

EXAMINING THE FEDERAL RESPONSE TO AUTISM SPECTRUM DISORDERS

HEARING

BEFORE THE
SUBCOMMITTEE ON GOVERNMENT OPERATIONS
OF THE
COMMITTEE ON OVERSIGHT
AND GOVERNMENT REFORM
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CONTENTS

Hearing held on May 20, 2014	Page 1
WITNESSES	
Mr. Thomas R. Insel, M.D., Director, National Institute of Mental Health, Chair, Interagency Autism Coordinating Committee	
Oral Statement	7
Written Statement	10
Mr. Michael K. Yudin, Acting Assistant Secretary, Office of Special Education and Rehabilitative Services (OSERS), U.S. Department of Education	
Oral Statement	24
Written Statement	27
Ms. Marcia Crosse, Ph.D., Director, Health Care, U.S. Government Account- ability Office	
Oral Statement	34
Written Statement	36
APPENDIX	
Statement of Rep. Gerald E. Connolly	00
Federal Autism Activities	76
Statement of Donald J. Mueller, Executive Director	79
Statement for the record by Safeminds, submitted by Mr. Mica	82
Responses for the record by Michael Yudin	88
Responses for the record by Dr. Thomas Insel	92
Responses for the record by Dr. Marcia Crosse	106
Statement by Autism Speaks	109

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Tuesday, May 20, 2014

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON GOVERNMENT OPERATIONS,
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:07 a.m., in Room 2247, Rayburn House Office Building, Hon. John Mica [chairman of the subcommittee] presiding.

Present: Representatives Mica, Turner, Amash, Woodall and Connolly.

Also present: Representative Posey.

Staff Present: Will L. Boyington, Deputy Press Secretary; Molly Boyl, Deputy General Counsel and Parliamentarian; Adam P. Fromm, Director of Member Services and Committee Operations; Linda Good, Chief Clerk; Mark D. Marin, Deputy Staff Director for Oversight; Emily Martin, Counsel; Sarah Vance, Assistant Clerk; Jeff Wease, Chief Information Officer; Jaron Bourke, Minority Director of Administration; Courtney Cochran, Minority Press Secretary; Katie Teleky, Minority Staff Assistant; Cecelia Thoms, Minority Counsel; and Michael Wilkins, Minority Staff Assistant.

Mr. MICA. Good morning. I would like to call to order the Subcommittee on Government Operations. Welcome everyone this morning, a beautiful day in Washington.

Welcome to my colleague, our ranking member, Mr. Connolly, and we will have the introduction of Mr. Posey, and acceptance of him into the committee's proceedings today.

Mr. CONNOLLY. Mr. Chairman, just before you begin your statement, if you wouldn't mind, I would ask unanimous consent that our colleague from Florida, Mr. Posey, be allowed to participate in today's hearing.

Mr. MICA. Without objection, so ordered.

Mr. CONNOLLY. I thank the chair.

Mr. MICA. Thank you.

Well, again, I would like to welcome everyone. The order of business will be opening statements by Members, and we have I see three witnesses this morning. We go to our panel of witnesses after we have heard from the Members. We will hear from our three witnesses.

And welcome to them this morning.

And then we will go into questions.

So that will be the order of business, and the title of today's hearing is Examining the Federal Response to autism spectrum

disorders. And this is a hearing that the chairman, Mr. Issa had also committed to conduct, and we are pleased to cooperate in conducting today's important hearing.

First of all, I always have an opening statement about the purpose of the committee, and we do have important work. We are the chief investigative and oversight panel in the House of Representatives and probably in the Congress, and it is an important responsibility. When you are home, like we were last week, there are people working hard, making a living trying to feed their families, keep up with all of the responsibilities that they have as citizens, and they send us here to make certain that government is efficient, effective, and it works for them.

Today is a particularly important hearing because it deals with the affliction that many families have had to experience, unfortunately, with their children, autism, and it has impacted dramatically their lives, and we will hear in just a few minutes some of the questions that are being raised right now about Federal response and Federal programs. So it is important that we, in fact, review what is going on with these programs, especially the Federal aspects and their impact, again, on the issue of autism, a problem that so many families and children face.

So, again, thank you for coming, and as I said, the hearing is going to try to focus on the government's response and also to the rise in the diagnosis of autism spectrum disorders, or ASD. We will hear from some distinguished witnesses who hopefully can shed light on, again, the Federal perspective that we are centering and focusing our attention on today.

