AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 111–332

AUTISM RESEARCH, TREATMENTS, AND INTERVENTIONS

HEARING

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

SPECIAL HEARING

AUGUST 5, 2009—WASHINGTON, DC

Printed for the use of the Committee on Appropriations



Available via the World Wide Web: http://www.gpoaccess.gov/congress/index.html

U.S. GOVERNMENT PRINTING OFFICE

54–469 PDF WASHINGTON : 2010

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON APPROPRIATIONS

DANIEL K. INOUYE, Hawaii, *Chairman*

ROBERT C. BYRD, West Virginia
PATRICK J. LEAHY, Vermont
TOM HARKIN, Iowa
BARBARA A. MIKULSKI, Maryland
HERB KOHL, Wisconsin
PATTY MURRAY, Washington
BYRON L. DORGAN, North Dakota
DIANNE FEINSTEIN, California
RICHARD J. DURBIN, Illinois
TIM JOHNSON, South Dakota
MARY L. LANDRIEU, Louisiana
JACK REED, Rhode Island
FRANK R. LAUTENBERG, New Jersey
BEN NELSON, Nebraska
MARK PRYOR, Arkansas
JON TESTER, Montana
ARLEN SPECTER, Pennsylvania

THAD COCHRAN, Mississippi
CHRISTOPHER S. BOND, Missouri
MITCH MCCONNELL, Kentucky
RICHARD C. SHELBY, Alabama
JUDD GREGG, New Hampshire
ROBERT F. BENNETT, Utah
KAY BAILEY HUTCHISON, Texas
SAM BROWNBACK, Kansas
LAMAR ALEXANDER, Tennessee
SUSAN COLLINS, Maine
GEORGE V. VOINOVICH, Ohio
LISA MURKOWSKI, Alaska

CHARLES J. HOUY, *Staff Director*
BRUCE EVANS, *Minority Staff Director*

SUBCOMMITTEE ON DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES

TOM HARKIN, Iowa, *Chairman*

DANIEL K. INOUYE, Hawaii
HERB KOHL, Wisconsin
PATTY MURRAY, Washington
MARY L. LANDRIEU, Louisiana
RICHARD J. DURBIN, Illinois
JACK REED, Rhode Island
MARK PRYOR, Arkansas
ARLEN SPECTER, Pennsylvania

THAD COCHRAN, Mississippi
JUDD GREGG, New Hampshire
KAY BAILEY HUTCHISON, Texas
RICHARD C. SHELBY, Alabama
LAMAR ALEXANDER, Tennessee

Professional Staff

ELLEN MURRAY
ERIK FATEMI
MARK LAISCH
ADRIENNE HALLETT
LISA BERNHARDT
BETTILOU TAYLOR *(Minority)*
DALE CABANISS *(Minority)*
SARA LOVE SWANEY *(Minority)*

Administrative Support

TERI CURTIN
JEFF KRATZ *(Minority)*

CONTENTS

	Page
Opening Statement of Senator Tom Harkin	1
Statement of Thomas R. Insel, Director, National Institute of Mental Health, National Institutes of Health, Department of Health and Human Services	2
Prepared Statement of	7
Statement of Senator Thad Cochran	9
Statement of Geraldine Dawson, Chief Science Officer, Autism Speaks, Charlotte, North Carolina	16
Prepared Statement of	17
Statement of Senator Arlen Specter	22
Statement of Joshua Cobbs, Chairperson, Iowa Autism Council, Sioux City, Iowa	23
Prepared Statement of	25
Statement of Nicole Akins Boyd, J.D., Vice Chairman, Mississippi Autism Task Force, Oxford, Mississippi	27
Prepared Statement of	29
Statement of David Miller, J.D., Board of Directors, Northern Virginia Community College, Annandale, Virginia	32
Prepared Statement of	35
Statement of Dana Halvorson, BEAT-Iowa, Ankeny, Iowa	38
Prepared Statement of	40

AUTISM RESEARCH, TREATMENTS, AND INTERVENTIONS

WEDNESDAY, AUGUST 5, 2009

U.S. SENATE,
SUBCOMMITTEE ON LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES,
COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:05 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Tom Harkin (chairman) presiding.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Good morning. The Subcommittee on Labor, Health and Human Services, and Education will come to order.

Today's hearing is on autism, regarding research, treatments, and interventions. The Centers for Disease Control and Prevention (CDC) estimates that 1 out of every 150 children born this year will be diagnosed with autism. Among boys, the rate is even higher, 1 of every 94. We don't know what causes this disorder. Most researchers agree there is a genetic component, at least in some cases.

Every discovery seems to raise more questions. It now looks as though autism has, not just one genetic cause, but many, and we still don't know what the triggering mechanisms are. Many experts suspect that environmental factors may also be at play, but, again, we don't know what they are exactly, or whether they take effect during a child's first few months or years, or maybe during gestation.

We know a little bit more about interventions. Some behavioral interventions seem to help, if started early. But, we are nowhere near a cure. The number of people with autism continues to grow; the rate of incidence is growing.

This subcommittee has taken a strong interest in autism in recent years. We held a hearing on autism 2 years ago, in April of 2007, and the fiscal year 2010 appropriations bill that was approved by the full committee on July 30 includes a range of activities related to autism, such as outreach and education, surveillance, medical research, and the Interagency Autism Coordinating Committee (IACC). This year's bill also includes $14 million for a new program to help students with intellectual disabilities make the transition to college and complete their postsecondary education.

We have an outstanding panel of witnesses today to help us examine autism from many different perspectives—research, treat-

ment, interventions—and another problem that hasn't received enough attention to date, how to address the needs of the growing population of adults with autism.

Let me just thank all the witnesses for coming here today. And before we begin—Senator Cochran is on his way—I will leave the record open for his introductory statement.

We have two panels. The first panel is—Dr. Thomas Insel is the Director of the National Institute of Mental Health (NIMH). Panel two is Dr. Geraldine Dawson; Mr. Joshua Cobbs, from Iowa; Ms. Nicole Akins Boyd is from Mississippi; David Miller, from Virginia; and Ms. Dana Halvorson, from Iowa. So, I think we can address just about all the aspects that we wanted to cover on autism, with these two panels.

First, we will open up with Dr. Thomas Insel, the director of the NIMH at the National Institutes of Health (NIH)—not a stranger to this subcommittee, been here many times. Again, Dr. Insel, welcome.

As with you and with all of the people testifying this morning, your statements will be made a part of the record in their entirety. Dr. Insel, we'd just ask you to go ahead and proceed as you so desire.

STATEMENT OF THOMAS R. INSEL, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH, NATIONAL INSTITUTES OF HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. INSEL. Thank you, Mr. Chairman. And let me state that it's a real pleasure and honor to be here with the other panelists. I know this is a very busy time for you and your colleagues, and we greatly appreciate your taking time here in the middle of the summer, just before recess, to hear about the latest research and the latest challenges with autism.

My brief statement is to get you a quick update on the research since we last met, which was a little more than 2 years ago. And I can tell you, this has been an extraordinary period, with lots of exciting progress. I'm going to try to review that. The testimony, I hope, will be submitted for the record, so rather than just reading that, or going through it, I thought I would just take you very quickly through three questions—What do we know at this point? What do we need? And what are we doing?—and will try to summarize those very, very quickly.

DEFINING AUTISM

To get you, sort of, on track here, let me just make sure we're all on the same page in what we're talking about. Autism, by definition, starts by age 3. We're talking about three different kinds of symptoms that characterize autism: reduced social behavior, abnormal language, and, as we've talked about before, repetitive, restrictive behaviors that often are called stereotypes; they have many other names.

It's clear that, though these are the definitions, that many children with autism come in with additional complicating features, and I've just listed a few of them here. Some 20 to 30 percent will have an associated seizure disorder that can be part of the autism syndrome, intellectual disability of various sorts, and gastro-

intestinal problems of many different kinds. About 10 percent of children who have an autism label have odd faces or odd appearances. We call that dysmorphic. And then, somewhere between 10 to 20 percent have what is often called "regression"; that is, while everybody may regress to some degree, there are children who seem to develop quite well for the first 18 months, and then will clearly lose language, lose function.

AUTISM SPECTRUM

The result of understanding these complicated features, and the fact that this is such a heterogeneous syndrome, is that we increasingly talk, not about "autism," but about "autisms," and we really think about this as many different disorders. And in some ways, we're prisoners of our own language, here, by thinking about it as a single syndrome.

The term that has now been most widely accepted, and that you'll hear about most of all this morning, is called the "autism spectrum," or "autism spectrum disorder." And all that really means is that we're talking about a range within the syndrome. At one end are those children who really have very limited functioning, often have no language whatsoever, may have severe intellectual disability, show no interest in social interaction, and have lots of motor abnormalities, including the most common and what we call "diagnostic one" is hand flapping, and they're the ones that often have these dysmorphic facial features.

At the other end of the spectrum are children who are going to grow up to be, often, highly successful. I mean, they may, in fact, have social awkwardness, they may be called "geeky," or "nerdy," or something like that. They may be more interested in numbers than in people. But, they may be tremendously useful and tremendously successful and make huge contributions as engineers, as computer scientists, in areas that probably aren't going to tap so much into their social awkwardness, but allow them to really use what they do best, which is to be able to think about the mechanical, numerical, and less social aspects of the world.

All of those people, whether you call them classic autism or Asperger syndrome fit within this spectrum. And so, as you hear the debate about what's available and what the treatments are and what the causes are, you have to remember that we're talking about this tremendous heterogeneity within the spectrum.

So, let's dive into what do we actually know, and what have we learned in the last couple of years that will be important for us in thinking about this as we go forward?

WHAT WE KNOW

First of all, I think there is wide recognition that this is a developmental brain disorder. We don't know yet where in the brain, or what in the brain, or even when in the brain, things go off track, but the most recent research would suggest that what we're talking about here isn't a specific lesion in a particular area, but it may be more likely what we call a synaptic disorder. It's a problem of brain connections. And that may be very diffuse, and it's quite possible that the reason you see problems in language and problems in social interaction is that those are functions that require the

greatest number of synapses. And if you're not able to process information as quickly as you need to, or if you process information in a way that is too quick and isn't filtered, you're going to see deficits. If your connections aren't working, you're going to see deficits in just those kinds of functions.

GENETICS

Probably the greatest degree of progress has been in genetics. And that's not surprising. That's true in almost every area of medicine. The last 3 or 4 years has really seen what we're calling an "explosion" of information from genomics. That hasn't necessarily delivered the cures that many of us were looking for, yet, but it has helped us to understand much more about the heterogeneity of these disorders.

Two years ago, when I spoke to you, I talked to you about how we think genomics will be important. At that point, we would have said that it's important because we know that a couple percent of the children who present with autism have recognized syndromes—Rett syndrome, Fragile X syndrome, tuberous sclerosis—these are single-gene mutations, in which perhaps 50 percent of the children, sometimes more, have a diagnosis of autism, as well.

In the last 2 years, we've discovered a range of other rare, but apparently highly significant, mutations that are in the form of structural lesions within the genome, that also seem to contribute. And so, where 2 years ago I might have said 2, 4, perhaps 5 percent of any population of children with autism would have one of these syndromes, I think now we can say that number's going to be considerably higher, perhaps more than 10 percent. We don't have names for all of these syndromes, but we have, in the last couple of years—and I must say it's changing almost every 2 months—there are new reports out about rare mutations that may explain another 1 or 2 percent of the children who have this disorder.

So, there's clearly a genetic factor at work here. It doesn't explain all of autism. We still need to learn a lot more about how genes and environment interact. And there will be lots more research on that in the near future. But, that is clearly an important area of progress.

BEHAVIORAL INTERVENTIONS

We know that—and we spoke about this 2 years ago—that, as you said in your opening remarks, behavioral interventions are helpful. And they're especially helpful when they're started early. Now, you'll hear more about this from other panelists. I'm not going to take a lot of time, except I want to flag this, because I think the issue here is making sure that the best behavioral interventions are available to the people who need them. And here, we're not just talking about children, but also about children in transition to adulthood, and adults themselves. These do work, but they're not always available, and they're not always paid for, at least not paid for through insurance. And so we do need to have a conversation later this morning about how that's going to happen.

I also would recommend that you might want to ask Dr. Dawson about the impact of behavioral interventions. Some of her own work in this area is really, I think, setting a new bar for how far these behavioral interventions will go if they're done early.

PREVALENCE

Finally, the issue that you brought up in your opening remarks, and I know it's one that is of great concern to you specifically, is this increase in prevalence. And as you mentioned, the CDC now reports, from 2007, a rate of about 1 in 150 children being given a diagnosis of something on the autism spectrum. I don't think that that number is at great variance with numbers we've seen elsewhere. It's also true that that's about a tenfold increase over the numbers coming from the CDC from the 1992–1993 period.

So, the tenfold increase in prevalence is of great interest to many of us. I want to just caution you that a change in prevalence is not unique to autism. We have seen a 40-fold increase in prevalence of pediatric bipolar disorder over this same period. We've seen perhaps a tenfold or greater increase in attention-deficit/hyperactivity disorder in children over the last three or four decades.

So, this kind of a change isn't unique to autism, but it's certainly one that deserves our attention. And we have to remember the difference between "prevalence"—which can be affected by ascertainment, by change in diagnosis, or a number of other features—and "incidence". We don't have, right now, good evidence that there's a true increase in incidence—in the rate of new cases. And that's an area that requires more research.

WHAT WE NEED TO KNOW

So, if that's what we know, what do we need? Well, part of what we need is to fill in the gaps of what we don't know. And I'll just take you through the kinds of things we're thinking about. Certainly, understanding more about risk. The risk architecture of the whole spectrum is going to be critical. Genes are important, and environmental factors, as you mentioned, will be important, but most important will be how they interact. That's not unique to autism, it's true for asthma, it's true for many other areas of development.

We want to know about molecular targets, to the extent that we can get those, because that's where new therapies are going to come from, and they already have begun to emerge in some aspects of this syndrome. And then we want to understand this heterogeneity far better.

The point of all this is to be able to develop ways of detecting this disorder much earlier. We know, in general, that for brain disorders, behavior is one of the last features to change. That's true for Alzheimer's, it's true for Parkinson's, it's true for Huntington's. That is why it will be most important to have a biomarker that will allow us to detect risk and detect the disorder much earlier.

We want to have interventions that are more effective. Behavioral interventions are effective for many children, but they're expensive, they're extensive, they take a long time to work, and we're not yet where we want to be at the end of the day. We want to be able to offer much more than just the behavioral interventions.

And we want to know which treatments are going to work best for which people. You'll hear a lot, over the next year, about personalized medicine. We're hoping that the new NIH Director will be confirmed by the full Senate this week; and should that be the case, I think you'll hear from him the high priority put on personalized medicine. That's something that we'll need for autism as much as we need it for cancer and heart disease and diabetes.

ADULTS WITH AUTISM

I also want to just point your attention to an issue that's not so much on the research agenda, but needs to be very much on the social policy agenda. As you mentioned in your opening remarks, we have a whole wave of children with autism who will soon be adults with autism. How we make sure that they have the access to services, that we take care of this transition to independence and the coverage for the different kinds of care they need, deserves urgent attention from this subcommittee and from others who make policy.

IACC STRATEGIC PLAN

Finally, let us just say a little bit about what we're doing, what we know, and what we need. What we are doing can be summed up fairly quickly. Through the work of the IACC, we have a new strategic plan, which was released in January of this year. That provides a whole range of activities, both short term and long term, that we hope to be able to invest in so that we can get some of the answers we need.

We have an extraordinary opportunity now. When we first released this plan in January, the comment that we heard most often was, "This is a great road map, but is there any gas in the car?" And what happened soon thereafter, with the American Recovery and Reinvestment Act (ARRA), was the opportunity to make some very substantial new investments to jumpstart this strategic plan, particularly focusing on the short-term objectives. And we hope, within the next 6 weeks, to be able to announce publicly the large number of grants that have been funded through the ARRA. These include not only the special request for applications that was done through five institutes to support new autism research, to the tune of about $60 million, but also a large number of challenge grants and grant opportunity awards that will be made. Awards will be announced before September 30 of this year.

NATIONAL DATABASE FOR AUTISM RESEARCH

Finally, I will just mention that we've also tried to jumpstart much of this progress by creating the National Database for Autism Research, which will be essentially a meeting ground, electronically, for scientists around the world to be able to share data and to share the tools that are necessary to accelerate progress in this area.

As you'll see in the IACC's strategic plan, there were really six questions that guided the effort to steer research and to help us think about what the most important issues were. The IACC, which was reconstituted through the Combating Autism Act of

2006, includes both public members and Federal members. The six questions it developed really came out of a very rich discussion about, What is it that families, and people themselves on the autism spectrum, most are looking for?

We have taken each of these questions to heart. We've come up with a summary of what we know and what we still need to know for each of these six questions. And we have, now, short-term and long-term objectives that are being addressed through the ARRA and through other sources of funding at NIH.

I'll finish with this vision statement, which I thought would be worthwhile sharing with you, from the strategic plan, which talks about what we're trying to do here as we move forward, and that's, "'To inspire research that will profoundly improve the heath and well-being of every person on the spectrum across the life span."

And I can't emphasize enough the importance of, now, attention to adults and soon-to-become adults with autism. This plan will not only provide the road map for research, but also set the standard for public-private cooperation and for engaging the broad community, who will be so invested in trying to make sure we expedite research progress.

ELLEN MURRAY

And with that, I'll just make one final comment. I know you've been thanked for many things that you have done, both for autism and for NIH, and for many of the other issues that you deal with. But, I would like to send a personal thank you for giving us Ellen Murray, who will be joining Health and Human Services (HHS), I understand, very soon. I understand this was a lot to offer and a lot to give up, but for those of us at HHS, it's a terrific gift. And we're delighted that you saw to it to share her expertise with us.

So, thank you, sir.

Senator HARKIN. Thank you very much, Dr. Insel.

[The statement follows:]

PREPARED STATEMENT OF THOMAS R. INSEL

Mr. Chairman and members of the subcommittee: I am pleased to address the state of autism spectrum disorder research and include a brief review of the prevalence of the disorder, research findings, and recent initiatives at the National Institutes of Health (NIH).

Autism spectrum disorder (ASD) is a group of complex neurodevelopmental disorders that range in severity and that are characterized by social impairments, communication difficulties, and restricted, repetitive, and stereotyped patterns of behavior. The most recent Centers for Disease Control and Prevention estimate for ASD prevalence indicates that 1 in 150 children in the United States is affected by the disorder—more than a tenfold increase from the early 1990s.[1] While much of this increase appears to be due to factors such as the use of broader definitions for ASD, better diagnostic tools, or increased ascertainment, recent research demonstrates that none of these factors fully explain the increase in ASD prevalence. Whatever the cause, scientists, clinicians, and families now agree that ASD has now become an urgent public health challenge, with enormous financial and societal costs. Estimates of the combined direct and indirect costs to care for all Americans with ASD during their lifetimes exceed $34 billion,[2] with estimated costs for each person over

[1] Centers for Disease Control and Prevention. Prevalence of Autism Spectrum Disorders: Autism and Developmental Disabilities Monitoring Network, 14 Sites, US, 2002. *MMWR* 56 (SS–1), 2007.

[2] Ganz, ML. *Arch Pediatr Adolesc Med*. 2007 Apr;161(4):343–9.

his or her lifetime totaling $3 million.[3] Families often incur large debts for medical and education services that public programs or medical insurance do not cover. Beyond the financial costs, ASD often leads to profound emotional hardships for persons with the disorder and their families. As more children with ASD become adults with ASD, access to services and lack of accommodation is a growing challenge.

