has been doing quite a bit of series on the opioid and heroin addiction plaguing our country, and a recent article cited some startling statistics the epidemic is having on hospitals in Indiana, so I am very, very pleased that you are here.

At Eskenazi Health, a hospital in downtown Indianapolis, officials say the hospital is on track to see a 22 percent increase this year in the number of newborns experiencing narcotic withdrawal. A doctor at St. Vincent's, a north side Indianapolis hospital, said between 20 and 30 percent of the babies admitted to the NICU suffer from drug dependency--20 to 30 percent. And obviously, and as Matt Tully has written, wrote of a 5-day-old at Franciscan St. Health on the south side of Indianapolis--so this knows no geographic boundaries in our community or in our districts--who was receiving morphine treatments because his body was shaking so bad and he was wracked with diarrhea so bad that it was affecting his skin and it was just horrible watching the withdrawal, which

actually this columnist was seeing, but I think what I learned today, Dr. Terplan, you indicated the babies can stay in the hospital for an average of 3 weeks when they are going through this type of withdrawal, and I must say that Representative Kennedy and I just recently introduced a companion bill to the Senate to Senators Donnelly and Ayotte of the Heroin and Prescription Opioid Abuse Prevention, Education and Enforcement Act, and it is a multipronged approach, and it focuses on a number of things including interagency task forces to try to get better prescribing practices specifically, focusing on prescription drug monitoring programs, but I have to tell you one thing. I am a former U.S. Attorney. I have been involved in the criminal justice system most of my career, and I appreciate that punitive approaches aren't appropriate, as you say. However, many of these women are in the criminal justice system or find themselves in the criminal justice system, and I am curious what you think our approaches should be with those who are in the criminal justice system. They are in there, in all likelihood, for other crimes they are committing during this time or maybe for being arrested for dealing or for possession, and so what approach do you think should work specifically for our children in our jails and our prisons with respect--because there are a lot of them, and so this is

the hospitals, but I think if we talk to our sheriffs around the country, they are experiencing these issues too. What is the best approach that we should have for the so many pregnant women in our jails and prisons?

Dr. {Terplan.} That is a great question, and our jails and prisons are the largest behavioral healthcare systems in the United States, unfortunately, and there are--I mean, I have spoken of barriers to access to medication-assisted treatment amongst pregnant women in general. Those barriers are far higher in prisons. So some of it has to do with how prisons are financed and the cost of medications, even though cheap, methadone across a huge population of prisoners who need it is a costly thing. So I think what we really need is access to prisoners and people in detention need access to behavioral healthcare in general and for opioid use disorders to medication-assisted treatment in particular.

In addition, we need better linkages from release into the community. So right now in the State of Maryland, only individuals who are arrested and are on methadone receive methadone in the jail. People who have an opioid use disorder come to jail and they withdraw. We know withdrawal for pregnant women is dangerous to the fetus, and we need to find ways to provide medication and other counseling services and then linkage upon release into the community.

Mrs. {Brooks.} Dr. Patrick, do you have any thoughts on our jail and prison issues with pregnant women?

Dr. {Patrick.} I would just echo the access to medication-assisted treatment when it is needed for pregnant women. It is really the standard of care and improves infant outcomes as well.

Mrs. {Brooks.} Have you done any work with our drug treatment courts? Because a lot of times those judges who are presiding in the drug treatment courts see the same women. They may or may not be in jail or prisons, people who are in the drug treatment courts, and I know that we have struggled with learning whether or not--some believe in abstinence as the best method but certainly have you done any work in following drug treatment courts or advising drug treatment courts?

Dr. {Terplan.} A little bit in Baltimore City, and mostly around educating, not just the staff but especially the judges and also the judges who aren't drug court but might be subbing for somebody else around the importance of the evidence base for treatment for substance use disorders.

Mrs. {Brooks.} Thank you. I yield back.

Mr. {Pitts.} The Chair thanks the gentlelady. We are about to see another vote series, so we will try to move this along.

The Chair recognizes Ms. Matsui of California 5 minutes for questions.

Ms. {Matsui.} Thank you, Mr. Chairman, and thank you to the witnesses for being here today and a special thank you to Dr. Chell and Dr. Kurtzberg for testifying today about the importance of the National Marrow Donor Program and cord blood banking.

Every 4 minutes, someone is diagnosed with blood cancer or another blood disorder. Often, the only cure for these fatal diseases is a bone marrow or a cord blood transplant. Congress has recognized the national need for bone marrow transplant since 1987, and 10 years ago formally added the National Cord Blood Inventory to the C.W. Bill Young Cell Transplantation Program.

A big part of the Stem Cell Therapeutic and Research Act is the national registry known as Be The Match, which matches as many patients as possible to bone marrow or cord blood donations that they need, and during the last 30 years, the registry has grown to include over 12 million adult volunteer donors and over 200,000 cord blood units donated by moms after the birth of their children.