In March, the Center for Disease Control and Prevention, CDC, they issued a report that estimates that now 1 in 68 children in the United States has been identified with ASD. This estimate is roughly 30 percent higher than CDC's estimate from 2 years ago, which showed ASD in 1 in 88 children. ASD causes, of course, some very significant financial burdens for diagnosed individuals and their families. Individuals with autism on average spend \$4,110 to \$6,220 more on medical expenditures every year than individuals without ASD. In 2011, the additional cost of having a child with ASD was estimated to be \$17,000—more than \$17,000 a year. In the United States, spending on autism costs \$126 billion every year, including associated costs for health care, education, intervention services, as well as wages lost by parents who sometimes have to quit their jobs to care for their children.

The Federal Government also spends money on autism, and that is one of the things we are going to review today. In fiscal year 2012, Congress appropriated—not a huge sum but significant money—\$230 million for autism-specific research and services. This includes \$161 million for research for the National Institutes of Health; \$21 million for CDC surveillance and research efforts; and some \$48 million for Health Resources and Services Administration within HHS; and another \$5 million for autism research within the Department of Defense's congressionally directed medical research program.

Of course, the Federal Government has an important responsibility, and that is to ensure that these funds are spent both effectively and also efficiently. In 2006, Congress established the Inter-

agency Autism Coordinating Committee, IACC. That agency and committee coordinates all efforts within the Department of Health and Human Services and other Federal agencies regarding autism-related research. And it was formed, as I understand it, to make certain that efforts are coordinated and that we have the most effective possible programs.

The IACC's mission is to provide advice on Federal activities related to ASD, also to facilitate the exchange of information and coordination of ASD activities and increase public understanding of ASD research and services.

However, and I think that, Gerry—Mr. Connolly—you may recall when we had the Government Accountability Office in recently, and they went over a list of some of the major issues, and problems with various agencies. In their GAO report to us in November, they stated there was a potential duplication in 84 percent of the autism research projects funded by Federal agencies and that better coordination was needed from the IACC, which was actually set up for that purpose. That is a pretty astounding figure, and we want to review that, and that is one of the reasons for the hearing today.

So the IACC and other agencies have disputed some of GAO's findings, noting that research projects with similar titles may have substantially different hypotheses, and the growth of scientific knowledge depends on multiple studies that investigate similar research questions at the same time. As I said, we are going to examine, again, some of the points of view on this report. The recently introduced Combating Autism Reauthorization Act of 2014 would change the law to provide coordination between agencies, first by appointing a point person at HHS to coordinate research efforts within HHS; secondly, to require agencies to implement IACC's strategic plan; and then, thirdly, adding, preventing duplication to IACC's list of statutory responsibilities.

So, today, we are going to look at ways to ensure that the potential duplication of research efforts does not become actual duplication. We are going to look at all of the associated testimony that will be provided today and see if we can make some sense out of this and make certain that we are heading in the right manner, again, efficient and effective use of taxpayer dollars in this important area. We will also take the opportunity to explore how the Federal Government responds to the evolving needs of individuals with ASD within the health care and public school systems.

So we have got a number of areas we want to cover today, and we will hear from now from the ranking member, Mr. Connolly.

Please to yield to him.

Mr. CONNOLLY. Thank you so much, Mr. Chairman.

And thanks for holding today's hearing to examine the Federal Government's response to autism spectrum disorders, ASD, with a particular focus on strengthening the Interagency Autism Coordinating Committee efforts to coordinate and monitor Federal ASD research initiatives and treatment activities.

I know I have been involved for the last 20 years in my community in Northern Virginia with parents of autistic kids and with various support groups. I know that one of the things that plagued autism families dealing with this challenge was the fact that some insurers, in fact, treated the autism as a preexisting condition. And

the good news is the Affordable Care Act made that illegal, lifting that burden from parents who were already dealing with many other challenges.

On behalf of the millions of Americans and their families living with ASD, I know it is your hope and mine, Mr. Chairman, and our expectation that our expert panel of witnesses will engage in a productive discussion this morning aimed at identifying shared principles around which stakeholders can coalesce and build on to ensure Federal ASD activities are carried out in the most efficient and effective manner possible.

The Centers for Disease Control and Prevention estimated, as you indicated, Mr. Chairman, that as many as 1 in 68 kids in the United States are living with ASD. That is clearly a serious public health challenge, as millions of individuals battle daily with symptoms that vary greatly in severity and scope but often involve impaired social interactions, problems with verbal and nonverbal communication, and repetitive behaviors. According to the CDC, it is estimated, as you indicated, Mr. Chairman, to cost perhaps as much as \$17,000 more per year to care for a child with ASD compared to a child without it. And of course, those costs arise in the form of medical and nonmedical expenses ranging from medicines, therapies, and special education, to caregiver time and adult housing.

A recent National Institutes of Health study concluded the economic burden associated with ASD is substantial and can be measured across multiple sectors of our society and calculated that the total societal cost for caring for children with ASD exceeded \$9 billion as of 2011.