Matching the increasing public health urgency, NIH research funding for ASD has increased progressively over the past decade, reaching $118 million in fiscal year 2008, an increase of nearly sixfold from fiscal year 1998. What has been the yield from this investment? I will summarize the research findings in three areas: diagnosis, causes, and treatment. A fundamental insight and challenge is the heterogeneity of ASD. While we use one diagnostic category, research increasingly demonstrates that ASD covers many disorders, with different causes and possibly requiring different treatments.

Diagnosis.—Early diagnosis is critical because earlier interventions are associated with the best outcomes. Research has found that by age 2 children with ASD show unusual patterns of eye contact compared with typically developing children. Recent studies of children at high risk for ASD indicate the potential for even earlier detection. Simple tests of joint attention or responding to spoken name suggest that diagnosis at 12–14 months of age may be possible for many children. Ongoing research using neuroimaging and serum samples is looking for a biomarker that might permit diagnosis even earlier.

Causes.—Scientists are looking for genetic and environmental causes across the autism spectrum. In the past 2 years, genetic research has proven especially informative, as more than 50 variations in the genome, alone or in combination, have been linked to ASD. Importantly, several new, rare mutations have been discovered. Along with known genetic disorders that cause ASD, such as Fragile X and Rett Syndrome, these new mutations may collectively account for 10 to 15 percent of ASD cases. These rare mutations and the many common variations which confer risk for ASD have one striking thing in common—nearly all of the genes implicated are critical for brain development. In fact, most are closely linked in the developing synapse—the connection between neurons—suggesting that ASD can now be approached as a synaptic disorder and that new treatments can be developed for specific synaptic targets.

Just as with other complex medical disorders, ASD research increasingly focuses on the interaction of environmental factors with genetic vulnerability. For ASD, the research evidence has pointed to prenatal environmental factors as most salient. While there is increasing research into environmental factors that might contribute, thus far no one factor appears to explain the large number of, or apparent increase in, cases of ASD.

Treatment.—In addition to breakthroughs in the diagnosis and causes of ASD, recent research has shed light on the treatment of ASD. NIH-supported randomized, controlled trials of behavioral treatment approaches have shown positive effects, and early behavioral interventions have been found to improve functional capabilities and reduce the severity of challenging symptoms.[4] Additionally, NIH has supported double-blind, randomized, controlled trials of pharmacological treatments. For example, the atypical antipsychotic medication risperidone was shown to be better than placebo for reducing aggression, self-harming behavior, and other serious behavioral problems, without impairing the cognitive skills of children with ASD.[5] Conversely, a multisite, controlled trial to evaluate the efficacy of the antidepressant citalopram to treat the occurrence of stereotyped, repetitive behaviors in children with ASD found that this medication worked no better than placebo.[6] Double-blind, placebo-controlled trials are essential for assessing treatments for ASD. Positive effects are frequently observed with new experimental interventions for ASD, but equivalent effects are often seen with placebo. Only by including rigorous controls can we attribute clinical improvement to the experimental intervention.

NIH will play a major role in the administration's new initiative to significantly increase services and research into the causes of and treatments for ASD. Prior to this initiative, NIH will be using funding from the American Recovery and Reinvestment Act of 2009 (ARRA) as an opportunity to fuel further research on ASD, including its underlying biology, methods for earlier and more effective diagnosis, and improvements in treatment. The new Interagency Autism Coordinating Committee

---

[3] Ibid.

[4] Rogers, SJ, & Vismara LA, *J Clin Child Adol Psychol*. 2008; 37(1): 8–38.

[5] Aman MG, Hollway JA, McDougle CJ, Scahill L, et al. *J Child and Adolesc Psychopharmacol*. 2008 Jun; 18(3): 227–236.

[6] King BH, Hollander E, Sikich L, McCracken JT, et al. *Arch Gen Psychiatry*. 2009;66(6):583–590.

(IACC) Strategic Plan for Autism Spectrum Disorder Research, released in January 2009, provides the scientific goals and benchmarks for this endeavor. The Combating Autism Act of 2006 (CAA) requires the IACC to develop and annually update this Plan. The IACC is currently in the process of monitoring the implementation of the Plan and gathering information to update the document in January 2010. With the arrival of ARRA funds, we will be jumpstarting many of the short-term objectives in the Plan, utilizing economic recovery to support science that facilitates the best possible outcomes for individuals with ASD and their families.

NIH recently issued a series of ARRA funding opportunity announcements (FOAs) to address ASD, entitled "Research to Address the Heterogeneity in Autism Spectrum Disorders." This collaborative effort among several NIH Institutes and Centers is the largest single funding opportunity for ASD research in NIH's history. The FOAs encouraged applications for 2-year projects that address ASD measurement, identification of biomarkers and biological signatures, immune and central nervous systems interactions, genetics/genomics, environmental risk factors, and ASD intervention and treatment. Participating NIH Institutes intend to contribute over $60 million of ARRA funds to support many of the grant applications received in response to this initiative. Additionally, NIH will be supporting ASD research with ARRA funding through the Challenge Grants in Health and Science Research Program (RFA–OD–09–003) and the Grand Opportunity grants (RFA–OD–09–004). Targets for these grants included improving access to services by individuals with ASD and their families and expanding NIH's National Database for Autism Research (NDAR) in order to accelerate the availability of new data for the ASD research community. NIH has recently completed the scientific peer review of ARRA applications. The advisory councils for each NIH Institute and Center are currently in the process of evaluating the reviewed applications in order to guide final funding decisions, which are expected shortly.

Finally, NIH will continue to build its investment in ASD research via its base budget, which supports a broad range of individual grants for research and training related to ASD, a new intramural program for ASD research, and the Autism Centers of Excellence (ACE) program. The ACE program focuses on identifying the causes of ASD and developing new and improved treatments. An example of the kinds of innovative research emerging from the ACE program is the Early Autism Risk Longitudinal Investigation (EARLI). Coordinated by researchers at the Drexel University ACE network, EARLI will explore the impacts and interplay of environmental factors and genetic predisposition in the cause of ASD. About 1,200 mothers of children with ASD will be followed as soon as they become pregnant again and throughout the early life of the new baby. Through extensive data collection on a number of possible ASD environmental risk factors and biomarkers, the study holds great promise in advancing understanding of the causes and progression of ASD.

In summary, ASD is a developmental disorder that affects too many families; research represents our best hope for making a difference for them. We at NIH are determined to continue to use the best available tools, to fund excellent and innovative science, and to encourage input from—and dialogue with—parents, teachers and individuals with ASD. Only in this way, and only with your continued support, will we be able to continue to fuel the vital research that we believe will reveal the mysteries of ASD and lead to prevention and effective treatments.

I appreciate the interest of the members of this subcommittee on ASD research and look forward to answering your questions.

STATEMENT OF SENATOR THAD COCHRAN

Senator COCHRAN. Mr. Chairman, I'm pleased to join you at this hearing, to thank our witnesses who've come to share with us their experience and thoughts about what we can do to more effectively deal with the challenge of autism. We've had hearings before, but it is important for us to continue our efforts to stay up-to-date and join forces with the victims and their families to help make sure we triumph and don't let the victims and their families down. We want to support the cause.

Thank you for being here to lead it off.

Dr. INSEL. Thank you.

Senator HARKIN. Well, thank you again, very much, Dr. Insel, for your leadership.

On the Interagency Coordinating Committee, I was just looking at the list of the people on the committee. As you know, our interest, obviously, is in research and finding causes, which hopefully will lead to prevention and cures. But, also we're interested in early intervention programs and how you get to these kids early. Do you feel you have enough expertise on this panel? Are you looking at that aspect, what are the most effective early intervention programs that we can find and work on?

IACC EXPERTISE

Dr. INSEL. So, on the IACC specifically, do we have the expertise?

Senator HARKIN. Yes.

Dr. INSEL. Well, we bring in the expertise. One of the things we do each year is to update the strategic plan. And we do that by bringing in the experts from all the areas of concern.

We've heard about both ends of this spectrum. The early detection and early intervention—we like to use the term "preemption," when we can—as one of the places that needs a big push. And the other end of the spectrum are adults who need a lot more in the way of interventions.

Senator HARKIN. So, your group, this interagency group, is actively out there looking at different interventions and trying to find out which ones work best and—are you also promoting different types of—in other words, are you instigating different types of early interventions, to track them, to see which ones work the best?

DEVELOPING THE RESEARCH AGENDA

Dr. INSEL. Right. So, let me just go through the process very quickly. The first thing we did was to do a research portfolio analysis. And I think this was unprecedented. We—on the question of interventions or any of the other aspects of the strategic plan's six questions—we sought input from not only NIH and CDC and the Department of Education, but also from all the Federal players that invest in this area, including the Department of Defense, and also all the private groups, which are very substantial players for autism and are putting in very significant amounts of research dollars. For the first time, everybody has shared their information about every grant they fund, including how much they're putting into it. And we were able to use that to map onto these six questions and say what's missing.

One of the places where it looked like we were underfunded, or underinvested, across the six questions, is in this area of interventions. How do we then fill that in? Well, the first thing we do is bring in the experts to tell us not only what the needs are, but also what are the opportunities. What could we do? What's really hot right now, in terms of techniques or things that are going on in other areas in medicine?

The meeting this year will be on September 30 and October 1. We did a previous one, which was in January 2008. We used 4 days to hear from a broad panel of experts.

I might add that it's not only your typical academic grantee that we're hearing from, but we're bringing in family members who may have had a very interesting experience that they think we should hear about, and we're bringing in clinicians, as well, who may be

trying things that we don't know very much about yet. So, we're trying to throw as broad a net as possible, to make sure we're getting all of the best ideas onto the table before we decide what we want to recommend for NIH and CDC and DOD and others to be looking at for funding.

Senator HARKIN. What do we know works for treating autism—we talked about this applied behavior therapy, seems to be successful. But, how early an age can you start that? And—yes, do we know what age you should start that at?

Dr. INSEL. Well, I'm going to duck that question, because the world's expert on that is sitting right behind me, and you're going to talk to her in a few minutes——

Senator HARKIN. Oh, behind——

Dr. INSEL [continuing]. Dr. Dawson——

Senator HARKIN. All right.

Dr. INSEL [continuing]. Who—and I don't want to put her on the spot, but she has just completed, really, what is the landmark study on just that question, going as early as possible. I'd love to steal her thunder, but because she's a friend and I don't want to alienate her, but it would be better for you to hear from her, directly, about her own data.

Senator HARKIN. We'll do that.

VACCINE

Dr. Insel, I hear a lot about this issue of vaccines and autism. Can you summarize the state of the science regarding that issue?

Dr. INSEL. Well, I can tell you what we know, scientifically, and that is that this is—I think there's no question, from the community, that there are environmental factors at work and that some aspect of the environment is going to be interacting with genetics to make children, and maybe even unborn children, vulnerable, because it may be that these are prenatal environmental factors.

The only factor that has been explored in great detail would be vaccines. And part of that has to do with the increasing number of vaccines, which has—as we talked about at the previous panel—gone up over that last 30 years or so. In fact, I've made a slide so you can see what that looks like. There have been this really striking increase from 1900, as you can see, to about 2009. So, there are more vaccines that are now in the recommended schedule. There are more injections, and perhaps even more injections per visit, at least that are possible currently.

It's also important for you to realize that, while the number of vaccines has increased, the quality of vaccines has really changed in the same time. And so, if you look at the number of antigens that go into these vaccines, although it doesn't show it here, actually the amount of protein that actually goes into any of these—into the full group of vaccines that children are receiving—is less than it was when you were getting a single shot in 1900.

So, the vaccines today are far more refined, far more targeted. They look very different than they would have, even when your children would have been vaccinated, in the 1970s and before. So, it's not quite comparing apples and apples, when you look at this change over time.

The one—the research that's been focused on vaccines as a potential association with autism has been largely epidemiological research. And up until this point in time, I believe there have been a total of about 16 studies involving hundreds—literally hundreds of thousands of children, and there is no evidence, at this point, of any association between vaccines—the number of vaccines, the kind of vaccines—any of the things we're showing here—and the increase or the particular vulnerability to autism.

Senator HARKIN. Well, I guess what I don't understand is how you can have a study involving hundreds of thousands of children and all with the same number of vaccines, because they're all getting the same number, before the age of 2? If you go back to your first chart, Dr. Insel—I have a little bit of different information. I have an excerpt from the Centers for Disease Control and Prevention that shows that, in 1983, the maximum number of vaccine doses administered before age 2 was eight. In 2009, it is a minimum of 21 and a maximum of 29; and from everything I can ascertain, it's closer to 29. So, we've gone from 8 in 1983 to 29 this year, before the age of 2. Most pediatricians do that. So, how would you ever find a group of kids that don't get those?

VACCINE FORMULATION

Dr. INSEL. I want to again remind you, it's not comparing the same thing—the 8 are not the same as 29. You look at the number of antigens that are present in 1980—or 1983—versus what's present in the vaccines that a child would receive in 2000 or 2008, and there's this striking, striking decrease. These are not the same formulations, they're not the same kinds of vaccines. What we're talking about today, while the numbers have gone up, is a profound reduction in the amount of protein, in the number of antigens that are given.

Senator HARKIN. Dr. Insel, some of these vaccines weren't around at that time, in 1980. I mean, we've got a number of them here, like pneumococcal conjugate, we've got influenza, varicella—some of these weren't even around—hepatitis A—they weren't around in 1980.

Dr. INSEL. Right. And the vaccines that were around in 1980 have been changed, in many cases; they're far more refined——

Senator HARKIN. The vaccines that were there then that we're using now are——

Dr. INSEL. Yes. They are not actually the same vaccines, in many cases. So——

Senator HARKIN. They're the same.

Dr. INSEL. They're not the same. They may have the same names, but they—the formulation has been greatly refined. And that's how you get these kinds of changes.

Senator HARKIN. Yes, I get confused when we get into this area, because I just wanted to focus on the number of vaccines, and the fact that they're all given together, a lot of times, before the age of 2. I'm not talking about the number of antigens in them, or anything like that, just that the total number has gone up. And I don't know of any studies—and you may know of some that I don't know about—but, any studies that would compare a cohort of children from 0 to age 2 that didn't get these shots, and the incident of au-

tism; and those that did receive 29 vaccines and then were diagnosed with autism. I don't know of any study out there that's done this.

FEASIBILITY OF STUDY

Dr. INSEL. Well, we've had a discussion within the IACC about just this issue. That is could we mount a study of the vaccinated versus unvaccinated children? We don't have, in fact, the vaccine expertise on the IACC. And so, we have decided to consult the National Vaccine Advisory Committee, which is another Federal advisory committee that reports to the Secretary, to get their expertise. Because they do have expertise.

And we met, about 1 month ago, to have this conversation with them. Before meeting with them, we sent them the question, asking if there had been such a study, just the kind that you described. And if not, why not? And could we do such a study?

And their first response back to us was, first of all, it hasn't been done. They didn't think that it was feasible to do it. But, most of all, they didn't think it was ethical. They had real concerns about the ethics of randomizing a group of children to not receive vaccines, because they were particularly concerned about the risk involved in not vaccinating a large number of children—and you would need a very large number of children for such a study.

Senator HARKIN. That's right. So, we really can't tell that. Now, I do know of people who are not letting their children get those numbers of vaccines. And some of these are highly educated, professional people, and they have decided that they are going to stretch them out over a longer time—they are not going to give it to their children before the age of 2; maybe by the age of 5 or 6. I know a lot of that is happening out there.

Now, a lot of pediatricians will not treat a child if, in fact, they are not receiving these immunizations. They will tell the parents, "Well, if you don't agree to the vaccination schedule, I cannot—you cannot be a patient of mine." But, I do know a lot of people that basically are not having their kids vaccinated. I don't know the ramifications of that, I don't advise that, or anything like that, but I just know that this is happening.

Dr. INSEL. So, we can imagine there's——

Senator HARKIN. The problem is, we don't know. We don't know if 29 vaccinations—immunizations—by the age of 2 do have an effect. We don't know that.

Dr. INSEL. Let me share with you the conversation we've had on the IACC, because, as you can imagine, this is a topic that has come up. It's a highly charged topic. The——

Senator HARKIN. Sure.

FAMILIES AND VACCINATIONS

Dr. INSEL [continuing]. Community is highly polarized on just this point.

Senator HARKIN. Sure.

Dr. INSEL. And we hear not only from those people who are convinced that vaccines are the problem, and from those who are convinced it's not. I must say, these are both ends of the spectrum, here—but, we also hear from lots of families who've had a child

with autism, and they're wondering what they should do about their next child. And that's often the question that is on the table, because they just don't know whom to believe, and they don't know what to listen to.

Senator HARKIN. That's right.

Dr. INSEL. The group of people who feel that there really is an issue here, who are really concerned that there's a relationship between vaccines and autism, point to the numbers that you point to, the large increase, and they say that, yes, there have been 16 studies, and all 16 studies demonstrate no relationship. However, those are all epidemiological studies, and you can't rule out the possibility that there's a very small signal there that might have been missed.

On the other side of the coin, the other end of the spectrum, we're hearing from other people—and not just scientists, but even family members on the IACC—who are saying, "Enough already. If there's an environmental factor at play here, then we've spent a lot of money and a lot of time doing these 16 studies, and nothing has shown up on this question, maybe we don't need to turn that rock over a 17th time. Let's move on, and let's look at something that is more likely to shed light on what could be an important factor in increasing the prevalence, or increasing the risk, for autism."

So, that's what we're hearing. And we're trying to balance both of those points of view, and also trying to make sure that there's information available for people who are most concerned about what they should do with their next child.

Senator HARKIN. Well, that is true. And that is why I say—we have got to do both—the research on the causes and the triggers, but also interventions. We need to look at early interventions, and how we might help people that are having a tough time dealing with children of their own, right now. We have got to focus on those early intervention programs, and we'll get to that in the next panel.

Senator COCHRAN. Mr. Chairman, thank you. I want to join you in welcoming Dr. Insel to the hearing, and also to recall that we've had hearings efforts in the past to try to develop a body of information that will help us identify better ways of dealing with autism. What are the causes? What are the possible changes in environment or nutrition or healthcare generally, that we can turn to for help in—helping to deal with the sorrow and the challenges and the difficulties that autism brings to our society.

I can recall back in Mississippi, joining with families to help raise money—have benefits, events, go on television, invite people to attend and contribute and the like. And some of the experiences that I had then, observing the children who were victims of autism and talking with families, getting to know more about it, really made a big impact on me, and how challenging this situation really is. And so, my heart goes out to those families who are dealing with it.

HOPE FOR THE FUTURE

And I just want to be here today to support the effort to identify how Government can be more helpful. What are the other possible causes for autism? What are the things that we can do? And to con-

tinue to work, and not give up. A lot of people have invested a lot of time and effort, research, dollars, personal energies, to cope with this situation.

And I'm curious to know from you, Is there hope? Have we discovered things? Have we learned things, over the last several years that we've embarked on this joint effort, that give us any hope that we're making progress?

Dr. INSEL. Absolutely. There is always hope. But, there's—even more than that, right now, there's very rapid progress.

And I think this next period of time is even going to be more extraordinary, because we're ramping up the investments very rapidly. In 2008, our budget for autism research at NIH went up 25 percent over 2007. In 2009, it will go up much, much more than that, because we are seeing this ARRA effort, and we have put money specifically into an autism request for applications though the ARRA. It's, I think, the only disease-specific such request in the ARRA from NIH for this year. We've got lots of other things going for the $10.4 billion, but this is the one that does have a disease name on it. And—because we realized that there's an urgent need, and, equally important, there's a tremendous opportunity right now for progress. We have the tools we need, that we can really start to move quickly. And so, we want to do that over the next 2 years.