The growth of the registry over the last decade is promising but we know we must continue our efforts to encourage donors.

Dr. Chell, as you mention in your testimony, some of the roles that the National Marrow Donor Program plays in addition to running the national registry. Can you elaborate a bit on all the work that Be The Match and NMDP does?

Dr. {Chell.} So we are responsible for a network of centers all over the world that help recruit donors and recruit moms to donate their cord blood, to create that inventory, and yet that inventory, despite having 25 million donors worldwide and over 600,000 cord blood units, is really only meeting less than half the need in the United States and only 5 percent of the need worldwide, and that is because the population of the United States as well as the world becomes more diverse, and so that diversity requires us to continue to add more donors to the registry.

But we also advocate for patients from the time of diagnosis through survivorship through multiple languages so they can get the education and the information they need. Through the SCTOD portion of the contract, we create the infrastructure and the reporting mechanism so that we can collect data on every single transplant done in the United States and 60 percent of the transplants done worldwide so that researchers from all over the world can enter that database and help us define new ways of using these therapies and rapidly turn those discoveries into use throughout the

world. We also work with a cord blood coordinating center to manage the relationships with the cord blood banks as well as multiple centers that recruit adult donors.

Ms. {Matsui.} Okay. Thank you.

Dr. Kurtzberg, as you know, the goals in creating the NCBI were to create a network of high-quality, diverse cord blood units and to make cord blood units available for research. Can you elaborate on the work that you do to meet these goals?

Dr. {Kurtzberg.} Sure. I have run a public cord blood bank named the Carolinas Cord Blood Bank at Duke and work every day to collect cord blood units from moms who donate their baby's cord blood after a healthy pregnancy and delivery. We also work to develop new models to increase the opportunity for cord blood donation from moms of minority backgrounds. We have opened a program recently at Grady Hospital to do that. We are looking at ways to decrease cost of cord blood donation and banking, which is always an issue in the field, and we are looking at ways to apply cord blood transplantation to new diagnoses.

Ms. {Matsui.} Okay. Thank you.

Dr. Chell, you mentioned that the number of transplants for racial and ethnic minority patients has increased substantially from the year 2000 to today, and I just want to

follow up on what my colleague, Mr. Butterfield, was talking about because he mentioned the African American population. I know that the Asian American population is feeling a great need, and you see the individual-type activities more forward trying to find a match. What efforts can Be The Match make to continue to increase the diversity of the registry to ensure that minority patients can find matches, understanding that this country itself is such a diverse country that we need to figure out a system. There is a lot going on, but what do you think you can do to help increase the diversity of this?

Dr. {Chell.} I think it is important also to raise awareness. If we were to take a Caucasian patient as well as an Asian American patient, if they are in the right healthcare system and get access to a search, the likelihood to move on to transplant is equal. The challenge is, many Asian Americans don't have access to that first initial step of doing a search, being in a healthcare system to do that search. But with that, we need to across all ethnic groups significantly increase the diversity of the registries. For Asian Americans, we also benefit from having partnerships with China, Japan, Korea, Hong Kong and other countries to allow us to increase the diversity. For African Americans, we don't have partners in African companies that help us with

diversity.

Ms. {Matsui.} Well, I know my time is up, so thank you very much.

Mr. {Pitts.} The Chair thanks the gentlelady.

We have less than 10 minutes left. We are going to try to conclude the hearing.

The Chair recognizes Mr. Bilirakis 5 minutes for questions.

Mr. {Bilirakis.} Thank you, Mr. Chairman. I appreciate you very much holding this very important hearing on some really good bills.

Dr. Martin, in the interests of time, I really have a lot of questions but we will start with the hearing loss screening. You stated that the number of individuals who have lacked follow-up care from their initial screening has been reduced by half over the past 10 years. H.R. 1344 states that one purpose for which States can use funds is to develop models that will ensure babies identified as needing follow-up care receive those services.

My first question is, what are the challenges for a child who does not receive follow-up care with an early intervention provider and how is it harmful to the child?

Ms. {Martin.} There is this critical period for children to acquire communication that really, birth to 3 is

the most critical time period, and so we have seen rapid improvements in the outcomes for children when they enter the educational system and their long-term outcomes if they have been identified early within the first year of life as compared to children who are identified after that. So kids who are lost to follow-up fail their newborn screen and then show up at a pediatrician's office at 3 or 4 or fail a kindergarten screening, they are already significantly behind their typically hearing peers and are really going to have a difficult, if not impossible, time catching up with a language linguistics sort of base and from a psychosocial base as well.

Mr. {Bilirakis.} Thank you.

A question for Dr. Patrick and Dr. Terplan. Counties within my district were found to be suffering from some of the highest numbers of babies born with neonatal abstinence syndrome. What practices have been successful at addressing this issue in other regions? How would this legislation help those at-risk populations?