In passing the Combating Autism Act of 2006 and subsequently reauthorizing that act in 2011, the Congress began to address the rising rate of ASD and established the IACC to coordinate all efforts within the Department of Health and Human Services concerning ASD. Creating the IACC was an important first step in ensuring that the Federal response responsibly leverages taxpayer dollars to engage in a systematic and comprehensive approach to watch over research and treatment activities across government, academia, and the private sector.

I am concerned, as you are, Mr. Chairman, that the Federal Advisory Committee Congress established to coordinate ASD activities according to the GAO, is relying on data that is outdated, not tracked over time, inconsistent and incomplete, and risks duplication of research efforts as you cited, Mr. Chairman.

Of course, we also must recognize that GAO only addressed potential duplication of Federal ASD activities. So this panel is going to be important in terms of hearing testimony about what actually is occurring. As GAO has consistently stated in these reports, determining actual duplication for research projects would require a more extensive review of voluminous and scientific data and was beyond the scope of the study. HHS makes a fair point in noting that duplication in and of itself, is not necessarily a negative characteristic with respect to effectively conducting scientific research activities.

I look forward to learning more about the IACC plans to enhance the reliability and usability of the research and the data. Specifi-

cally, I hope we will examine how all stakeholders work together to improve the quality of the IACC data, to enhance coordination and monitoring of Federal autism activities, and how the Departments of Defense, Education, HHS, and National Science Foundation will better coordinate ASD research activities to ensure that we get the most bang for our buck from finite taxpayer resources.

As the GAO will testify today, I expect, researchers have yet to identify the root causes of autism, and there are no known cures. Thus it is absolutely vital that we sustain our Nation's robust commitment to funding Federal research that may enhance our knowledge of this condition and improve treatment options for families coping with ASD. If there is one singular principle that we can all embrace, surely, it is that no family or child should be forced to face living with ASD alone, particularly when we know that early detection and intervention can make a dramatic difference in the quality of life for an individual living with ASD.

I look forward to hearing about how we can improve the efficiency, effectiveness of our Federal response, and I want to thank our witnesses for being with us today.

Thank you, again, Mr. Chairman, I yield back.

Mr. MICA. Thank you, and we don't have any other members at this point, but members may have 7 days to submit opening statements for the record.

We do have Mr. Posey, who, if he would like, can be recognized at this time.

Mr. POSEY. Thank you very much, Mr. Chairman, it was very kind of you.

I would like to enter into the record, if I might be able to at this time, from SafeMinds. It's an organization of people who are affected by autism, and it's testimony submitted for the record on the Committee on Oversight and Government Reform, Subcommittee on Government Operations hearing of May 20, 2014.

Mr. MICA. Without objection, that will be made a part of record. You may proceed.

Mr. POSEY. Thank you.

Thank you, Mr. Chairman, as you know, and you have expressed interest in before, Representative Carolyn Maloney and I introduced H.R. 1757, the Vaccine Safety Act, which calls for the National Institutes of Health to conduct a comprehensive study comparing the health outcomes, including the incidence of autism spectrum disorders between individuals who are vaccinated and those who are unvaccinated. It was announced previously during the April 8th, 2014, Interagency Autism Coordinating Committee meeting that a study of vaccinated versus unvaccinated children is being undertaken under an existing NIH contract with The Lewin Group. While I appreciate that a study is being undertaken, I think it is imperative that it be a little bit more transparent and that the stakeholders should have more participation and input into the process.

It's important that all data sets developed as a part of this study at each step in the process be preserved for independent review in the future. I came across a May 15th op ed by Sallie Bernard. Sallie is a board member of Autism Speaks and the president of SafeMinds, but more than that, she is the mother of a 26-year-old,

Bill, who has autism, and let me quote from her op ed: “Now a new study of over 2 million children born in Sweden between 1986 and 2006, which has been published in the Journal of the American Medical Association, confirms what SafeMinds and parents have been saying for decades. Children are as much at risk of getting autism from environmental factors as they are from their genetics. The study by Sven Sandin and his colleagues follows on the heels of another landmark study of twins by Joachim Hallmayer of Stanford published in 2011, which showed the larger component of autism risk arise from environmental, not heredity factors.

“Since genes and environment interact to increase autism risk, this means that we are doing something to our children, exposing them to something harmful either while they are still in utero or during their first months or years of life that is altering their biology. The scientific evidence is overwhelming. Researchers and science policymakers can no longer deny that there is a clear and strong environmental component to the skyrocketing rates of autism.

“By ignoring the environmental component to autism, the government and scientific community have made a massive strategic error, wasting enormous amounts of money and time and mostly fruitless genetics-only research that has not helped us stop the new causes of autism or help people living with severe autism.”