Senator COCHRAN. Well, thank you very much for your efforts and being involved as the director of the NIMH. We appreciate your being here with us this morning and helping us fully understand the challenges we have ahead.

Dr. INSEL. Well——

Senator COCHRAN. Thank you.

Dr. INSEL [continuing]. Thank you for your interest and support.

Senator HARKIN. Well, thank you very much, Dr. Insel.

We would like to call our second panel. I didn't talk to you earlier about this, but if you have the time to stay, I would appreciate that. If you have to get back to the Institute, I understand, but if you can stay for a second panel, I would appreciate that.

Dr. INSEL. I'd be happy to stay, and I, most of all, want to hear the copanelists——

Senator HARKIN. Good.

Dr. INSEL [continuing]. Because I think all of us need to hear some of the personal experiences——

Senator HARKIN. Good. You—why don't you just stay up here, or——

Dr. INSEL. Will do.

Senator HARKIN [continuing]. Stay where you are. You don't have to move, just stay——

Senator HARKIN. Let's call our——

Dr. INSEL. You got me.

Senator HARKIN. Let's call our second panel: Dr. Geraldine Dawson—let's just start from left to right, as I call the name—Dr. Geraldine Dawson, Mr. Joshua Cobbs, Ms. Nicole Akins Boyd, David Miller, and Dana Halvorson.

Thank you all for being here. Some of you have come a great distance. And again, your statements will be made a part of the record

in their entirety. And if you could kind of summarize—5 minutes or so—I'd appreciate it very much.

We'll just start from left to right, here. Dr. Geraldine Dawson, the chief science officer for Autism Speaks. Prior to that position, she was a professor of psychology and psychiatry at the University of Washington, the founding director of the University's Autism Center. Dr. Dawson received her Ph.D. from the University of Washington.

Dr. Dawson, thank you very much. And please proceed. And if you would, just summarize it in 5 to 7 minutes, that would be appreciated.

STATEMENT OF GERALDINE DAWSON, CHIEF SCIENCE OFFICER, AUTISM SPEAKS, CHARLOTTE, NORTH CAROLINA

Dr. DAWSON. Good morning, Mr. Chairman. I want to thank you for inviting me. I'm very honored to appear before this subcommittee. And I want to thank the subcommittee members, and you, Mr. Chairman, for your leadership in providing full funding for the Combating Autism Act, and also for your most recent fiscal year 2010 appropriations bill.

Now, this year more children will be diagnosed with autism, as you may know, than with AIDS, diabetes, and cancer combined. Autism research, however, is still significantly underfunded, despite greater public and congressional awareness. For example, leukemia affects 1 in 25,000 people, but receives research funding of $310 million annually. Pediatric AIDS affects 1 in 8,000 children. Its funding is $255 million a year. Autism, as you know, affects 1 in 150 individuals, and yet NIH funding for fiscal 2009 is estimated to be $122 million.

Now, as you've heard, most scientists agree that autism is caused by a combination of both genetic risk factors and environmental factors. Now, we've discovered some of the autism-risk genes, but we still know very little about the role of the environment and how it interacts with these genes.

We have come to understand that autism is not one disease, but many different diseases that has many different causes, and each cause will likely only explain a minority of cases. So, piece by piece, we must discover each of these causes so that effective treatments and prevention will be possible.

To identify the causes, it'll be necessary to invest in large-scale, population-based studies that broadly examine genetic factors and environmental triggers, such as the NIH National Children's Study. It'll also be important to invest in large-scale databases and bio repositories, such as the National Database for Autism Research, the Autism Genetic Resource Exchange, and the Autism Tissue Program.

Now, recent studies suggest that autism may be, fundamentally, a problem of the synapse, as you've heard from Dr. Insel, the connection between brain cells. Some of the very best neuroscientists in the world are working hard at understanding how genetic mutations can change the way in which neurons communicate, and they're developing therapeutic strategies that might restore the function of the synapse. Now, while this work is offering real hope,

the pace of discovery is simply too slow, in large part because of lack of adequate funding.

And we can now screen for autism at 18 months of age, and Autism Speaks is funding several clinical trials that are evaluating interventions for at-risk infants who are as young as 12 months of age. The hope is that by detecting autism early, we'll be able to reduce its severity or even prevent the syndrome from developing. However, the impact of this work will not be felt unless pediatricians are using the available screening methods and parents have access to trained professionals who can deliver these interventions.

That's why it's critical that we continue to study dissemination methods, invest in training professionals and caretakers, and support federally mandated insurance coverage for behavioral interventions, which we know are cost effective in the long run.

Now, while behavioral interventions are effective for some individuals, most individuals with autism suffer without relief from the autism itself and a wide range of medical conditions, such as sleep disorders, gastrointestinal problems, and epilepsy. Very few clinical trials have been conducted that address these medical conditions, and virtually no cost-effectiveness studies have been conducted to determine which treatments are most effective. Thus, parents are left to sort through confusing and often inaccurate information about the various treatment options and claims, and clinicians are often at a loss in helping parents to make evidence-based treatment decisions. This gap in autism research must be addressed.

Very little research has been conducted today that addresses the issues that adults with autism face, despite the fact that adult care accounts for the bulk of the $35 billion that is spent annually on caring for individuals with autism in the United States. Unlike other health conditions, we have limited information about autism health care utilization, barriers to access, healthcare disparities in the United States, or cost-effectiveness models.

Mr. Chairman, over the past 2 years you and your subcommittee have been responding to the challenge of autism with resources, and this is beginning a meaningful fight against this very challenging disorder. But, more is needed to better understand the disorder, to diagnose it, and to better treat those individuals who have it.

PREPARED STATEMENT

I want to end by thanking you for your time, for your commitment, and for your leadership, and I'm very happy to entertain any questions that you may have.

[The statement follows:]

PREPARED STATEMENT OF GERALDINE DAWSON

Good morning, Mr. Chairman. I am Dr. Geraldine Dawson, Chief Science Officer of Autism Speaks. I also serve as a Research Professor of Psychiatry at the University of North Carolina at Chapel Hill.

I am honored to appear before the Senate Appropriations Committee Subcommittee on Labor, Health and Human Services, and Education, and related agencies at its second hearing on autism and the status of autism research, treatments, and services. I want to thank this subcommittee and you, Mr. Chairman, for your leadership in providing full funding of the Combating Autism Act (CAA) over the last 3 years, and more specifically, for your most recent fiscal year 2010 appropriations bill.

Autism Speaks was founded in February 2005 by Bob and Suzanne Wright, grandparents of a child with autism. Since then, Autism Speaks has grown into the Nation's largest autism science and advocacy organization, dedicated to funding research into the causes, prevention, treatments and cures for autism; increasing awareness of autism spectrum disorders; and advocating for the needs of individuals with autism and their families. We are proud of what we've been able to accomplish and look forward to continued success in the years ahead.

Here are a few facts about autism:

—According to the Centers for Disease Control and Prevention (CDC), autism is diagnosed in 1 in 150 children in the United States, and 1 in 94 boys.

—A decade ago, experts estimated the prevalence of autism to be 1 in 2,500.

—This year more children will be diagnosed with autism than with AIDS, diabetes, and cancer combined.

—Autism costs the American economy more than $35 billion in direct and indirect expenses each year, according to a Harvard School of Public Health study. Caring for a child with autism is estimated to cost over $3 million over that person's lifetime.

When Bob and Suzanne Wright founded Autism Speaks just 4 years ago, they were shocked that a disorder as prevalent as autism commanded so little in terms of resources devoted to research and treatment—when compared to other, less common disorders. That disparity continues, despite greater public and Congressional awareness, and despite the efforts of you and this subcommittee to direct additional resources into autism research.

—For example, leukemia affects in 1 in 25,000 people, but receives research funding of $310 million a year.

—Pediatric AIDS affects 1 in 8,000 children; its funding, $255 million a year.

—Compare these figures with those for autism, which affects 1 in 150 children and yet the National Institutes of Health (NIH) funding for fiscal 2009 is estimated to be $122 million.

To close the gap, Autism Speaks raises its own funds to support autism research. We hold walks and special events, and cultivate major giving opportunities for individuals as well as corporations and foundations all to help accelerate the pace of autism research. We are proud to be putting our hard-earned dollars to work to move forward in finding a cure for autism.

Through our grants (scientist-initiated requests for funding) and initiatives (targeted projects designed by Autism Speaks), we support research designed to answer questions poised in each of five targeted areas: What causes it? (etiology); What is it? (biology); How do you know if someone has it? (diagnosis); How do we make it better? (treatment); and How do we effectively disseminate best practices to the community? (dissemination). Since its founding in 2005, Autism Speaks has committed more than $130 million toward autism research.

But we realize, Mr. Chairman, that our nonprofit, no matter how successful we may be in raising funds, cannot match the resources that the Federal Government could marshal in the campaign to find treatments and cures for autism. For that reason, we also worked together with thousands of families affected by autism to introduce, pass and have former President George W. Bush sign into law the Combating Autism Act in December 2006. This historic act, considered by some to be the most comprehensive piece of single-disease legislation ever passed by Congress, authorizes appropriations of $920 million over the 5-year period, from fiscal year 2007 to fiscal year 2011, for autism research, surveillance, awareness and early identification.

Combating Autism Act

Mr. Chairman, let me elaborate on each of the three sections of the CAA.

For the NIH, the funding increases are incremental, from $100 million in fiscal 2007 to an authorized level of $158 million for fiscal 2011. Most important, the act directs NIH to spend those dollars strategically, according to a Strategic Research Plan devised by the Interagency Autism Coordinating Committee (IACC) with consumers and advocates comprising a third of its membership. The act also directs NIH to increase its investment in research into potential environmental causes of autism.

For the CDC, whose autism portfolio would increase from $15 million to $21 million over the 5-year span, its increased funds are targeted for expansion of its awareness and intervention activities to reach new parents, healthcare professionals, and healthcare providers.

The Health Resources and Services Administration (HRSA) autism activities, which would increase from $32 million in fiscal year 2007 to $52 million by fiscal year 2011, are designated for creation of new and innovative State-based programs

in autism education, detection and early intervention and for best practices research on autism interventions, an area in which Autism Speaks is at the forefront through a cooperative agreement between our Autism Treatment Network and HRSA.

Our investment in the Autism Treatment Network, a collaborative network of 15 hospitals providing care for children with autism, is now being leveraged by the Federal Government through this HRSA funding and through a developing collaboration with Dr. Susan Swedo's National Institutes of Mental Health (NIMH) Intramural Research program on autism. The establishment of research networks by private funders, like Autism Speaks, has created the infrastructure that can now benefit both HRSA and the NIH, providing significant time and cost savings. The collaboration with the NIMH Intramural Research Program is an excellent example of a productive public-private partnership.

Autism Speaks also recently contributed $5 million to expand and link two NIH-funded large-scale, multi-site studies investigating genetic and environmental risk factors for autism in 2,000 infant siblings of children with Autism Spectrum Disorders (ASDs). These are only a couple of examples of the many ways that Autism Speaks is collaborating with the NIH to facilitate research on the causes and treatment of autism.

President Obama and Autism

Congress' commitment to autism has now been matched by the President. Last year, Mr. Obama committed to increasing ASD funding for research, treatment, screenings, public awareness, and support services to $1 billion annually by the end of his first term in office. He also pledged to end insurance discrimination against people with autism. (Of course, Autism Speaks is now working to bring this promise to fruition through the healthcare reform process.)

President Obama fulfilled his campaign promises in the fiscal year 2010 budget he submitted to Congress in February of this year. That budget includes $211 million in Department of Health and Human Services (HHS) funding for research into the causes of and treatments for ASD, screenings, public awareness, and support services.

Appropriation's Leadership

The authorizations and Presidential budgets will mean little if not matched by real dollars appropriated by your subcommittee, Mr. Chairman. And you have done a heroic job of identifying and targeting the resources to match the authorization targets set by the Combating Autism Act for HHS's autism activities.

In your fiscal year 2008 and 2009 bills, the Senate Appropriations Committee matched or beat the CAA authorized levels for CDC and HRSA. And in each of those years, you also provided the resources to NIH to create and fund the operational costs of the IACC, and to adhere to the research funding targets set by the Combating Autism Act. As of just last week, the Senate Appropriations Committee fiscal year 2010 bill provides $71 million for CDC and HRSA's autism activities, the same levels proposed by the President.

On behalf of Autism Speaks, I also want to thank you for ensuring that $2 million of the increase proposed for HRSA's autism activities will be targeted for expansion of research on evidence-based practices for interventions for individuals with autism and other developmental disabilities, for development of guidelines for those interventions, and for information dissemination, as directed by the CAA. As I mentioned earlier, this program, in particular, is already being leveraged to the benefit of other Federal research.

State of Autism Research

Causes of Autism.—Most scientists agree that autism is caused by a combination of genetic susceptibilities which interact with environmental risk factors. We have learned that autism is a complex genetic disorder involving many genes. In recent years, studies have shown that several rare mutations confer significant risk for autism. While we have discovered some of the risk genes for autism, we still know little about the potential environmental risk factors. We also have come to understand that there are many different causes of autism, and that any one cause will likely only explain a minority of cases. Piece by piece, we must discover each of these causes so that effective treatments and prevention will be possible.

To identify the genetic and environmental risk factors for autism, it will be necessary to conduct large scale population-based studies that broadly examine both genetic susceptibilities and environmental exposures. The NIH National Children's Study, a prospective longitudinal study of 100,000 children in the United States, potentially provides such an opportunity and should be fully utilized to increase our understanding of autism. Autism Speaks is currently advising the staff of the National Children's Study on ways the study could be leveraged to better understand

how genetic and environmental risk factors may increase risk for autism. Autism Speaks also is funding expansion of two NIH-supported Autism Center of Excellence Network studies to include the capture of a number of environmental exposures and the analysis of how they interact with genetic vulnerability. In addition to funding large scale studies of risk factors, continued investment in large-scale databases and biorepositories, such as the National Database for Autism Research, the Autism Genetic Resource Exchange, and the Autism Tissue Program, will be crucial for understanding the causes of this complex disorder. By identifying the causes, we will be able to identify individuals at risk for the disorder as early as possible and develop methods for treating and preventing autism.

Biological Mechanisms.—We are also gaining an understanding of the underlying biological mechanisms in autism. Evidence is converging that autism may be fundamentally a problem of the synapse, the connection between brain cells (neurons). Neuroscientists are mapping the biochemical pathways that appear to be disrupted in autism and that are interfering with how neurons in the brain communicate with each other. Some of the very best neuroscientists in the world are working hard at understanding how genetic mutations can change the way in which neurons communicate and developing therapeutic strategies that might restore synaptic function. While this work is offering real hope, the pace of discovery is simply too slow in large part because of a lack of adequate funding for such research. Barriers to translational science that can bring basic findings from the bench to the bedside are significant. The gulf between a basic discovery and the development of a new treatment is so overwhelming that it has been called "a valley of death" by some scientists. Scientists are ill-equipped to develop the technologies that are required for translational research, and funding of such research is often a lower priority relative to discovery-focused research at the NIH. Thus, translational research must be supported through multi-disciplinary collaboration and targeted funding to support technological and scientific advances that will help pave the way to treatment, prevention, and cure. This is why Autism Speaks strongly supports Senator Specter' s "Cures Acceleration Network" (CAN Act) and hopes that the policies addressed in that bill will be incorporated into the final healthcare reform legislation.

It will be crucial for the Federal Government to provide the necessary resources needed to move scientific discovery from the lab to the clinic. Autism Speaks is poised to help in this process not only with scientific grants, but also with our support for the large scientific databases, such as the Autism Genetic Resource Exchange, and collaborative networks that are capable of conducting clinical research and disseminating evidence-based methods, such as the Autism Treatment Network and the Clinical Trials Network.

Early detection and early behavioral intervention. Two areas in which we have made significant progress in the past several years are early diagnosis and early intervention. Screening methods for autism now exist for children as young as 18 months of age, and the American Academy of Pediatrics now recommends that all babies be screened for early signs of autism at 18 and 24 months of age. Autism Speaks and the NIH are funding several studies focused on detecting autism in even younger infants. Building on these important findings, researchers have developed a variety of protocols to intervene at early ages, and Autism Speaks is funding several clinical trials that are evaluating the efficacy of these intervention methods for infants as young as 12 months of age. The hope is that, by detecting autism early in life before the full syndrome has become manifest, we will be able to reduce its severity or even prevent the syndrome from developing. However, the impact of this work will not be felt unless pediatricians are using the available screening methods and parents have access to trained professionals who can deliver these interventions. That is why it is critical that we continue to study dissemination methods, invest in training professionals and caretakers, and support federally mandated insurance coverage for behavioral interventions which are very cost effective in the long run.

Treatment Across the Lifespan.—While behavioral interventions are effective for some individuals, there is significant individual variability in response to such interventions. Biological research is offering hope that medical interventions that address core symptoms of autism will someday be available. Today, however, many individuals with autism suffer without relief both from the autism itself and also from a range of medical conditions that are associated with autism, such as sleep disorders, gastrointestinal problems, epilepsy, anxiety, and depression. Very few clinical trials have been conducted that address these co-morbid medical conditions. Practice standards that can guide physicians on how to detect, assess, and treat these conditions do not exist. Virtually no comparative effectiveness studies have been conducted to evaluate which treatment methods are more effective for treating core autism or its associated conditions. Thus, parents are left to sort through con-

fusing and often inaccurate information about various treatment claims and options. Without the benefit of comparative effectiveness research, clinicians are often at a loss in helping parents make evidenced-based treatment decisions. This is a gap in autism research that must be addressed.

It is imperative that enhanced effort be directed toward developing effective treatments across the entire lifespan. Very little research has been conducted to address the issues that adults with autism face, despite the fact that adult care accounts for the bulk of the $35 billion that is spent annually on caring for individuals with autism in the United States. Unlike other health conditions, we have very limited information about autism healthcare utilization, barriers to access, health care disparities in the United States, or cost-effectiveness models.

A major barrier to appropriate treatment for individuals with autism is lack of access to well-trained providers. Research must identify the most effective, scalable, and feasible models for community-based delivery of services. This will require identifying factors that impede or promote the adoption of optimal practices. Training and capacity-building are needed to increase the number of well-trained professionals, including physicians and allied health professionals, such as nurses, psychologists, and educators, as well as physical, occupational, and intervention therapists.

In summary, it is clear that the insights we have gained have resulted directly from investments in scientific research on autism. However, without further and increased investment in science, our progress will be very slow. The IACC Strategic Plan for Autism Research has benefited greatly from input from the autism community, including private funding agencies. The IACC conducted a portfolio analysis of public and private autism research to enable future iterations of the Strategic Plan to build on existing research. We have seen how important this coordination and collaboration has been, and we must, as a community, continue to insist on it. The Strategic Plan was completed in January 2009, so it remains to be seen how closely it will be followed by the NIH with respect to research support. But I am hopeful that the collaboration between public and private funders of autism research will result in significant and innovative research that advances our understanding of the causes, prevention methods, treatments, and a cure for autism.

Next Steps

Mr. Chairman, the challenge of autism and its impact on our children, our families, and our Nation are daunting, and the plans of Autism Speaks are equal to the task.

In the short term, we are focused on ensuring that Congress matches in its appropriations bills the authorized levels for HHS's autism research, surveillance, education and treatment set by the Combating Autism Act over the next 2 fiscal years. We are also planning for the reauthorization of the Combating Autism Act which is set to expire on September 30, 2011.