Dr. {Patrick.} Well, as far as treating infants with neonatal abstinence syndrome, the practices that have been most effective have really been around standardizing care and working together through networks of hospitals and neonatal intensive care units. That has really been effective in

making sure that we are treating these infants the same collectively. I mean, the bill brings together data and evidence. It also brings together a multidisciplinary group of people who think about how we attack every part of the problem including before pregnancy, in pregnancy and in the treatment period for the infant. So I think we will see a positive effect in communities like yours and mine as well.

Mr. {Bilirakis.} Thank you, and Mr. Chairman, I will submit the questions for the record because I want everyone to have an opportunity. Thank you.

Mr. {Pitts.} The Chair thanks the gentleman and now recognizes Ms. Castor 5 minutes for questions.

Ms. {Castor.} Thank you, and I thank Mr. Bilirakis as well, and I want to thank our witnesses for being here today to testify on these important public health bills. I want to thank Representatives Clark and Stivers for their work on H.R. 1462 especially, Protecting Our Infants Act of 2015. I am a cosponsor of the bill, and I think it is clear that we need additional efforts and resources to address the challenges of neonatal abstinence syndrome, and the bill before us does that in many critical ways. Mr. Bilirakis and I share the counties, and I just want to get this on the record. In 2007, our counties had 67 reported cases; 2008, 108; and by just 2011, about 280 reported cases. So we have

got to do more.

These are the questions I would like you to answer for the record. According to the GAO report, there are a number of existing research gaps relating to best practices in the screening, diagnosis and treatment of NAS. You have discussed them, and if you would also discuss them in more detail in written testimony.

Dr. Patrick, what do we know about the best practices and screening and diagnosis and treatment, and what are the most pressing research gaps? How does the Protecting Our Infants Act help to address the gaps? And then if you could also share in written response, are we underinvesting in research related to NAS, given the significant public health burden that it presents?

Thank you all again for being here today, and I look forward to your written response.

Dr. {Patrick.} Well, your first question was about best practices, and I think it begins with identifying the infants, so it begins with that transition from pregnancy to the infant being cared for. We have to know the infant has been exposed, and so screening, universal screening through both standardized verbal screenings as well as diagnostic screenings, using the same scoring system to identify and be consistent with that. Treatment--it is clear from the

evidence that using an opioid like methadone or morphine is the most effective though we see some hospitals using other drugs like phenobarbital that may actually have some long-term harm. And--

Ms. {Castor.} I am going to cut you short so Mr. Collins can do it, but I do want to express my gratitude to All Children's Hospital and St. Joseph's Children's Hospital and all of the medical professionals across the country who are tackling this issue, and I yield back the balance of my time.

Mr. {Pitts.} The Chair thanks the gentlelady, and you can respond more fully in writing to that question. We will provide the questions to you in writing. Thank you.

Dr. {Patrick.} Thank you.

Mr. {Pitts.} Mr. Collins, you are recognized. We have 2 minutes left on the Floor.

Mr. {Collins.} Well, I will be quick. Luckily they always hold votes over, and also if you could, I will direct this to Dr. Patrick perhaps answer in more detail.

I am one of the cosponsors on H.R. 1462. Your testimony here has done a great job in showing the importance of reauthorizing these. What I would like you to perhaps respond in writing is, some of the differences between NAS and fetal alcohol syndrome. We know about those. If you

could maybe compare and contrast what is going on in those two fields, I think that would be helpful to truly show the importance on the opioid abuse, which we have had several Oversight hearings on, and maybe simply--also, could you just confirm verbally now, is a child born with NAS impaired for life or are the treatments in fact moving them into what could be a normal life?

Dr. {Patrick.} There is no evidence that the infants are impaired for life. There has been some subtle evidence of some behavioral issues. It is definitely an area that needs to be more well studied but I think it would be very unfair to say that the infant is affected significantly for life.

Mr. {Collins.} Well, and that is what I would hope you were saying so the treatments in fact are life-changing, and that is what we are all about here.

So Mr. Chairman, I yield back, and I guess we will go down and vote.

Mr. {Pitts.} The Chair thanks the gentleman.

We will provide questions in writing from those of us who were here and those who were in other hearings. We would ask that you please respond promptly.

We thank you very much for your patience, for all the interruptions, really a very interesting, very important

hearing.

I have a unanimous consent request. I would like to submit for the record statements of Doris Matsui, Gene Green and the American Academy of Pediatrics. Without objection, so ordered.

[The information follows:]

********** COMMITTEE INSERT **********

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Mr. {Pitts.} I remind Members they have 10 business days to submit questions for the record. I ask the witnesses to respond promptly. Members should submit their questions by the close of business Thursday, July 9th.

Thank you very much for this very important testimony today. Without objection, this hearing is adjourned.

[Whereupon, at 12:23 p.m., the subcommittee was adjourned.]