We have also been working on the next phase of the autism agenda—the provision of enhanced treatment, support, services, and research for individuals with ASD. That effort, which began with preliminary discussions with then-Senator Barack Obama, has produced the Autism Treatment Acceleration Act of 2009 (ATAA), introduced in the Senate by Senator Richard Durbin (S. 819) and in the House by Congressman Mike Doyle (H.R. 2413). The ATAA includes a number of key authorizations, including Autism Care Centers and an Adult Services Demonstration, a population-based autism spectrum disorders registry, a National Network for ASD Research and Services, and most important, a requirement that health insurers cover diagnostic assessment and treatments for autism, including Applied Behavioral Analysis therapy. Of course, we are making every effort to see to it that this insurance component of the ATAA becomes law as a component of healthcare reform.

The Continuing Challenge

At the Senate Labor-HHS Subcommittee's first hearing on autism in April 2007, Autism Speaks co-founder Bob Wright issued a challenge to Congress and our Nation, when he stated:

"The public health crisis posed by autism requires an extraordinary response. With every new child diagnosed with autism costing an estimated $3 million over his or her lifetime, we cannot afford to rely on standard, 'business as usual' practices. The autism crisis demands a focused, coordinated, and accountable response by our public health agencies, similar to the federal response to the AIDS crisis in the 1990s, with line-item appropriations for autism intervention, surveillance and research tied to a strategic plan."

Mr. Chairman, over the past 2 years, you and your subcommittee have met this challenge and responded to autism not with promises, but with resources to begin a meaningful fight against this public health crisis.

But more is needed to better understand the disorder, to better diagnose it, to better treat those children who have it, and ultimately to find cures for this spectrum of disorders. We do not need only to ramp up the NIH's investment in autism research, we also need to ensure that every dollar spent on this disorder is targeted and maximally impactful.

Thank you, Mr. Chairman, for your time, for your commitment, and for your leadership.

Senator HARKIN. Thank you very much, Dr. Dawson.

And before we go on with the rest of the panel I want to recognize my good friend and colleague, from Pennsylvania, with whom I've shared the gavel here over the last almost 20 years. Senator Specter is a member of the Judiciary Committee; they are over on the floor now with the Sotomayor nomination, so he may have to go to the floor. And, I would yield to Senator Specter.

STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Well, thank you, Mr. Chairman, for yielding. We're taking up the confirmation hearing of Judge Sotomayor for Supreme Court, and I'm due on the floor shortly, but I wanted to thank you, Mr. Chairman and Ranking Member Cochran, for scheduling this hearing on this very important subject, and thank the witnesses for coming in.

Autism is a heartbreaking ailment, and of the many issues we have to face, among the toughest, talking to parents who have children who suffer from autism, and there's a real question of doing more.

Senator Harkin and Senator Cochran and I have worked hard on funding for the NIH, and for a decade we were able to raise funding from $12 to $30 billion, at a time when Senator Harkin and I have transferred the gavel, Senator Cochran was chairman of the full Appropriations Committee; and regrettably, that's not enough. I note that funding for autism was slightly under $52 million in 2000, up to $122 billion—million now, and estimated to $141 million, and CDC's spending has increased from a little over $1 million to a little over $22 million. We have been successful in getting into the stimulus package $10 billion, as you doubtless know, and it is my projection that some of that will be going to autism.

These funding levels were set by NIH in order to avoid what we call "politicization." Our job is to get the money, but not to distribute it. And I think there ought to be a bigger share for autism, and we're pushing to make that happen.

And on comprehensive healthcare reform, which we're working on now, we're trying to get $10 billion added, as a base of 30—start with 40—which would give us a better opportunity to do more on this very, very important ailment.

So, I wanted to express those views today. And staff will be here to follow the testimony. We'll have a chance to review it.

I appreciate your coming in. And you have our assurances that we'll do everything we can on this very important malady.

Thank you, Mr. Chairman.

Senator HARKIN. Thank you very much, Senator Specter. And I understand you have to be on the floor for the nomination.

And now we'll go to Mr. Cobbs.

Mr. Cobbs, if I remember right you're from Iowa, up near Sioux City.

Mr. COBBS. Yes, sir, I grew up in the Sioux City area, of course.

Senator HARKIN. And you're the chairman of the Iowa Autism Council, the father of a 9-year-old boy with autism, Noah. I understand your wife, Tina, is with you here.

Mr. COBBS. She's in the audience.

Senator HARKIN. Okay. And two other children—Ethan, 16, and Sidney, 8. And you were here at our last hearing. Weren't you here a couple of years ago?

Mr. COBBS. I was, sir, I was in the audience in the last hearing.

Senator HARKIN. And you've been involved in the telehealth project with a young boy, with Noah, right?

Mr. COBBS. Yes. Yes. Correct, sir.

Senator HARKIN. Well, I'm interested in, what's happened in the last couple of years. So, welcome to the subcommittee. Please proceed.

STATEMENT OF JOSHUA COBBS, CHAIRPERSON, IOWA AUTISM COUNCIL, SIOUX CITY, IOWA

Mr. COBBS. Thank you for having me.

Good morning, Mr. Chairman and members of this distinguished subcommittee. My name is Joshua Cobbs. I am the chairperson of the Iowa Autism Council, a parent advisor to Cnow, and, most importantly, a parent of a child with autism.

I've spent over 7 years trying to better the lives of individuals and families affected by autism, through insurance and education reforms. When I was last in front of this distinguished committee, I spoke of the successful and cost-efficient services my son received using telehealth technology. These services were provided in my home, in Iowa, from professionals in Florida, through the Celeste Foundation's federally sponsored National Research Project. We are one of 15 families that participated in this demonstration across the nation.

In this model, after a brief phase of onsite, face-to-face training, which is crucial to build a therapeutic relationship, we were linked to professionals by an interactive video system that enabled live training, consultation, and support directly into our home, when and where we needed it. Through this telehealth model, we receive professional support in teaching our son language, life skills, and, overall, improving his quality of life.

One of the main components of participating in this study was the reduction in our family stress through empowering us as frontline teachers and therapists. Additionally, through training and education in this project, we had a better understanding of our child's condition and those things we could do—could bring to bear to improve his life.

Not only did it improve my son's quality of life, but it had an impact on my life—on my family, as well. Also, as a family we showed a dramatic reduction in stress, anxiety, and became more focused as a family unit.

I'll never forget the call my—I will never forget the call from my wife, saying, "You'll never guess what our son did. He went potty

on the big-boy potty." This moment was a monumental moment for the entire family. While many consider toilet training a milestone, it becomes a super-milestone when your child is 5 years old with autism and has the additional burden of societal rejection. Through our telehealth connections and access to certified professionals, we were given the right teaching skills and able to achieve what previously was unobtainable.

Our experience was chronicled in a two-part series filmed by the CBS affiliate in Sioux City, Iowa, and aired during Recognition of Autism Awareness Month. We have copies of the footage that we would like to share with the subcommittee, and it can also be viewed at www.CelesteFoundation.org.

I cannot stress enough that the needs of a—of persons with autism do not conveniently conform to clinic hours or professional appointments. We were able to access these professionals' health when we needed it, and it made all the difference. Also, just having the support in my home allowed natural interaction for my son, and allowed the professionals to see the behaviors as they really occur.

As chairperson of the Iowa Autism Council, I have the opportunity to speak with many family members and stakeholders within the autism community to learn their needs. From my perspective and my experience, these families are desperately in need of services.

Today, as parents search online for appropriate telehealth services for their children, they are confronted with an array of unvalidated technologies and various individuals claiming expertise in treatment. Unfortunately, there are no safeguards for—in place to protect vulnerable parents and children.

For example, from anywhere in the world, anyone with a personal computer, a Web cam, and Internet access can offer video services termed as "advice." Under these circumstances, any individual or group can claim qualifications in helping parents and children with autism. Not only are families experiencing the emotional burden of treating a child with a disability, but they also have the financial burden of paying for this treatment, with no assurance as to the quality of care provided. When individuals or organizations that are collecting fees for services can distance themselves into the cloud that is the Internet, what can families expect for recourse to failed expectations?

The reality of standard-setting is evidence—is evident, because, without standards there can be no reimbursements. While the method and systems are cost effective, without a proper reimbursement model they still remain unobtainable for most parents, who, similar to the rest of the nation, are struggling financially to find care for their children.

There are millions of dollars being placed into rural telehealth networks. However, there are few, if any, methodologies for reimbursement for autism telehealth treatments. Additionally, the current wave of statewide health insurance requirements, aimed to provide reimbursements for individuals with autism, do not have well-defined standards for telehealth reimbursements. In absence of consistent reimbursement policy and standards, families and children are not granted access to proven and effective care.

I know this subcommittee, through report language, has recognized the need to assess, quote, "best practices and professional criteria standards, and to make recommendations to the committee concerning national standards for telehealth reimbursement, which advances and encourages this technology," end quote. I commend the committee's foresight in doing so, and simply urge that this momentum continues.

In closing, you may be wondering how my son is doing today. He's now 9 years old, and my family is still utilizing telehealth technology. We are currently addressing such behaviors as food selectivity, expressive language, academic skills, just to name a few. It is important to note that, as my son grows, his treatment program continues to grow and address his ever-evolving needs. We continue to use telehealth treatment because it's been an effective delivery system for our family. In fact, it has been so effective that now my 8-year-old daughter has become a mini-therapist, using teaching strategies that we learned in the telehealth program with my son.

PREPARED STATEMENT

At this point in my son's life, he continues in the role of student and teacher to us all. Indeed, his future is bright.

I'd like to thank you for your time and the opportunity to share our story, and the stories of thousands of families, here today.

Thank you.

[The statement follows:]

PREPARED STATEMENT OF JOSHUA COBBS

Good morning, Mr. Chairman and members of this distinguished subcommittee. My name is Joshua Cobbs. I am the Chairperson of the Iowa Autism Council, a Parent Board member of the Iowa Association for Behavior Analysis, the Autism Speaks Chapter Advocacy Chair for Iowa, the Co-Chair of Marketing and Fundraising for the Siouxland Autism Support Group, a Chapter of the Autism Society of America, a Parent Advisor to Cnow and most importantly, the parent of a child with autism. I have spent over 7 years trying to better the lives of individuals and families affected by autism by working on education and insurance reforms.

When I was last in front of this distinguished subcommittee I spoke of the successful and cost-efficient services my son and family received using telehealth technology. These services were provided in my home in Iowa from qualified professionals in Florida through the Celeste Foundation's federally funded national research project. We were 1 of 15 families that participated in this demonstration across the Nation. In this model, after a brief phase of on-site, face-to-face training (which is crucial to build a therapeutic relationship), we were linked to professionals by an interactive video system that enabled live training, consultation and support directly into our home when and where it was needed. Through this telehealth model, we received professional support in teaching our son language, life skills, and overall improving his quality of life. One of the main components of participating in this study was the reduction in our family stress through empowering us as frontline teachers and therapists. Additionally, through training and education in this project we had a better understanding of our child's condition and those things we could bring to bare to improve his life. Not only did it improve my son's quality of life, but it had an impact on my family as well. Also, as a family we showed a dramatic reduction in stress, anxiety and became more focused as a family unit.

I will never forget the call from my wife saying, "You'll never guess what our son did, he went potty on the big boy potty!" This was a monumental moment for the entire family. While many consider toilet training a milestone, it becomes a supermilestone when you're child is 5 years old with autism and has the additional burden of societal rejection. Through our telehealth connections and access to certified professionals, we were given the right teaching skills and able to achieve what previously was unobtainable. Our experience was chronicled in a two part series filmed

by the CBS affiliate in Sioux City, Iowa, and aired during recognition of Autism Awareness Month. We have copies of this footage that we would like to share with the subcommittee and it can also be viewed at www.celestefoundation.org.

I can not stress enough that the needs of persons with autism do not conveniently conform to clinic hours or professional appointments. We were able to access these professional's help when we needed it and it made all the difference. Also, just having the support in my home allowed natural interaction for my son and allowed the professionals to see the behaviors as they really occur.

As chairperson of the Iowa Autism Council, I have the opportunity to speak with many family members and stakeholders within the autism community to learn their needs. From my perspective and my experience, these families are desperately in need of services. Today, as parents search online for appropriate telehealth services for their children, they are confronted with an array of unvalidated technologies and various individuals claiming expertise in treatment. Unfortunately, there are no safeguards in place to protect vulnerable parents and children. For example, from anywhere in the world anyone with a personal computer, a webcam and Internet access can offer video services termed as "advice". Under these circumstances, any individual or group can claim qualifications in helping parents and children with autism. Not only are families experiencing the emotional burden of treating a child with a disability, but they also have the financial burden of paying for this treatment with no assurance as to the quality of care provided. When individuals or organizations that are collecting fees for services can distance themselves into the "cloud" that is the Internet, what can families expect for recourse to failed expectations?

The reality of standard setting is evident because without standards there can be no reimbursements. While the method and systems are cost effective, without a proper reimbursement model they still remain unobtainable for most parents who, similar to the rest of the Nation, are struggling financially to find care for their children. There are millions of dollars being placed into rural telehealth networks. However, there are few, if any, methodologies for reimbursement for autism telehealth treatments. Additionally, the current wave of state-wide health insurance requirements aimed to provide reimbursements for individuals with autism do not have well-defined standards for telehealth reimbursements. In the absence of consistent reimbursement policies and standards, families and children are not granted access to proven and effective care.

I know this subcommittee, through report language, has recognized the need to assess "best practices and professional criteria standards and to make recommendations to the Committee concerning national standards for telehealth reimbursement which advances and encourages this technology." I commend the Committee's foresight in doing so and simply urge that this momentum continues.

In closing, you may be wondering how my son is doing today. He is now 9 years old and my family is still utilizing telehealth technology. We are currently addressing such behaviors as: food selectivity, expressive language, academic skills, etc. It is important to note that as he grows, my son's treatment program continues to address his ever evolving needs. We continue to use telehealth treatment because it has been an effective delivery system for our family. In fact, it has been so effective that now my 8-year-old daughter has become a mini-therapist using teaching strategies learned in the telehealth program with my son. At this point in my son's life he continues in the role of student and teacher to us all. His future is bright. Thank you.

Senator HARKIN. Thank you very much, Mr. Cobbs. We'll have some questions for you later.

And now, we turn to Ms. Nicole Akins Boyd, vice chairman of the Mississippi Autism Task Force, an attorney, mother of two children. Her second child—"Spite?"

Ms. BOYD. "Spate." [Speight]

Senator HARKIN. Sorry for mispronouncing that—her son Speight developed regressive autism at around 22 months of age. She was recently appointed to Mississippi's Department of Education, Special Education Advisory Committee. Ms. Boyd attended Mississippi State and received her Juris Doctor degree from Ole Miss.

Welcome to the subcommittee. Please proceed.

STATEMENT OF NICOLE AKINS BOYD, J.D., VICE CHAIRMAN, MISSISSIPPI AUTISM TASK FORCE, OXFORD, MISSISSIPPI

Ms. BOYD. I want to thank this subcommittee, on behalf of the many Mississippians and families with autism I represent, and Senator Cochran's leadership as he's held meetings with many of us throughout the State of Mississippi.

In late fall of 2005, our family was living in San Antonio, Texas, while my husband completed his surgical fellowship. My youngest child, Speight, at the age of 22 months, developed regressive autism. Almost overnight, he digressed, from using words and sentences in two languages, with fine gross motor coordination well above his developmental peers, to someone who lost almost all of those skill sets. It was as though a tornado had hit our lives, and there was no end in the foreseeable future.

At age 25 months, my son began a rigorous program filled with behavioral, speech, and occupational therapy that has continued after our move back to Mississippi. Currently, we can see progress, and we're cautiously optimistic about the future. He's quite verbal, and his gross and fine motor skills have greatly improved. His medical condition is always tenuous, as he's believed to suffer from a mitochondrial disorder which is proposed to be a contributing factor to his autism. Simple viruses will turn this very high-functioning child—on the spectrum—to a low functioning child within just a matter of hours.

Today, he will attend his kindergarten open house at Bramlett Elementary, in Oxford, Mississippi. He'll attend a regular education class, and he'll have some classroom and resource assistance. As the class of 2022 starts kindergarten, schools across this country are going to look very different. Twenty years ago, in this country, Speight would have probably been the only child in his kindergarten class with autism, or even his whole school district. However, his kindergarten class of roughly around 200 students will have 6 children diagnosed with the autism spectrum. All are very high functioning. If you do the math, that's roughly 1 in 34.

Now, in Mississippi, according to the surveys we did on the task force, we know that children typically don't get diagnosed until much later than 5, so that number is probably going to be higher. This is a very high number compared to what we see as national statistics, but, unfortunately, I think you will see this number replicated in kindergartens throughout this country in various places. We know that the rate of autism goes up 10 to 17 percent per year, so it—this next decade, can you imagine what autism is going to look like?

The medical establishment, as it often is, gives itself a pat on the back for saying they're doing a better job diagnosing this, but we know there's got to be contributing factors that are the root of this autism increase. It does—better diagnosis doesn't completely explain the explosion that we're seeing here in America.

What—oftentimes—we see adversarial relationships develop between pediatricians and family members who believe that their autism was caused by vaccines. We see, also, relationships—adversarial—when parents don't accept the advice of physicians that there could be multiple causes of the autism. And thus, we reach

an impasse, and help for the child, as you pointed out, Mr. Harkin, is very hard to come by.

The Autism Society of America currently estimates that the lifetime cost of caring for a child with autism is from $3.5 to $5 million. Taking those numbers, we're looking at facing almost a $90 billion annual cost in autism. The question that we have to ask this subcommittee, and this whole Senate body, is, Can we afford not to put the money into research and treatment if these are the numbers that we're looking at?

The Combating Autism bill brought great hope to parents, and we appreciate your work in passing that. However, we've got to move quicker. We've got to see the Interagency Coordinating Committee look at all aspects and possible causes to autism. We've also got to see that subcommittee quickly make some identifiers and look at populations of these children to find out, What are the general pictures that we see of these children's parents, their family members? What are some health indicators that we see? And it's got to be done quicker than we usually operate at Government bureaucracy levels.

The other thing, too, I would be remiss in representing the parents that I feel like I represent, even across this country, if I did not go back to your question, Senator Harkin. We have to look at the causal—causation with vaccines. Dr. Bernadine Healy, who I'm sure has testified before this subcommittee many, many times and really doesn't have any financial interest, pecuniary or otherwise, has noted that there is a dearth of research in truly looking at the vaccine-autism connection. There are some very good studies that are yet to be done. And I know this subcommittee, and this Senate, doesn't like to tell the NIH how to spend those research dollars, but on behalf of the parents across America, I ask that you particularly look at this, particularly when you're confirming a new NIH director.

I want to give you some optimism that—as we talk about autism. In this classroom—in the children—Bramlett Elementary group of six, five of those children have been blessed to be able to receive intensive behavioral therapy. Their families have—one of the situations, they've taken two jobs to be able to afford this intensive behavioral therapy. That's not often the case in Mississippi. And that's a rarity. With Mississippians, the average annual income is less than $35,000 a year, and yet this private intensive behavioral therapy runs most of us around over $50,000 a year. So, it is impossible for many of the constituents back home to afford the therapy that they know will make their child better.

So, on behalf of those Mississippians, I beg you to look at ways that we can afford intensive behavioral therapy for all children. These children, that I mentioned, that have received this intensive behavioral therapy, even at the age of 5, they already are requiring less classroom supports than they would have. It is—you can see the financial bright spots, down the road, of investing in early intensive behavioral therapy.

PREPARED STATEMENT

So, the question I guess I will leave you with is, If we know that we are looking at a $90 billion annual healthcare cost, and we're

looking—and I put the information that—I've turned in to you—and we're looking at initial investments of around $32,000 a year, and we know that, over that child's life, we can see healthcare returns roughly at about $2.5 million of healthcare savings for those children who get this, the question is, Senators, "Can we afford not to make that investment?"

[The statement follows:]

PREPARED STATEMENT OF NICOLE AKINS BOYD

In the late fall of 2005 our family was living in San Antonio, Texas, while my husband completed his surgical fellowship. My youngest child, Speight at around the age of 22 months developed regressive autism. Almost overnight he digressed from using words and sentences in two languages with fine and gross motor coordination well ahead of developmental milestones to a child who lost nearly all language with impaired neuromuscular control. It was as if a tornado had hit our lives with no end in the foreseeable future to the destruction.

At age 25 months Speight began a rigorous program filled with behavioral, speech, and occupational therapy that has continued after our move to Mississippi. Currently, we can see progress and are cautiously optimistic about the future. He is quite verbal and his gross and fine motor skills have greatly improved. His medical condition is always tenuous as he is believed to suffer from a mitochrondrial disorder which is proposed to be a contributing factor for his autism. Simple viruses will turn a high functioning child on the spectrum to a low functioning child within a matter of hours. Today, he will attend his kindergarten open house at Bramlett Elementary in Oxford, Mississippi.

Speight will attend a regular education class and will have some classroom and resource assistance. As the class of 2022 starts kindergarten, schools across this country will look very different. Twenty years ago in this country Speight would have probably been the only child in his kindergarten class or even his school with Autism Spectrum Disorder (ASD). However, his kindergarten class of around 200 students will have 6 children diagnosed with ASD. If you are trying to do the math that is roughly 1 in 34. In Mississippi, a small survey conducted by the State task force indicated that many Mississippi children are often not diagnosed before age 5 and therefore it is probable this number may go even higher. Although this number of 1 in 34 may be somewhat of an anomaly, it is unfortunately less of an anomaly than we would all like to believe in the kindergarten classes around this country.

The February 2007 Centers for Disease Control and Prevention Autism Prevalence Report was of no surprise to Americans or those of us in Mississippi living with the effects of ASD. The report, which looked at a sample of 8 year olds in 2000 and 2002, concluded that the prevalence of autism had risen to 1 in every 150 American children, and almost 1 in 94 boys. Based on the statistics from the U.S. Department of Education and other governmental agencies, autism is growing at a rate of 10 to 17 percent per year. At this rate in the next decade the prevalence of autism could reach 4 million Americans. Indeed, the class of 2022 will look very different.

Despite the fact the incidence of autism has risen almost 6,000 percent since the 1980s, we have yet to clearly define why there has been such a dramatic increase. The medical establishment, as is often the case, gives credit to itself by stating that better diagnoses is the root cause of the increase. However, this does not completely explain the explosion of autism in America. Currently, there is no "mainstream" medical treatment for autism. Yet, there are more camps and theories that have lined up in this debate than mosquitoes in Mississippi. And yes, all are lined up in the name of science and of "helping my child."

Everywhere a parent turns there are those telling them the "reason" their child has autism as if they had been whispered a reason by God on high. Parents who believe that vaccines harmed their children have been marginalized by their pediatricians when their have been clear clinical vaccine reactions that propel children into autistic behavior. Physicians who try to suggest a multiple set of reasons for autism are ignored and rebuffed by their patient's families. An adversarial relationship is thus created, leading to an impasse in determining why my child developed autism and what the underlining medical conditions that prevent his full recovery. Moreover, we also do not know how we keep your children and grandchildren from suffering the same fate.

As parents we appreciate that Congress has devoted attention to autism, starting with the Children's Health Act of 2000, now almost a decade ago. But, after so many words and so many years, it's absolutely clear that autism is still woefully under funded by the National Institutes of Health compared to the prevalence and the costs to our society of the condition. The Autism Society of America currently estimates that the lifetime cost of caring for a child with autism ranges from $3.5 million to $5 million, and that the United States is facing almost $90 billion annually in costs for autism.

For parents, the passage of the Combating Autism Act (CAA) brought great hope that research would begin promptly in identifying children at greater risk for developing the disorder and whether there were sub-populations more predisposed to have ASD children. Yet, to date research has failed to make those clear identifications. Parents and autism professionals are voicing their frustration with the speed or lack thereof with The Interagency Autism Coordinating Steering Committee that is responsible for disbursing the millions of dollars in CAA funds. For parents, this subcommittee looks like the height of Washington bureaucracy.

The parents of ASD children were thrilled this last year when autism became a major issue for both parties in the Presidential campaign. And this year when President Obama became the first President ever to specifically call for a significant increase in autism research in his budget, this subcommittee did not ratify that policy. I understand Congress's reluctance to mandate NIH dollars for specific research. However, you will understand that parent's confidence is lacking in an entity where their biggest highlight on their "Health Publications about Autism and Related Disorders" web page is about dental and oral care of the special needs population. Parents want more than how to brush and care for our kid's teeth.

On behalf of parents, I am asking this subcommittee in the future to be very explicit to the NIH in how research dollars are spent for autism. We want the questions answered that identify children more likely to develop autism by looking at the current parents of ASD children. Also, we want the true research questions answered on vaccines and autism that have been pointed out by Dr. Bernadine Healy, the former director of the NIH.

For the population of children already with ASD we know certain behavioral therapies can greatly diminish a child's autism. Let's look back at my son's kindergarten class and these "Bramlett 6." For the "Bramlett 6" there are signs of optimism. Five of the six children with ASD have been fortunate enough to receive private behavioral therapy. Studies have shown that as many as 47 percent of the ASD children that undergo early intensive behavioral therapies achieve higher education placement and increased intellectual levels in programs that use the science of Applied Behavior Analysis (ABA). The 2001 U.S. Surgeon General's Report on Mental Health states, "Among the many methods available for treatment and education of people with autism, ABA has become widely accepted as an effective treatment. Thirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior." A significant portion of children who receive ABA are placed into mainstream/regular educational settings. These results have been shown to last well beyond the end of treatment. In addition, when implemented intensively and early in life (beginning prior to the age of 5 years), ABA may produce large gains in development, reduce in the need for special services and forego costly intensive special education in the future.

Although these "Bramlett 6" are still not finished with this therapy, you can already see positive signs from the intensive behavioral intervention. One child went from hiding under a table in a complete meltdown due to overstimulation at another child's birthday party to being the center of attention at her own birthday party just 6 months after intensive therapy was initiated. For the "Bramlett 6" needed classroom supports are already decreasing from their pre-kindergarten years. It is easy even at this very early age to understand why the investment in intensive therapy is critical.

A February 2009 report from Autism Speaks on Arguments in Support of Private Insurance Coverage of Autism Related Services notes:

"A 1998 study by John W. Jacobson and others titled, Cost-Benefit Estimates for Early Intensive Behavioral Intervention for Young Children with Autism—General Model and Single State Case, examined the cost/benefit relationship of early intensive behavioral intervention treatment at varying levels of treatment success. The study used estimates of costs for early intensive behavioral interventions (EIBI) from childhood (age three) through adulthood (age 55) based on prices in the Commonwealth of Pennsylvania and compared these costs with the expected amount of income the child would earn later in life to arrive at an estimated cost savings. With

a success rate of 47 percent for early intensive behavioral intervention therapy (as determined by Lovaas), Jacobson's study found that cost savings per child served are estimated to be from $2,439,710 to $2,816,535 to age 55.

The study also accounts for the initial investment in early intervention by concluding that, with an initial annual cost of $32,820, the total cost-benefit savings of EIBI services per child with autism or PDD for ages 3–55 years averages from $1,686,061 to $2,816,535 with inflation."

Additionally the report found:

"According to a 2005 Government Accounting Office (GAO) report, 'the average per pupil expenditure for educating a child with autism was more than $18,000 in the 1999–2000 school year. This amount was almost three times the average per pupil expenditure of educating a child who does not receive any special education services.'"

Investments into this intensive therapy will, in the long run pay benefits, both economic and social, to the greater population. However in Mississippi this intensive therapy is not an option for all concerned parents. These "Bramlett 6" are a rare story in Mississippi. The Mississippi autism task force noted:

"At present, funding for comprehensive treatment must be provided privately in most instances by families as there is limited governmental or insurance support. The average cost for a privately-contracted comprehensive treatment plan is well over $50,000.00 a year. When the average Mississippi family only makes $34,343.00 annually according to the 2006 U.S. Census Bureau, the amount of financial stress is overwhelming for parents trying to provide private therapy for their child with ASD."

One autism mother (who had private health insurance) noted to Mississippi's task force: "The part of this disease that makes me the saddest is the fact that I know the therapy my child needs to become better and I do not have the money to give my child the therapy." For the parents of these "Bramlett 6", paying for this therapy has been financially stressful. For one child's parents, they both took second jobs. Sadly, both parents had private healthcare insurance which would not pay for the needed therapy. For the other parents of the "Bramlett 6", cushioned bank accounts, big vacation trips, and college savings accounts are nonexistent.

The question we have to ask ourselves as a Nation is not whether we can afford to provide these therapies but whether we can afford not to. It is imperative that we look at both the private and public sectors for this support as the costs of autism is borne by everyone. On behalf of the parents, I implore you to end the insurance discrimination for our children, fund intensive intervention through early intervention programs, and look at mandating coverage for those on Medicaid systems. Additionally, I would give a cautionary word of warning when looking at a national single payer healthcare system. For parents who are utilizing Medicaid services, the services can be described at best as "limited." For example, in Mississippi, speech therapy services for special needs children were essentially eliminated as of July 1, of this year. Furthermore, provider numbers willing to see these children is limited due to low reimbursement rates.

Additionally, I ask you as Senators to support legislation such as S. 493 that would create tax-exempt savings accounts to care for individuals with disabilities and other measures that would ease the burden of our families.

When the Mississippi Autism Task Force held public hearings financial issues were not the only stressors. The lack of medical care, insurance coverage, inadequate educational supports, finding additional therapy services and time away from job and home to obtain the needed services for their family member with ASD were listed as major stressors for families.

ASD not only affects individuals with the diagnosis, but the entire family. Raising any family can be difficult, but it becomes even more complex when a family member is diagnosed with ASD. After the diagnosis, families are filled with questions, confusion, anger, grief, and despair. Physical stressors, compounded by psychological stressors further complicate the issues for parents. Because of the unusual behaviors and a lack of social skills that are common in those with ASD, families face isolation from friends, family and their community. Nationally, divorce rates of parents with ASD children are about 80 percent.

Another, sometimes unnoticed, turmoil created by autism is the affect on the siblings. An excessive amount of parents' time has to be focused on the child with ASD. Siblings commonly experience diminished attention and support from parents while parents devote substantial energy and resources getting a diagnosis and treatment for the child with ASD. Often, siblings find themselves socially isolated from friends,

family, and community because the brother or sister's behaviors are so erratic. Typical assistance offered by family and friends are less available as a result of the difficultly in managing behaviors.

For the above reasons, depression is often high among our parents. This year in our region of Mississippi we lost two parents from the stress and depression produced due to the difficulties from parenting an ASD child.

However, we see our families improve as their children's prognosis improves. Senators with the growth of the disorder and its impact on families we must move quickly to provide the necessary treatment and intervention for these ASD children and their families.

Senator HARKIN. Very profound statement. Thank you very much, Mrs. Boyd. Thank you.

And now we'll turn to David Miller, a resident of Fairfax County, Virginia; he serves on the board of directors at Northern Virginia Community College, where he cofounded the Community College Consortium on Autism and Intellectual Disabilities. He received his B.A. degree at Boston University, a masters in public administration at Northeastern, and his law degree at George Mason University. He's retired from the Armed Forces. He's the father of two 7-year-old autistic boys. Who are identical twins?

Mr. MILLER. Yes, they are.

Senator HARKIN Mr. Mueller, welcome to the subcommittee.

Mr. MILLER. Thank you.

STATEMENT OF DAVID MILLER, J.D., BOARD OF DIRECTORS, NORTHERN VIRGINIA COMMUNITY COLLEGE, ANNANDALE, VIRGINIA

Mr. MILLER. Thank you very much, sir. Chairman Harkin and Senator Cochran, again, thank you very much for holding this hearing.

As the Chairman indicated, I am a board member of Northern Virginia Community College, where I represent Fairfax County. We are the second-largest community college in the Nation.

As you indicated, again, Mr. Chairman, I'm the cofounder of the Community College Consortium on Autism and Intellectual Disabilities, which is comprised of 41 community college presidents from those States that have the highest incidence of autism in the country.

I'm pleased to say, Mr. Chairman, that Mr. Nick Starcevich, from Kirkwood Community College, based in Iowa, is a very active member of our consortium, as is Dr. Clyde Muse, president of Hinds Community College, which I understand—he tells me repeatedly, is the largest community college in Mississippi. Both of these respected leaders could not be here today because of previously scheduled board meetings. But, we do have some community college presidents here, that I would like to introduce the subcommittee to.

The first one is Willie Duncan, who I believe is behind me. President Duncan is the chairman of Taft College and is the chairman of our Consortium on Autism and Intellectual Disabilities. The second president we have accompanying me today is Dr. Wayne Burton—Wayne?—who's the president of North Shore Community College, based up in Massachusetts. We have Steve Rose, who I think is here today, who is the chairman of Passaic County Community College.

Also with me today is Dr.—is Mr. Jeff Ross, the director of Taft College's Transition to Independent Living program, which, in my

opinion, is one of the foremost postsecondary programs in the country for students with autism and intellectual disability. In fact, if you look at my testimony, on page 2 or 3, I really—the summary of the measurable results that Taft has achieved these last 13 years with respect to students with intellectual disability and developmental disability is astounding. In fact, we, at the community college level, aspire to have programs as effective as the Taft program.

This hearing today has particular poignancy to me because, as you indicated, Mr. Chairman, I'm the father of two 7-year-old autistic boys who are identical twins, Joseph Harris Miller and William Louis Miller. Their sister, Sallie Kathryn Miller, is the youngest of these triplets—she's here today—and thankfully she's a healthy, happy, 7-year-old princess.

Sallie, I know you're back there somewhere.

Mr. MILLER. My comments are purely those of a parent who is concerned about the long-term ability of my children, and children in similar circumstances, to live independently and to develop a career track that will enable them to support themselves financially while at the same time meeting and overcoming challenges that, frankly, I have never faced and probably you have never faced in our entire lives.

I am not an educator, like President Duncan or President Rose, or President Burton; I'm not a therapist in the field, as is Jeff Ross; nor am I as well versed in the nuances of autism and as well read as my wife is—who really, on a daily basis, meets the challenges, not only during the day, but in evening, as was pointed out before, in terms of the nocturnal tendencies of autistic children. She's a wonderful woman, and a very accomplished woman. She, frankly, should be seated in this witness chair. So, if you do another hearing, she needs to be invited.

You know, people talk about takeaways—and I'll go through the testimony in a second. I think that, when this hearing is over and when you go on to further activities, the two takeaways I would like you to have from my testimony are these:

Number one, my kids are here. They're here to stay. I think what you're doing with respect to research is excellent. We need to have funds invested in screening and diagnosis and all that good stuff. I think it's tremendous. We need to do that. But, having said that, my kids are here. And all the panelists that have autistic kids are here. So, what are we going to do with these kids?

And I think the second thing that I find more and more, as I talk to more and more autism advocates and more and more proponents is, What's the game plan here? What's the end result? What are we looking toward? What are we working for? It's true that most of these kids are below the age of 17 at this stage, but more and more of these kids right now are entering middle school, they're entering high school. At some point they're going to be adults. What are we going to do with these kids? And I think that's a critical question that we all have to consider, and I think we need to keep that objective in mind.

We, at the community college level, are seeing our first beginnings of autistic kids on our campus. The HELP Committee chairman, by the way, Chairman Kennedy, obviously gets it. We've had

a number of discussions, our Community College Consortium and he, and he's called this a "tsunami." He's said to us that we've not invested in the infrastructure to deal with this coming tsunami, as he described it.

Section 767, Higher Ed bill, based on his authorship and that of Senator Enzi, authorized the Secretary of Education to award 5-year grants in support of model demonstration programs that, quote, "promote the successful transition of students with intellectual disabilities into higher education." There's no specific amount authorized, and I have a letter—I'm sure you've seen it, Chairman Harkin; I know you've seen it, Senator Cochran—from Senator Kennedy, where he requests $35 million for fiscal year 2010 to fund this—to fund these types of programs.

The reason for this funding request is that, as stated in the chairman's correspondence, that vast majority of autistic and intellectually disabled students are currently at community colleges, and will attend community colleges, because we have what are called "open admissions policies." They graduate from secondary school or they reach age 21, and they come on our campuses, They are here. And, frankly, we have no programs, effective programs, to—with the exception of Taft—to deal with these children. What they do is, they come on our campuses, they enroll in normal academic courses, they're soon put on academic probation, and they're soon academically dismissed, and that's it. They have no further contacts, with respect to job training programs, albeit perhaps sheltered workshops. They have no further—or additional educational opportunities. That is it. So, what happens to these kids after that?

And again, that's what Senator Kennedy is really focused on. Schools like Kirkwood will tell you, and schools like Hinds Community College will tell you, these are expensive programs. They run roughly $30,000 a school. And President Starcevich tells me, as does President Muse, that they are limited by law to approximately $2,000 to $3,000, as far as tuition. They don't have access to any further funding. That's it. And with the reduction in State operating funds right now, they just do not have the financial resources to develop programs to assist these students.

I think one thing—and I realize I'm way over my time—I think one thing that—you have to look at these funds. They're essentially investment—they're essentially economic development funds. They're essentially local stimulus funds. These funds will be focused, by community colleges, in life-skills training and in vocational training.

PREPARED STATEMENT

So, again, Mr. Chairman and Senator Cochran, we appreciate the fact that you've seen fit to put approximately $15 million toward this program, and we hope that, in conference, that, at the end of this conference, you will walk away at least with that minimum amount of money.

Again, thank you very much.

[The statement follows:]

PREPARED STATEMENT OF DAVID H. MILLER

Chairman Harkin and Ranking Member Cochran: Thank you for this hearing and for the opportunity to present my thoughts regarding autism, research, treatment, and intervention'.

I have the privilege of being here today, as a board member of Northern Virginia Community College (NVCC) which is the second largest community college in the United States. I have represented Fairfax County for the last 4 years on the NVCC board and have recently been reappointed to another 4-year term by Chairman Bulova and the Fairfax County Board of Supervisors.

I am also the co-founder of the "Community College Consortium on Autism and Intellectual Disabilities" which is comprised of 41 Community College Presidents from States that have the highest incidence of autism.

Dr. Mick Starcevich, the president of Iowa-based Kirkwood Community College is a member of our Community College Consortium as is Dr. Clyde Muse, president of the largest community college in Mississippi—Hinds Community College. Both of these highly respected leaders could not be here today because of previously scheduled board meetings.

Although I am the only "non-President" of our Consortium I have had the honor of working with 41 of the foremost educators in our Nation some of whom are here with me today.

I would like to take a moment to introduce to the subcommittee Mr. William Duncan, president of Taft College. President Duncan is also the chairman of "The Community College Consortium on Autism and Intellectual Disabilities"; Dr. Wayne Burton, president of North Shore Community College (member of our Executive Committee), and Dr. Steven Rose, president of Passaic County Community College.

Also with me today, is Mr. Jeff Ross, the Director of Taft College's Transition to Independent Living (TIL) program which in my opinion is one of the foremost post-secondary programs in the country for students with autism and intellectual disabilities.

This hearing has a particular poignancy to me because I am also the father of two 7-year-old autistic boys who are identical twins—Joseph Harris Miller and William Louis Miller. Their sister, Sallie Kathryn Miller, is the youngest of the triplets and is a healthy, happy 7-year-old "princess".

Let me preface my comments, by giving the subcommittee some perspective. I am not an educator by profession like President Duncan, President Burton, and President Rose. I am not a therapist or an expert in the field of autism and intellectual disabilities as is Mr. Ross. Nor I am not as well versed in the nuances of autism and in meeting the daily (and nightly) challenges of autism as is my wife Lynn.

My comments are purely those of a parent, who is concerned about the long-term ability of my children and children in similar circumstances to live independently and to develop a career track that will enable them to support themselves financially while at the same time meeting and overcoming challenges that probably you and I never had to face.

The chain of events that led me to this table begins like this. Almost 3 years ago, I was asked to give a presentation to the members of the Association of Community College Trustees on the authorization and appropriations process. During the course of that presentation, I referred to the then recently enacted "Combating Autism" legislation as an example of the Authorizing and Appropriations Committees working together to produce a truly remarkable piece of legislation. As you know the "Combating Autism Act of 2006" (Public Law 109–416) allocates nearly $1 billion for the National Institutes of Health (NIH) to conduct autism, research, screening, surveillance, and intervention.

As a preface to my comments, I indicated that I had two young sons (5 years of age at the time) who had been diagnosed with autism and that I as a parent was very concerned about their future. After my presentation, I was approached by the then president of Taft College, Dr. Roe Darnell. Dr. Darnell told me about the program at Taft College, called the TIL program, which since 1995 has developed a remarkable record of success with autistic and intellectually disabled post secondary students.

The Taft College Program is a 2-year residential program that houses 28 students in our dormitories and 20 students who live independently within the community. The curriculum consists of 38 courses which are approved by the California Community College Chancellors Office.

The curriculum is life skills and vocational based and the students receive a Certificate of Completion from Taft College when they demonstrate competency in the following areas: meal planning and preparation; housekeeping; laundry; money

management; personal safety; Internet access and safety; personal advocacy; individual rights and responsibilities; work ethic; and work experience.

As the TIL program services students from the entire State, TIL assists students with their transition back to local communities. The program also tracks all of its graduates for a period of 10 years and produces an annual "Student Outcome" report which demonstrates dramatic results:

—95 percent of TIL graduates live independently;
—93 percent are competitively employed (the national average is 14 percent);
—93 percent receive no financial assistance from other agencies or their families;
—97 percent report that they are satisfied with their adult life; and
—30 hours of home assistance is provided on average each month (the State average is 88 hours per month).

It is estimated that the above savings in home assistance services alone saves the citizens of California over $110 million over 40 years not counting the taxes TIL graduates pay as well as services that they consume. Obviously, "quality of life" has no price tag.

Taft College services all of California and has a waiting list of 4 years.

When I looked for similar services in Northern Virginia I found that there was almost no postsecondary educational or training opportunities for children with autism who had graduated from high school or had reached the age of 21.

Those opportunities that were available were either prohibitively expensive or were research based.

None of these "opportunities" were readily adaptable to the broad range and numbers of students we in higher education can expect to flood our campuses in the not too distant future.

As a harbinger of things to come for our college campuses and for our Nation, Director Ross, who follows these trends, reported the alarming statistic that the number of autistic children enrolled in California's fourth and fifth grades currently exceeds the entire number of adults receiving assistance for intellectual disabilities which numbers approximately 350,000.

The actual numbers of autistic children enrolled in California is indeed alarming however, the trend is identical for States that are not as large nor as diverse. In my own Commonwealth of Virginia a 10-year study of autism prevalence from 1992–2003 pursuant to the reporting requirements of the Disabilities Education Act (IDEA) reported a 519 percent growth rate of autism from 1992–2003 with a 17 percent annual growth. That study is now 6 years old and the numbers of children with autism reported in Virginia's public schools has almost tripled since 2003.

Mr. Chairman, in your State of Iowa, the prevalence study reported a 1,727 percent cumulative growth rate of autism from 1992–1993 with a 33 percent annual growth rate of 33 percent. Senator Cochran, the same study showed a 3,788 cumulative growth rate for autism in 1992–2003 with a 53 percent average annual growth rate. I am sure that the incredible growth of students with autism in Virginia since 2003 is similar in your States.

Clearly, the vast majority of autistic children are still under the age of 18 with a significant number just now entering middle and high school. We at America's community colleges, including NVCC, are beginning to see the first significant influx of students with autism.

Community colleges have, for a number of years, had intellectually disabled students on our campuses, often times with no programs to serve them. Because most States provide for an "open admissions" policy, many of these students enroll in regular academic classes. However, a great majority of these students are unable to meet the normal academic requirements of these classes; are soon placed on academic probation and later are dismissed for academic reasons.

Unfortunately, most of these students leave their secondary or post secondary experience with no preparation for living independently or with job skills. Although some States contribute to their welfare until the age of 21, the vast majority provide for no or minimal assistance after that age.

Thankfully, educators across the country, notably Dr. Starcevich and Dr. Muse are working on ways to provide innovative practical programs for these students once they leave the secondary school environment as are their colleagues in other States such as President Dale Chapman and Dr. Linda Chapman from Lewis and Clark Community College; Dr. Pamela Transue, president, Tacoma Community College; Dr. Debbie Sydow, president, Onondaga Community College; Dr. Peter Sireno, president, Darton College; Dr. Wright Lassiter, Chancellor, Dallas County Community College; Dr. Ray D. Pasquale, president, Community College of Rhode Island; Dr. Raymond Yannuzzi, president, Camden County Community College; and many others.

Your colleague, Chairman Edward Kennedy of the Senate Committee on Health, Education, Labor and Pensions (HELP) is very much aware of these trends and described the coming influx of autistic students at postsecondary level as a "tsunami".

Thanks to the efforts of Anthony K. Shriver, founder and chairman of Best Buddies International, Inc. and President Wayne Burton, we had the opportunity to speak directly with the chairman and work with him and Senator Enzi on designing a program to assist students with autism and intellectual disabilities.

While not perfect, section 767 of H.R. 4137 (the Higher Education Opportunity Act) authorizes the Secretary of Education to award 5-year grants to support model demonstration programs that "promote the successful transition of students with intellectual disabilities into higher education."

Although no specific amount is authorized in Public Law 110–315, Chairman Kennedy recently wrote a letter to you, Chairman Harkin, and to you, Senator Cochran, requesting funding for this program in the amount of $35 million for fiscal year 2010.

Chairman Kennedy's May 7, 2009 letter categorizes his funding request as follows:

"It is estimated that $24 million of the $35 million will fully fund programs at 10 community colleges, enabling each college to provide life skills and vocational training for approximately 75 intellectually disabled students.

"$9 million will provide funding for 30 programs at 4-year colleges, with an average funding of $300,000 per institution. Each grant will provide academic and other instructional courses for approximately 10 intellectually disabled students."

The reason for this difference in funding is that, as stated in the chairman's correspondence, the vast majority of autistic and intellectually disabled students "attend community colleges because of their open admissions policies."

In addition, community colleges are limited by law in their ability to pay for the true cost of these programs. Based on the experience of Taft College's successful TIL program the cost to operate this type of program for 75 students is approximately $30,000 per student with the average annual budget of around $1 million. A program at a typical 4-year university for 8–10 students will cost approximately $300,000 as the university serves far fewer autistic students and has the ability to draw on other sources of income including raising tuition.

As community colleges like Kirkwood or Hines can only charge a maximum of approximately $3,000, the remaining $27,000 in operational costs can only be borne by the Federal Government. Infrastructure and other nonoperational capital costs must be borne by the educational institution.

It is our understanding, Mr. Chairman and Senator Cochran, that your subcommittee has allocated approximately $15 million for this program. We are appreciative of your efforts particularly given the fiscal demands of your subcommittee in this time of economic hardship.

We hope that this amount at a minimum be retained in conference and that you consider allocating this amount, consistent with Chairman Kennedy's letter, on a 3 to 1 basis so that community colleges and universities are able to compete for these funds separately.

In addition, we thank you for the language that we understand is in the subcommittee's report that directs the Secretary of Education to award grants for no less than $1 million per grant. Anything less would preclude Kirkwood Community College, Hinds Community College, and most other community colleges from offering life skills and vocational training programs for their autistic students.

I thank you for the opportunity to testify and I look forward to answering any questions.

Senator HARKIN. Thank you very much, Mr. Miller.

And now we'll complete our testimony with Ms. Dana Halvorson, cofounder of BEAT-Iowa: Biological Education for Autism Treatments, Iowa. Usually when we are in front of all these people, we don't say "Beat Iowa".

Senator HARKIN. I should have looked at that before I said it. And that little clip could be misinterpreted, you know? She lives on a farm in Northwood, Iowa—that's way up in northwest Iowa—with her husband and three children. Her 7-year-old daughter, Robin, was diagnosed with autism when she was 15 months old. Ms. Halvorson has an associate degree in applied science and vet-

erinary technology from the University of Minnesota, and a B.A. in French from South Dakota State University.

Ms. Halvorson, welcome. Please proceed.

Ms. HALVORSON. She was diagnosed, a little over age 3; she regressed between 15 and 18 months.

Senator HARKIN. Oh, age 3.

Ms. HALVORSON. Yeah, the diagnosis was at 3 years and 3 months.

Senator HARKIN. Would you punch that button on your mic, there? There.

Ms. HALVORSON. Certainly.

Senator HARKIN. Thank you very much.

Ms. HALVORSON. Okay.

Senator HARKIN. Go ahead, Ms. Halvorson.

STATEMENT OF DANA HALVORSON, BEAT-Iowa, ANKENY, IOWA

Ms. HALVORSON. Thank you, Mr. Chairman and Senator Cochran, colleagues, for this opportunity to encourage more thought and action on autism.

My name is Dana Halvorson. On a daily basis, I am a wife and mother of an Iowa farm family. My days are filled, from very early to very late, with joys, blessings, and challenges. Of my three children, I have one daughter who has heavy-metal toxicity. Her original diagnosis, at just over age 3, was autism and mental retardation.

Although my daughter was given the label of "autism," this term fails to describe the physiological nature of her disorder. Shortly after her diagnosis, I discovered biomedical origins of her condition. Over the next several years, we confirmed multiple medical diagnoses, including intestinal dysbiosis, multiple food allergies, growth hormone deficiency, metabolic dysfunction, endocrine dysfunction, pituitary dysfunction, hypothyroidism, allergic colitis, immune dysfunction, and heavy-metal toxicity, to name a few.

We have only been able to help Robin by struggling to travel all over the country and working with many medical practitioners, spending thousands of dollars on tests and clinical visits, mostly not covered by insurance.

The list of diagnoses Robin carries is long for such a young child. Her healthy appearance belies the depth of her medical problems. Based on her appearance, people expect her to be able to respond to them, speak to them, and share with them. Robin has come a long way, but still has difficulties.

I know of children who have fully recovered, with the proper therapies for their medical conditions, and my daughter is on that path to recovery. I only hope that everything we have—are doing will be enough, so that someday she can live a normal life.

Once we learned of Robin's medical issues and sought out properly trained medical professionals for appropriate treatment, she began to improve. The symptoms we see in Robin and so many children like her are not psychiatric in origin, needing only psychological therapy. Autism is a neurobiological disorder, a set of physical disorders with behavioral characteristics. Many families hesitate to use the word "autism"—we call it the "A" word—because

these underlying medical problems exist in our children and can cause the very symptoms that are labeled "autism."

I have been involved in multiple meetings with elected officials, doctors, parents, and researchers for 8 years, discussing the root causes and treatment issues. Because no action has been taken, thousands more children have suffered damage, and their families' lives have destroyed. Very soon, the financial burden of their 24/7 care will not fall only to their parents and families, but to taxpayers, in general, as a large wave of some of the oldest children start aging out of school, cannot work, and must collect disability checks. Professionals in the field estimate that lifetime care for a child like Robin will cost millions of dollars.

I've accepted your invitation today because I want to set the record straight. You cannot address the "A" word, "autism," without addressing some other "A" words. You should all be very alarmed that we currently have the sickest generation of children in 60 years, with 1 in 9 children suffering from asthma, 1 in 6 children with some form of neurodevelopmental delay, and at least 1 in 150 with autism, the most severe disorder. Posing the right questions to unbiased and unconflicted scientists is essential to obtaining constructive answers.

Agencies charged with protecting the health of our children suffer from serious financial conflicts of interest. These Government agencies need to be held accountable. Senators, it is difficult for me to sit at this table and tell you that you have been lied to, that we have all been lied to. Mercury levels exceeding EPA safe levels were in Robin's vaccines, and in my RhoD immune globulin injections while pregnant and immediately after her birth. The industry material safety data sheet for thimerosal identifies the chemical's effects as follows: "The mercury component has caused nervous-system effects in experimental animals, including mild to severe mental retardation and motor coordination impairment."

You don't need to take my word for these scientific facts. Dr. George Lucier, former founding editor of Environmental Health Perspectives, the official journal of the NIEHS, for 28 years, and former associate director of the National Toxicology Program, considered the world's largest toxicology research and testing program, is with me today. He has, on many occasions, shared his view of the dangers of thimerosal, and the harm it has caused to many children.

The number of vaccines given since I was a child has risen from around 10 to 49, according to the National Vaccine Information Center. Those who create vaccines often sit at the table and vote to approve vaccines, reap the dollars from the products being used, and then are immune from legal liability. Where else in the world do we see this scenario of no accountability and conflict of interest?

Who is at the table demanding truth and voting on behalf of children? That is your job, as our elected officials, and for some reason, very few are doing it. We need transparency, honest communication, and, once and for all, as you suggested earlier, Senator Harkin, a valid, unbiased study of vaccinated versus unvaccinated populations.

Congress scrambled to hold hearings about grown men voluntarily injecting themselves with steroids, while thousands of chil-

dren have continued to be injected with vaccines containing a known neurotoxin, under Government mandate.

We all know that some children are injured by vaccines. Unfortunately, their access to justice and compensation is barred by many legal obstacles. Our compensation system for vaccine-injured children needs reform. Although I do not have time to describe the necessary reform, please take a look at the unfairly restricted 3-year statute of limitations, among other legal problems facing these families.

Heavy metals, like mercury and other toxic substances, should not be injected into people, especially babies and young children and other individuals susceptible to vaccine injury. Vaccine safety certainly encompasses more than concerns only about mercury. However, mercury is so highly toxic that it is the 600-pound gorilla in the living room. It only takes 0.6 micrograms of mercury, in the form of thimerosal, to harm human tissue, according to valid peer-reviewed scientific studies.

Thimerosal continues to be used in some vaccines, including tetanus and flu shots. That is a fact. Thimerosal is damaging at nanomolar levels. That is also a fact, and has been documented, replicated, and ignored. It is in front of us, but we pretend not to see.

Those in power have not listened and discerned facts, and acted on those facts to protect the health and future of the children of this Nation, and instead have protected industry and Government.

My hope, on behalf of this vaccine-injured generation, is for action. Can we really afford, with continued inaction, to risk losing another generation?

PREPARED STATEMENT

Thank you for listening and allowing me to share my concerns. As I return to our Iowa farm, I will reflect upon what my daughter and my family have lost, and the many other mothers and fathers whose hopes and dreams have been crushed with this chronic illness. We will continue to hope for action. Our children and our future depend on you.

[The statement follows:]

PREPARED STATEMENT OF DANA HALVORSON

Thank you Senator Harkin and colleagues, for this opportunity to encourage more thought and action on autism. My name is Dana Halvorson. On a daily basis I am a wife and mother of an Iowa farm family. My days are filled from very early to very late with joys, blessings and challenges. Of my three children, I have one daughter who has heavy metal toxicity. Her original diagnosis at just over age 3 was autism and mental retardation.

Although my daughter was given the label of "autism", this term fails to describe the physiological nature of her disorder. Shortly after her diagnosis, I discovered biomedical origins of her condition. Over the next several years we confirmed multiple medical diagnoses including intestinal dysbiosis, multiple food allergies, growth hormone deficiency, metabolic dysfunction, endocrine dysfunction, pituitary dysfunction, hypothyroidism, allergic colitis, immune dysfunction, and heavy metal toxicity, to name a few. We have only been able to help Robyn by struggling to travel all over the country and working with many medical practitioners, spending thousands of dollars on tests and clinical visits, mostly not covered by insurance. The list of diagnoses Robyn carries is long for such a young child. Her healthy appearance belies the depth of her medical problems. Based on her appearance, people expect her to be able to respond to them, speak to them, and share with them. Robyn has come a long way but still has difficulties.

I know of children who have fully recovered with the proper therapies for their medical conditions, and my daughter is on that path to recovery. I only hope that everything we are doing will be enough, so that someday she can live a normal life.

Once we learned of Robyn's medical issues and sought out properly trained medical professionals for appropriate treatment, she began to improve. The symptoms we see in Robyn and so many children like her are not psychiatric in origin, needing only psychological therapy. Autism is a neurobiological disorder—a set of physical disorders with behavioral characteristics.

Many families hesitate to use the word autism—we call it "the A-word," because these underlying medical problems exist in our children and can cause the very symptoms that are labeled "autism." I have been involved in multiple meetings with elected officials, doctors, parents and researchers for 8 years. discussing the root causes and treatment issues. Because no action was taken thousands more children have suffered damage and their families lives have been destroyed. Very soon, the financial burden of their 24/7 care will not fall only to their parents and families, but to taxpayers in general, as a large wave of some of the oldest children start aging out of school, cannot work, and must collect disability checks. Professionals in the field estimate that lifetime care for a child like Robyn will cost millions of dollars.

I have accepted your invitation today because I want to set the record straight. You cannot address the A-word, "autism," without addressing some other A-words. You should all be very "alarmed" that we currently have the sickest generation of children in 60 years with 1 in 9 children suffering from "asthma," 1 in 6 children with some form of neurodevelopmental delay, and at least 1 in 150 with autism the most severe disorder. Posing the right questions to unbiased and unconflicted scientists is essential to obtaining constructive answers. Agencies charged with protecting the health of our children suffer from serious financial conflict of interest. These Government agencies need to be held accountable. Senators, it is difficult for me to sit at this table and tell you that you have been lied to, that we have all been lied to. Mercury levels exceeding EPA safe levels were in Robyn's vaccines and my RhoD Immune Globulin injections while pregnant and immediately after her birth. The industry material safety data sheet for thimerosal identifies the chemical's effects as follows: "the mercury component has caused nervous system effects in experimental animals, including mild to severe mental retardation and motor coordination impairment."

You don't need to take my word for these scientific facts. Dr. George Lucier, former founding editor of Environmental Health Perspectives, the official journal of the NIEHS for 28 years, and former associate director of the National Toxicology Program (considered the world's largest toxicology research and testing program) is with me today. He has on many occasions shared his view of the dangers of thimerosal and the harm it has caused to many children.

The number of vaccines given since I was a child has risen from around 10 to 49, according to the National Vaccine Information Center. Those who create vaccines often sit at the table and vote to approve vaccines, reap the dollars from the products being used, and then are immune from legal liability. Where else in the world do we see this scenario of no accountability and conflict of interest? Who is at the table demanding truth and voting on behalf of children? That is your job as our elected officials, and for some reason, very few are doing it. We need transparency, honest communication, and once and for all, a valid unbiased study of vaccinated wersus unvaccinated populations. Congress scrambled to hold hearings about grown men voluntarily injecting themselves with steroids, while thousands of children have continued to be injected with vaccines containing a known neurotoxin, under Government mandate.

We all know that some children are injured by vaccines. Unfortunately their access to justice and compensation is barred by many legal obstacles. Our compensation system for vaccine-injured children needs reform. Although I do not have time to describe the necessary reform, please take a look at the unfairly restricted 3-year statute of limitations among other legal problems facing these families.

Heavy metals like mercury and other toxic substances should not be injected into people, especially babies and young children, and other individuals susceptible to vaccine injury. Vaccine safety certainly encompasses more than concerns about only mercury. However, mercury is so highly toxic, that it is the 600-pound gorilla in the living room. It only takes 0.6 micrograms of mercury in the form of thimerosal to harm human tissue according to valid, peer-reviewed scientific studies. Thimerosal continues to be used in some vaccines, including tetanus and flu shots. That is a fact. Thimerosal is damaging at nanomolar levels. That is also a fact and it has been documented, replicated, and ignored. It is in front of us, but we pretend not to see. Those in power have not listened and discerned facts, and acted on those facts to

protect the health and future of the children of this Nation, and instead have protected industry and Government.

My hope on behalf of this vaccine-injured generation is for action. Can we really afford, with continued inaction, to risk losing another generation?

Thank you for listening, and allowing me to share my concerns. As I return to our Iowa farm, I will reflect upon what my daughter and family have lost and the many other mothers and fathers whose hopes and dreams have been crushed with this chronic illness. We will continue to hope for action—our children, and the future of our Nation, depend on you.

Senator HARKIN. Thank you very much, Mrs. Halvorson.

Well, I think we have heard the whole gambit of everything, we are confronted with.

And, Dr. Dawson, since you're first on the left here, I'll just start with you. You mentioned that virtually no comparative effectiveness studies have been done to evaluate treatments for autism. And again, I just want to say—this is something that we really have to focus on. I mean, we have to do the research. But, as Mrs. Halvorson so poignantly pointed out, we're in—and Mr. Miller also Mrs. Boyd—we're in the here and now, and families are struggling, and we're facing this whole generation growing up, and what's going to happen to them as adults. So, we have to focus on what are the most effective treatments we have now.

This subcommittee provided more than $1 billion to HHS in the recent ARRA—Dr. Insel mentioned that earlier—for comparative effectiveness studies—$1.1 billion, to be exact. Now, again, we don't say exactly where to put them. But, do you know if any of those dollars will be spent on autism? The Institute of Medicine, included autism as one of the conditions that should be studied. And I just wonder if you have thoughts on that. Have you been watching, or have you had any involvement in trying to see that some of these comparative effectiveness studies are done on early intervention programs?

Dr. DAWSON. Yes, I'm aware of the focus, by the Agency for Healthcare Quality, on comparative effectiveness, and we have submitted recommendations, in terms of the kinds of questions that we feel need to be asked. I think it's so critical that parents have a sense of, you know, whether one thing is effective, more than another treatment.

The other, I think, aspect of comparative effectiveness work has to do with method of service delivery. So, what we know now is that when children receive care, they often receive it by a set of professionals who individually work with the child. So—and the parent themself has to act as a case coordinator. There are other models, for how to effectively work with a child with autism, which involve a multidisciplinary team, which has different, kind of, financial aspects that go to coordinating care. But, we feel that this kind of model is much more effective. So, that's another example of a comparative effectiveness study that needs to be done, is to look at different models of service delivery to find out what is ultimately more cost effective.

The other question has to do with this issue of personalized medicine. So, what kinds of treatments work for which kinds of individuals? We know that autism is not going to be a one-size-fits-all kind of treatment approach, and so, we need to understand the effectiveness of understanding underlying biomarkers, whether we're

looking at medical conditions, such as one of the parents talked about, or genetic conditions, metabolic conditions, and so forth, and how these can direct treatment approaches.

So, it's very—we're at a very early stage in understanding the question of which treatments work best for which individuals, and until we do that, parents go onto the Internet, they seek out answers themselves, and often are acting on nonevidence-based decisions.

Senator HARKIN. That kind of brings me to Mr. Cobbs, and all of you here. I got interested in using telehealth sometime ago for a variety of different things. I come from a rural State, and we don't have a lot of the access to facilities that people in urban areas do, so I've been interested in telehealth in different areas. And then, finally, when I became more interested in, and more tuned in on, the issue of autism, a few years ago, it came clear to me that a lot of families that have young children that are diagnosed with autism, they're at their wit's end. They don't know what to do. And yes, there are some residential programs, Mr. Miller, mostly for older kids, for transitional things like you're talking about. But—and correct me if I'm wrong, and Dr. Insel, you can jump in on this, too—but, I think there is some pretty good evidence that the earlier you get to these kids and provide them with supportive services, interventions by trained people that know what they're doing, that they really do get over a lot of these problems. The earlier you get to them, the more effective it is. But, how do you get to them early if they're living in Sioux City or Northwood or Oxford, Mississippi, or someplace like that?

So, we've put some money in this project, looking at telehealth, and how you can get together with a group of professionals early on, and then, with a high-speed Internet connection, it's like you are in the doctor's office. So you get that guidance, 24/7.

Mr. Cobbs, tell me a little bit about this. You've been in this experimental program for 3 years?

Mr. COBBS. Well, since last time. We have continued with the services to continue the study so we can test the longevity, and also to show that the program can grow with the child throughout the lifespan.

Senator HARKIN. Now, have you talked with other people? You're the head of—chairman of the Iowa Autism Council now—have you talked to others about this? I don't know how many people are on this system right now. And what interest is there in this?

Mr. COBBS. Senator Harkin—Chairman Harkin, that's a great question. In fact, just this morning we were talking, and it's an "Aha" moment for parents. It's that light bulb that goes on, "Do you really mean I can get services when and where I need them?"

For instance, if Noah's having a great behavior day, and it's in-home, well, we can replicate that, we can start to build off that, with a foundational of applied behavioral analysis and other proven methodologies. Or, if he's having a bad day, it's not because we're in an abstract physician's office or a clinical environment; it's because he's in his own home, and there's something that has triggered that behavior. So, it's immediate response to track down what's causing the behavior, and we can get immediate results, when the behavior is happening, both good and bad.

Senator HARKIN. That's the other thing that kind of got me thinking about this a few years ago. A lot of times, kids with autism, they don't act up or anything when they're in the doctor's office, but then, when you get home, they do.

Mr. COBBS. In our case, Chairman Harkin, it might be the exact opposite. The environment of a doctor's office may have too much stimulus in the area and so, you're going to get the reverse effect. You're going to get—maybe we went in for an earache, but all of a sudden we have a—you know, a behavior taking place, and therefore, we may even have to leave that environment without properly getting the care. So, it's a really great adjunct piece to a complete behavior treatment program.

And to dovetail on—Ms. Dawson said is—it's also a great way to bring a comprehensive team together to treat the child in the natural environment.

Senator HARKIN. Are we doing any studies now to show comparative effectiveness? Or, is this something that hopefully, this billion dollars we put in the budget will start taking a look at? Does anyone know that? Do you know that, Ms. Dawson?

Ms. DAWSON. Right.

Senator HARKIN Have you looked at these early intervention telehealth-type of treatments?

Dr. DAWSON. Well, not with respect to the telehealth program, per se, that I'm aware of.

Dr. INSEL. We've just completed a fairly large telehealth study for autism, specifically. The good news is, again, the ARRA has given us this opportunity to open up the doors for additional work, and we do have some exciting proposals on just this topic, on telehealth for autism, specifically, that we're hoping we'll be able to fund. I can't say more until we actually have the notice of award. But, I think this is the chance to see real progress in this arena.

And just, again, to stress what Mr. Cobb's statement had already implied, is that it's not only for the child. This is for the family. And that's where some of the big implications will be.

Senator HARKIN. Now, Ms. Halvorson, I'm assuming that you're not on this telehealth?

Ms. HALVORSON. No.

Senator HARKIN. No?

Ms. HALVORSON. Our approach has been—well, we really hit all aspects. We found out about the biomedical side first, and then found out about ABA. And we've used both, and I feel both have been essential in Robin's progress. However, I know a lot of other families agree with me that at least exploring if your child does have these biomedical issues, you're going to get better results when you're using the ABA.

Senator HARKIN. I guess what I'm getting at is, How would you feel, as a parent, if you had access, in your own home, with your child, 24/7, so that anything that happens, in terms of behavioral problems, that you would have access, ready access, to trained specialists who you would be in constant contact with?

Ms. HALVORSON. My daughter responded so well to biomedical intervention that behaviors really became not nearly as much of an issue.

Senator HARKIN. I see.

Ms. HALVORSON. So it—for me—and the medical care that she needs, I can only obtain in our doctors' offices, other than——

Senator HARKIN. Oh.

Ms. HALVORSON [continuing]. Supplements that we use.

Senator HARKIN. I see.

Ms. HALVORSON. But, if I'm taking her in as a matter—well, as an example, monthly, right now, since the beginning of the year, she's been undergoing intravenous immune globulin therapy. That's a 6-hour infusion in our doctor's office.

Senator HARKIN. Yeah.

Ms. HALVORSON. And then we do some chelation, on top of that, to remove the metals. So, that has to be done for us. It's a drive, no matter what.

Senator HARKIN. I see the difference, okay.

Well, I've taken 10 minutes of time, so I would yield to Senator Cochran.

Senator COCHRAN. Well, Mr. Chairman, thank you, you're very kind. I appreciate your calling the hearing. It brings back memories of other hearings we've had and our efforts, as a subcommittee, to just try to tailor programs of support, research, that are needed, that will help make positive contributions to solving the problems that all of you face, personally or professionally.

So, I'm wondering, is there something that any of you have in mind to suggest? I know Ms. Halvorson talked about financial support and a willingness for Government, maybe, to find—figure out ways to be more supportive, tangible benefits of some kind, insurance programs that maybe the Government can help support, in terms of costs of premiums or disbursements, a sharing of responsibility. Seems to me we have a lot of organic medical disabilities and frailties, that come with the ambit of insurance, that this challenge is just not being helped with.

So, I wonder if you have any thoughts along those lines?

I'd start with Ms. Dawson.

Dr. DAWSON. Well, I'd like to comment, first, on this notion of early intervention, and actually tell you about the study that Dr. Insel was referring to.

So, this is a study that—I was the principal investigator of this study. And it's an NIMH-funded study, where children began the intervention below 30 months of age. It's the first randomized clinical trial that has been conducted with toddlers who are at risk for autism. So, the children were randomized into either standard care in the community or a—an intensive early behavioral intervention that focused, not only on working directly with the child with a therapist, but also taught the family how to use intervention strategies so that intervention occurred throughout the daily activities with the child.

The intervention went over a 2-year period, approximately 25 hours a week of structured intervention. All assessments were done blind, without—with respect to knowledge of whether the child had received early intervention.

At the beginning, both groups of toddlers with autism had IQs in the mentally retarded range, and after 2 years the children in the treatment group, their IQ had increased, the average IQ, to the extent that they no longer were in the mentally retarded range.

They had developed language. Their diagnoses were less severe. Many of the children went from a diagnosis of autism to what we can "pervasive developmental disorder," which is a less-severe diagnosis.

And this, remember, is only 2 years, so the children are only 4, and early intervention, you know, should continue for another at least 1 or 2 years, in terms of these intensive interventions.

So, we know these are effective. This study is in press in the Journal of Pediatrics, and will come out soon.

What we don't have is two things that limit access. One is financial support for families. It's absolutely essential that we get federally mandated insurance coverage for these. It's going to save us money. It's going to help families. And it's going to allow individuals to take advantage of some of the programs that we've heard about, the community colleges and so forth.

The second piece is training for professionals and for parents. So, many of the interventions that we're developing now, because we're working now with infants and toddlers, are actually teaching the parents to deliver the interventions, because in—many of these interventions occur throughout the day as we interact with the baby in normal settings.

So, we need programs such as telemedicine or—we're also developing web-based training programs that we're using to train parents and professionals, not only here in the United States, but really around the world. We're working in India, in Africa, and other developing countries to train processionals. So, this combination of insurance coverage and trained professionals is really going to be absolutely key.

Then we're going to get kids on the right trajectory, and then we need to look, step-by-step throughout the life span, at how we can continue to support people with autism to become the most productive citizens they can.

Senator COCHRAN. Thank you very much. That's very interesting and helpful analysis of some of the options that we should seriously consider. I think we should, too.

Ms. Boyd, you were seeking recognition, and I wanted to call on you next.

Ms. BOYD. The task force looked at this in Mississippi extensively because of our financial situation of many of our parents, and there were—publicly, early interventions presently don't cover behavioral services. And it's already a program that is out there, federally. It needs to now include behavioral services, because many of these children are starting to be identified very early.

I can anecdotally speak to the success of that. As we were in San Antonio this summer, getting some therapy, I met a precious child named Catalina. Her mother recognized that there were signs and symptoms at 8 months, began behavioral therapy after a year. The child is 4 years old now and is absolutely amazing, Senators; you would never recognize that she was a child on the spectrum. So, I, anecdotally, saw that working.

The other program, too, that has to be looked at is Medicaid. The States have an option of whether or not they can give autism-specific waiver. I would encourage you to look at that, and not give States that option, because it is one of the things that could defi-

nitely reach out to these families who don't have the finances to do that.

The other thing, obviously, that Dr. Dawson mentioned, is private insurance. There are virtually almost no policies in our State that cover autism therapies. There's none. In fact, not—it doesn't not only in cover behavioral therapy but, Senator Cochran and Harkin, it only covers 20 visits of any type of speech, OT or PT. So, usually by the first 6 weeks of the year, you've run through your insurance coverage for your child, because it—that is combined speech and OT. So, you can see why many of these children are not getting the assistance they need, because the visits are kind of costly. So, those are the things that we looked at, as to gaps that had to be filled within the State system and Federal system.

Senator COCHRAN. Mr. Chairman, I think we ought to introduce a bill to modernize our laws on Medicaid and reimbursement. This ought to be included.

Senator HARKIN. Yes, how do people afford to do this?

Senator COCHRAN. Well, they can't.

Ms. BOYD. They can't.

Senator COCHRAN. Ms. Halvorson.

Ms. HALVORSON. It's——

Mr. MILLER. They can't. I mean, frankly, they can't. I don't have the exact figures, but I know that we've been working quite a bit to get insurance in Virginia. A number of States have insurance coverage, they've mandated insurance coverage within their States. But, it's a foxhole-by-foxhole fight.

In Virginia, the average income, which, unfortunately, is still rather modest, is about $40,0000–$50,000, and the average cost of services is about $85,000. These families have to do without. They have to without.

And again, it's being done on a State-by-State basis. How you can do some sort of insurance preemption would be an ideal way to go. What the insurance people are saying to my local legislators is that this is not—this is an educational issue, it's not a health issue.

And, Senator Cochran, if you see my two sons, who are wonderful children, it is clearly a combination of an educational health-related problem.

Ms. BOYD. The other factor that didn't get brought up, that I would be remiss if I didn't quickly tell you, is the financial—not—the financial stress, what it leads to with families—I was talking to Dr. Insel earlier—is—the divorce rates. Conservative estimates—and we see this anecdotally—all these families do—is, at a minimum, around 80 percent. There's some estimates—there was a speaker from California last week, and the group that—the people that she counsels, her divorce rates were among 90 percent. So, I mean, these are absolutely incredible numbers.

In Mississippi, in our region, we lost two parents, this year, who could no longer handle the stressors of having a child in the spectrum. And one of them was a dear friend of ours.

And so, those are—but—and you—that is not unique to Mississippi; that is things that we foresee all around the country, and we hear about all around the country.

Senator COCHRAN. Thank you.

Senator HARKIN. Mr. Cobbs.

Mr. COBBS. I would just like to go ahead and piggyback a little bit off that statement. Again, the Government needs to move rapidly to go ahead and advance great technology, such as telehealth technologies, and the insurance part—portion. They really work hand in hand. It's easy to go ahead and pass a bill here or there, but in order to make true change we have to have the standards, and we also have to have the reimbursement model for applied behavioral analysis and other proven therapies, as Ms. Dawson said. In fact, applied behavior analysis is recommended by the Surgeon General, yet private insurance companies typically don't reimburse that for families with autism.

Dr. DAWSON. I just wanted to say that, you know, we do have, I think, a unique opportunity, with healthcare reform, to address this issue. And the House bill does include a—coverage for behavioral intervention for autism, as well as ABA. And I think it's critical that, with this opportunity that we're looking at, in terms of healthcare reform, that we include this. And the payoff, in terms of the financial payoff down the road, is going to be tremendous. It's going to help with the "tsunami," and the impact on families will be, also, tremendous.

So, it's an opportunity that we must not miss, in terms of a Federal mandate for insurance coverage for these treatments that we know work and are cost effective.

Senator COCHRAN. We're going to introduce something together. We'll find out the details a little later, with the aid and assistance of our able staff.

Dr. INSEL. If I can also add, from the IACC perspective, we do have a services group, made up of family members, as well as someone from CMS who's been leading this charge, along with Lee Grossman, who's the president of the American—of the Autism Society of America. Together, they've been listening to families about these issues, trying to come up with some recommendations. And so, if we can be helpful as you pull together some ideas, I'm sure that group would love to have an audience and give you some ideas that they've been grappling with, as well.

Senator HARKIN. Thank you.

The other issue I want to discuss you just mentioned it is "standards." Someone mentioned about how you can go on the Internet and get all kinds of misinformation.

Mr. Cobbs, you've been on this telehealth program for 3 years now, but you're dealing with trained professionals. When you mentioned "standards," is that what you're talking about, setting up those kinds of standards?

Mr. COBBS. Absolutely. And I think it's important to realize that, when we started our treatment program, it was a comprehensive treatment program that first started with face-to-face interaction. Unfortunately, right now families can pretty much pop up any Internet search and type in "telehealth treatment" or "video chat treatment" and their first contact's video-to-video, which—I just can't see how that's possible to form a true therapeutic bond, and to actually get to know the child, to go ahead and treat the child. It's very disconcerting.

And Ms. Dawson also touched on the fact that you can query pretty much anything with autism and related disorders, and you'll get a myriad of different treatments, kind of, scattered amongst—whether it be somebody to repair your car, offer car advice, or for somebody to, you know, go ahead and—"Hey I'll paint your house"—I mean, it's just so sporadic. Parents don't have a consistent place to ensure that they're going to receive quality of care.

And I'm encouraged that you have folks meeting and talking about new treatments, and—but, until we get a set of parameters for standards, so, when parents go to get treatment—especially over innovative technology such as telehealth, which is reasonably new to a lot of folks—they have the assurance that they're going to get a trained, quality professional, and that there's actually some standards that they can rely on. Right now, those just aren't there.

Senator HARKIN. Go ahead.

Dr. DAWSON. Yeah. Well, I just wanted to mention a program that is, I think, a wonderful example of a public-private partnership that is beginning to address this issue of standards, and that is the Autism Treatment Network. This is built on the cystic fibrosis model, which—as you may know, decades ago, cystic fibrosis was in the same situation of not getting quality care, no standards for what—how a child should be treated.

And so, the way in which this model works is, it's 15 hospitals, that care for children with autism, that have come together to both look at quality of care, models of care, as well as to develop standards that can be—practice standards, published in journals, that physicians then can use to guide things like assessment—assessment of medical conditions, behavioral interventions, and so forth.

So, there is a mechanism where this is beginning to be addressed, but it's in the very early stages. It's cofunded by Autism Speaks and by HRSA.

STANDARDS OF CARE

Senator HARKIN. Dr. Insel, is your group working on standards, that interagency group? "Who does this? Who is charged with the responsibility of coming up with standards that have to be met so we don't have people out there that don't know what they're doing, trying to treat people?"

Dr. INSEL. I think you've stumbled onto a really important issue. It's not unique to autism. We've built standards around biomedical interventions that are essentially overseen by the FDA. But, in the broad psychosocial intervention arena, of which APA or behavioral interventions would be part of that, there is not an agency, and there's not a sort of licensing body, that oversees this in quite the same way. So, it's a gap as we look at this.

The question is, Even in this healthcare reform discussion, when you're talking about treatments that may not be given at a doctor's office, or may not be one of the 15 hospitals, but involves training families to administer care, 10, 15 hours a week, how does that get reimbursed? How do we look at quality measures for outcomes? And how do we set standards for the degree of care and the level of care that's needed to be reimbursed?

Senator HARKIN. Were you asking me that question or was that just rhetorical? I mean, have we got to answer that question now?

Dr. INSEL. Someone—I am a psychiatrist, so I——

Senator COCHRAN. Right. "How do I feel, Doctor?"

Senator HARKIN. That's true.

Well, again, obviously we have a whole range of interests here—everything from the research into the causes—I mean, obviously, Dr. Insel, there's a lot of talking about vaccines. You covered that in your testimony. We had a couple of little questions here about it—about the number of vaccines and how we set up that kind of a study. Ms. Boyd had talked—or, not Ms. Boyd, I think it was Ms. Halvorson—I forget just who was—talked about that kind of a study—but, I just don't know how you do it. As you said, it would be kind of immoral to just say, "Well, your kids are not getting immunizations, because we want to put them in a study. But, if you wanted to determine that, I just don't know how you would go about doing that.

Ms. BOYD. One of the reasons I wanted to bring that up, Mr. Harkin—Senator—is that there are so many families right now—and this greatly concerns me, because I actually am a vaccine proponent; I believe in vaccines, I think they're one of the greatest public health achievements that we've ever had. So, I'm actually a huge proponent of it. What I am concerned about—there are so many families right now that are not vaccinating their children—and we do vaccinate our children—but, there are so many that are not vaccinating right now, because of what they perceive as a huge risk—and so, I am concerned that the NIH and the CDC, by their failure to aggressively actually look at this and get good valid scientific studies, free of people who may have some interest, one way or the other, into this, that we—they are doing more harm to lower the herd immunization rates than anybody that is yelling out there, "Be concerned about vaccines."

There are so many people right now that are choosing not to vaccinate their children. I don't think that population is going to be as difficult as scientists perceive that it is, because within the autism community, we see that going on right now. And that concerns many of us, who feel that vaccines are very important, because—but, we hear families all the time come up to us and say, "We're not going to vaccinate our kids."

And that, as a—having a husband as a medical professional; I worked as an attorney in public health—that greatly concerns me, because many of these families that are saying they're not going to vaccinate their kids don't have any of the possible health characteristics that some of us who did have children with vaccine reactions had that could have been red flags, had they—now that we know that, could be possibly studied.

So, I think that you will—that the scientific community can find these people to do this.

Senator HARKIN. Well—Dr. Insel? And then we'll go to Ms. Halvorson. Go ahead. Or, Ms. Halvorson——

Dr. INSEL. I'll yield, and——

Senator HARKIN. Okay.

Dr. INSEL [continuing]. If I could——

Senator HARKIN. Ms. Halvorson.

Ms. HALVORSON. I was just going to mention, I don't know how many people you're thinking would need to be included in a study like this, but there's a physician in, I believe, the Chicago area that has a practice of about 3,500 patients and many of them choose not to vaccinate, and their autism rate is next to nothing. And so, there are populations of people who are—who have that documentation. I agree, I don't think it's going to be that hard to find.

You know, the Amish people can argue on that. There's, you know, maybe a—it's more of a closed situation. But, this population with Dr. Eisenstein is very broad-based. It's not—just people from every walk of life.

Senator HARKIN. I don't know about that.

Dr. Insel.

Dr. INSEL. So, let me——

VACCINE STUDIES

Senator HARKIN. I'd like to know more about it.

Dr. INSEL [continuing]. Just be very clear on this point, because I'm representing what we know about the scientific evidence so far. And that's really unequivocal. It's not that CDC and NIH, and actually now multiple European and Japanese studies, haven't looked at this. This problem has been looked at over and over again, 16 large-scale studies that have plowed into this question at many different levels and many different populations. And whether you read those studies or whether you listened to the Institute of Medicine, or whether you look at——

Senator HARKIN. Excuse me, Dr. Insel, for—studies on thimerosal or on the—just the total number——

Dr. INSEL. Both.

Senator HARKIN [continuing]. Of vaccines——

Dr. INSEL. Looking at——

Senator HARKIN [continuing]. That were——

Dr. INSEL [continuing]. The connection—the possibility of a connection between vaccination, with or without thimerosal, with particular formulations or without, and the prevalence of autism, whether this is a risk factor. The studies have consistently found no evidence of a connection. We heard that from the Institute of Medicine, that looked at this whole broad spectrum of studies. We heard it from the Vaccine Injury Court, which said there's not even plausibility here.

Senator HARKIN. But, I thought, earlier, Dr. Insel, you told me, when I mentioned getting a study done of the number of vaccines—not the thimerosal issue, but the number of vaccines—in the first 2 years of life, now, compared to what it was 20, 30 years ago, and I said, "Could we compare—what would the incidence of autism among a cohort of children age 0 to 2 that received 29 vaccines in 2 years, compared to a cohort of kids that got 5 or 6 or 7 or 8—what they did in 1980—compared to 29?" Do you see what I'm saying? How—I don't know of any studies. And you just told me there are no studies that have done that.

Dr. INSEL. So, if you're asking the question, "Has the prevalence of autism increased over the time when the number of vaccines has increased, is there a relationship?"——

Senator HARKIN. We don't know that.

Dr. INSEL. Well, we know that they're—we know they've both gone up, right?

Senator HARKIN. Both gone up.

Dr. INSEL. But, a lot of things——

NUMBER OF VACCINES

Senator HARKIN. But, we don't—but, what we don't know is, Is there any causal relationship between the number of vaccines that——

Dr. INSEL. Right.

Senator HARKIN [continuing]. Are given—now it's 29 over 2 years, now; we know in 1980, it was 8 or 9—what we don't know is, Is there any causal relationship between the number of vaccines—29 in 2 years—and higher incidence of autism? We don't know that, do we? Because there's no studies that have——

Dr. INSEL. So, the way to do such a study clearly would be asking—we'd have to do a randomized, controlled design.

Senator HARKIN. Sure.

Dr. INSEL. You'd want to be able to look very carefully at those who are vaccinated and those who are either unvaccinated, or vaccinated in a different way.

And that's where I said that we get into ethical problems. Most—because of the scientific evidence——

Senator HARKIN. I know that.

Dr. INSEL [continuing]. And I just can't stress this enough—the scientific evidence is so consistent——

Senator HARKIN. Ms. Halvorson says there are—she just mentioned someone in Chicago—I have no idea who this is—who doesn't vaccinate kids. I'm interested in that. She mentioned thousands of them who have not been vaccinated. Are there place like that? And you mentioned, Ms. Boyd, there are people down in your area that aren't getting their kids vaccinated now. Couldn't you set up a study like that?

Dr. INSEL. You could—if you were to set up a study like that, I think the question that one would ask is, not only about, does this have an impact on autism, but what's the impact on measles, on pertussis?

Senator HARKIN. Very true.

Dr. INSEL. What's the impact on rubella, on a whole——

Senator HARKIN. Yes.

Dr. INSEL [continuing]. Series of——

Senator HARKIN. Yes.

Dr. INSEL [continuing]. Preventable illnesses for which we know——

Senator HARKIN. Yes.

Dr. INSEL [continuing]. The cause, for which we know the vaccines can prevent them? Do you really want to ask parents to put their children at risk for those illnesses for which we could lose herd immunity so that we could investigate, for the 17th time, whether there's a potential relationship here?

Senator HARKIN. Ms. Boyd, I——

Ms. BOYD. Senators, this is where—there are many people in the medical community—and I mentioned Dr. Bernadine Healy—that feels like this issue has not been appropriately evaluated, particu-

larly also looking at subpopulations of the autism community, to look at whether there are immunological——

Senator HARKIN. Mitochondria.

Ms. BOYD [continuing]. Mitochondrial, thank you—where there are many issues involved with that. And she's articulately laid those things out that are missing from the studies right now. And I think it is imperative that we look at those particular studies. I understand the ethical delimination or—thing about asking about asking parents to do this. But, Senators, we already have populations of families that are not doing this, anyway. So, we're—and absolutely we should look at whether or not their children developed measles. But, quite frankly, Senator, measles and autism?

Senator HARKIN. If you had a—it's a terrible—have you got a choice?

CHILDHOOD ILLNESSES

Senator HARKIN. You know, I had all those diseases when I was a kid. We had mumps and measles and chicken pox, and I had everything like that.

Senator COCHRAN. Did you have whooping cough? That's a real——

Senator HARKIN. I don't think I had it. I don't—I may have. I don't know.

Dr. INSEL. So, it is important to recognize, many of us were exposed to those illnesses and did quite well. They're also fatal in a proportion of children. And I grew up, as a physician, watching children die with H flu meningitis, and watching children die with the ramifications of measles, because we weren't preventing all of those diseases at that point in time. I would be loath to go back to those days, I can tell you, to think that we've been able to finally succeed in that sphere, and to go backwards, and invite that to come back—it would—I just think we're better than that. We—the science tells us that we're better than that.

Senator HARKIN. Well, I would still like to see the studies done. I know we're better off, in that regard, but I'd like to see whether or not—I still have questions and—believe me, I've had a lot of hearings, I've talked to a lot of professionals about this, as to whether or not you need all of those vaccinations in the first 2 years of life. Or should they be stretched out longer? That's an open question. Don't know. I don't know the answer to that question.

Ms. Halvorson.

Ms. HALVORSON. I just have to point out also—vaccines don't always work all the time. My son is a walking example of this. The chickenpox vaccine was brand new when he was 2 years old, and my doctor said that I should get it for him. And I thought, okay, great. I had chickenpox as a kid. It was not a big problem. I came through it, but I missed a couple weeks of school. And 6 months later, after being immunized, my son developed a full-blown case, anyway.

That was my first clue that I was not necessarily going to choose immunizing my daughters for chickenpox—my future children; at the time, I didn't know I was going to have two more daughters—because I was pregnant at the time that my son developed chick-

enpox, 6 months after his vaccine, and had I not had it as a child, and had lifelong immunity, my baby could have been at risk for birth defects, as I understand it.

So, there's more to consider than just a blanket statement of, "The vaccine is automatically going to protect." It doesn't always work that way.

Senator HARKIN. Dr. Dawson.

Dr. DAWSON. I want to say that, in many ways I agree with Dr. Insel, that we have answered some questions definitively. It does not appear that thimerosal is—or, accounts for this large increase that we've seen in prevalence of autism. And the introduction of the MMR vaccine does not appear to account for the increase in the prevalence.

I do think there are important questions that still remain to be addressed, that have not been addressed by the large epidemiology studies that have been conducted so far. And, in particular, I think it's important to understand the role of underlying genetic and medical susceptibilities, and whether they may lead to an averse response to a single vaccine, or a set of vaccines that are given over a short period of time.

We know that the era of personalized medicine is beginning to infuse our practice of the infectious—treating infectious disease. But, our understanding of underlying variation in genetics has not been studied in the context of responses to vaccinations. And it's—so, it's—Autism Speaks' focus, in terms of our funding in this area, is trying to understand those medical or genetic vulnerabilities, whether it's mitochondrial disorder, sodium channel genes, which we know—that can affect responses to vaccines in developing seizure disorder, and so forth—whether these may account for, again, some minority of cases of autism.

The other thing I would like to put out is—or, suggest is—I agree with Tom—Dr. Insel—that a randomized study in which we ask parents to forego getting vaccines is not ethical and not feasible. We could, however, study the potential role of vaccines in the context of at least two ongoing NIH studies. One is a study, that both NIH and Autism Speaks are funding, which is following a cohort of at-risk infants. These are infants who have an older sibling with autism, and so, they have a much higher chance of developing autism. And we know that many of those parents are choosing to vaccinate their children, and some of those children are—parents are choosing not to vaccinate. So, it's important that we leverage those studies to look at how vaccination rates among these at-risk—genetically at-risk infants affects outcome.

The other study is the NIH National Children's Study. So, this is a cohort of 100,000 children that are being followed, prospectively, from conception through adulthood. Now, keep in mind that 600 individuals in that cohort will develop an autism spectrum disorder, based on our current prevalence estimates.

One of the weaknesses in the current design in—and Autism Speaks is overseeing the advisory—expert advisory panel that is advising the National Children's Study on how to leverage this study to inform autism—but, one of the weaknesses in the current design is that they're not collecting medical records, so they're not collecting information that would inform how parents are vacci-

nating their children. And again, with many parents now choosing not to vaccinate their children, this is another opportunity, with the collection of medical records, that we could leverage an ongoing study to address this important question.

And I want to say that our position at Autism Speaks is one of very evidence-based—we're really agnostic with respect to whether vaccines play a role or not, but we believe that, by addressing parents' questions, that this will increase confidence in the vaccine program and will ultimately lead parents to be more likely to vaccinate their children, which we think is going to be critically important for public health.

Senator HARKIN. I did not know this. I've been a big supporter of that Children's Study, and I have used my position on this subcommittee to make sure that we continue the funding for it, and keep it going. I think it's one of the most vital longitudinal studies that we've ever done.

Dr. DAWSON. Right.

Senator HARKIN. And you're telling me that of all the money we've put in for that, and we're going to continue to do this—what, 20—is this a 20 year? How many years is this longitudinal study? 20 years—that they're not keeping medical records?

Dr. DAWSON. Well, the—so, they don't have the—no, it's true—they have questionnaire data, but they do not have the funding to go back and actually obtain the medical records and extract the information that we need. And this not only affects our ability to address questions about vaccines, but it also affects our ability to address really, critically, scientifically based questions like, What's the effect of a mother having a flu infection during pregnancy? The specific medications that she received. Any kinds of prenatal and perinatal events. These are all only being obtained through a questionnaire, rather than medical records. And so, our advice to the National Children's Study is, this is a key component. And the reason for not doing it is strictly financial. They just don't have the funds to do it.

Senator HARKIN. Dr. Insel.

Dr. INSEL. I just want to make sure that you don't go away with the idea that they're not—that they don't have medical records. They're not able to obtain the original records, with the current budget. And they've looked at the possibility of getting supplementary funding that would allow them to obtain the raw records from the physician of referral. That has not been done. So, Dr. Dawson's right about that.

CAUSES OF AUTISM

I would just—I know we're running out of time, and I just think it should be said by someone here that there will be a time in the future that we will have a much better understanding of the environmental causes of autism. One concern that many people have is that if we get stuck by looking at one thing over and over again, that we're going to miss the opportunity to look at what may be a much more important cause.

Where Dr. Dawson and I agree is that the evidence now is very clear that, whatever the story is with vaccines, it doesn't explain very much about what we know about autism. And we may never

be able to fully eliminate a very, very rare event that may be in play here that would connect the two. But, all the evidence, so far, says this isn't the main story.

The question for us is, Where is the main story, and where should we be looking? And I would hope that the focus on this topic, particularly in this conversation today, doesn't obscure that fact that there's probably something out there that is truly important that we need to be focusing on very quickly, and move into very quickly. And the hope is that the kinds of studies that Dr. Dawson suggests, that are agnostic, that look broadly at a lot of prenatal factors, also include some postnatal factors—we'll begin to see a pattern emerge. But, so far, we don't have that.

Senator HARKIN. Well, we are going to explore that, the whole idea of the medical records. I wrote that down. We have got to—I have to find out about that.

I know we are out of time. We've got three things, I think. Let me see if I can summarize this.

One, the research that needs to be ongoing, that we are putting a lot of money into, to find what is causing this—that is basic research.

Then there is the other element of interventions and helping families right now. We know families, in the next several years, are still going to have children with autism. It is just going to happen. So, we have to think about what we do on early interventions and how we structure that to provide the most effective early interventions.

And the next thing is, we have a whole group of young people out there with autism, and they are going to be adults soon. What is happening to them, and how can we develop programs for independent living, and things like that.

So, it is a big task, but it is one that we can't shirk from trying to address in multiple ways. And that is what this subcommittee is going to try to do.

So, I picked up some good ideas here this morning. It is good to be refreshed on all of the information. I wish I had a simple answer.

Do you have anything to add, Thad?

Well, thank you—does anybody else have one last thing they want to get across, or not, before we leave?

Dr. INSEL. Thank you for your interest.

Ms. BOYD. Thank you for your leadership.

Senator HARKIN Well, it bedevils us, I can tell you that.

Yes, Ms. Halvorson.

Ms. HALVORSON. I would just encourage you all to continue to talk with more of our independent researchers.

I really take issue with Dr. Insel's statement, "all of the evidence says that this is not a connection." If you don't look, you won't find. There is evidence that does say that thimerosal is very much a concern. And I would really encourage you all to talk more with people like Dr. Lucier, who is seated behind me, Dr. Boyd Haley—I could name a whole bunch of scientists that you would glean a lot of really great information from.

Senator HARKIN. I believe in open inquiry. As I said to a group last night, I do not believe in closed minds or closed doors or closed

inquiry. I want open inquiry into this. But, again, if something has been looked at scientifically and the vast majority of the scientific community, after looking at this and going through it, says there is no correlation, well, then you have got to move on to something else at that point in time. But, again, I am always for open inquiry.

Any other last things before we go?

Mr. COBBS. And then we're going to have to adjourn. Chairman Harkin and Senator Cochran, I just wanted to thank you for, again, allowing us to tell the story of a truly innovative technology that has helped our family. Thank you so much.

Senator HARKIN. I'm still interested in telehealth, because there are so many families out there, and they are at wit's end on how to take care of their kids that have just been diagnosed. They can't go to a doctor's office every day. You are an example of what happens when you have someone—when the child is acting up, and someone—a professional, with good standards, can come in and say, "Here's what you should do. Here's how you should take care of that"——

Mr. COBBS. Absolutely.

Senator HARKIN. But, of course, the problem is, we don't get reimbursed for that.

Mr. COBBS. You hit the nail on the head, sir.

Senator HARKIN. You don't get reimbursed.

Mr. COBBS. Absolutely.

Senator HARKIN. If you go—probably if—I don't know, if you went to a hospital or someplace, there would probably be some reimbursement for that, I don't know. But——

Mr. COBBS. Somewhat. There still is, as Ms. Dawson and the others pointed out, a complete both public and private insurance breakdown——

Senator HARKIN. Yes.

Mr. COBBS [continuing]. For reimbursement, for autism.

Senator HARKIN. Yes, hopefully we'll look at that. And with healthcare reform, hopefully we'll look at the whole issue of reimbursement for preventative category of services.

Well, again, thank you all very much. This—to me, has been very informative. It's just good to be brought up to speed on it. And we will continue our involvement in this issue—it just, as I said, bedevils us all on getting a good handle on it.

But, Dr. Insel, thank you for your great leadership at NIMH and on the Interagency Task Force. Ms. Dawson, all of you here—Ms. Halvorson—thank you very much. And believe me, we'll continue to pursue open inquiry and if there's questions out there, let's have some answers, and let's pursue them.

Thank you all very much.

CONCLUSION OF HEARING

The subcommittee will stand recessed.

[Whereupon, at 12:18 p.m., Wednesday, August 5, the hearing was concluded, and the subcommittee was recessed, to reconvene subject to the call of the Chair.]

○