And this is a quote: “We can fix this. The study by Sven Sandin and Joachim Hallmayer can guide us to the end of the autism epidemic. The good news is that the environmental causes of neurological disorders are more easily fixed than genetics. When we invest in uncovering the environmental factors that are causing our autism spectrum disorders, we can remove those factors from our world. We can study how those factors alter biology and identify the treatments that can remediate those pathways.”

“Based on this latest evidence, funders like NIH should be charging scientists with the urgent task of discovering what the environmental causes of autism are. Clinging to outdated paradigms harms our community. To its credit, the NIH’s National Institute of Environmental Health Sciences just released a Request for Proposals on environmental contributors to autism spectrum disorders.” To its discredit—“the NIH’s Interagency Autism Coordinating Committee, continues to obstruct environmental initiatives contained in its own strategic plan for autism spectrum research,” and I left out mentioning any names in there.

This is all pretty serious, and when I listen to what others are telling me and what the GAO report says, that we will discuss today, and the data from the May 7th JAMA article, the message is clear. It appears NIH has been ignoring what parents have known for many years: Environmental exposures in utero or early life are changing the biology of children, and I’m out of words and out of time so I will pick this up later. Thank you, Mr. Chairman.

Mr. MICA. Well, I thank you for your participation, your opening statement.

And now, without further opening statements, we will turn to and recognize our panel.

Today, we have Dr. Thomas R. Insel. He is the director of the National Institute of Mental Health, and the chair of the Inter-

agency Autism Coordinating Committee. We also have Mr. Michael Yudin, and he is the acting assistant secretary for the Department of Education's Office of Special Education and Rehabilitative Services. And then, finally, we have Ms. Marcia Crosse, and she is the health care director for the U.S. Government Accountability Office.

As you all know, this is an investigative committee of Congress, and subcommittee, Government Operations Subcommittee you are testifying before. We do swear in our witnesses so if you will please stand.

Raise your right hand. Do you solemnly swear or affirm that the testimony you are about to give before this subcommittee of Congress is the whole truth and nothing but the truth?

Dr. INSEL. I do.

Mr. YUDIN. I do.

Ms. CROSSE. I do.

Mr. MICA. And the record will reflect that all three witnesses answered in the affirmative.

Again, welcome to each of you. We have sort of an SOP, standard operating procedure, 5 minutes for your presentation. If you have lengthy testimony or data that you would like entered into the record, do so through request of the chair.

And we are pleased, again, to welcome and recognize first, Thomas Insel, and he is, as I said, the director of the National Institute of Mental Health, and the chair of the Interagency Autism Coordinating Committee.

Welcome, sir, and you are recognized.

WITNESS STATEMENTS

STATEMENT OF THOMAS R. INSEL, M.D.

Dr. INSEL. Thank you, Chairman Mica, and Ranking Member Connolly, it is a pleasure to be here. And I appreciate your interest in this very important public health issue.

As you just noted, I have two hats here as head of the NIMH, which is the largest Federal funder for autism research, and as chair of the IACC, a job that I have had since 2002, so through many different iterations of the Combating Autism Act.

You have my testimony. I'm not going to read that. And I hope we can discuss much of what is in there, and I really, in the spirit of wanting to make this more of a conversation and hopefully create a teachable moment here, I would rather save time for questions and answers rather than taking a lot of time with an opening statement.

I would like to make a few comments, which probably are not going to be as apparent in the course of our conversation today. One is just to give you a sense of how remarkably fast things are moving in the realm of autism science. Last week was the 13th meeting of the International Society for Autism Research. Really, prior to 13 years ago, there was no annual meeting. There was no society. It was a very small research field. Last week, there were 2,000 people from 35 countries gathered together in Atlanta to talk about the most recent findings, which is a 30 percent increase in the number of abstracts just in 1 year. So we have got a field that is vibrant. That is exciting. That people are moving into.

But they are also, of course, huge questions. You talked already both of you about the issues around prevalence, and that is a concern that we see broadly. You also both mentioned costs.

And it is interesting, your figures were somewhat variant. I think Mr. Connolly said \$9 billion, and Chairman Mica, you cited \$128 billion. The truth is probably somewhere in between, but it is a lot of money. And the question I think in front of us is when you have a cost that great and a need this urgent, how much do you invest in science to preempt those costs and to mitigate that public health burden? And that's what I hope we will have a chance to talk about a little bit today. It is not only how we invest, and where we invest, but ultimately, how much should be invested? What should we be spending on a problem that has grown so much and is creating so much concern in your districts and across the country?

For us at the NIH, the good news is that the science is moving so quickly, and there are so many interesting new insights. It is actually at a point now where we believe very firmly that the kind of investments we are making will soon begin to mitigate these staggering costs and reduce the disability of this disorder. A lot of the science that we are most excited about actually does not have autism in the title. It is the science of trying to understand how the brain develops, developing technologies that allow you to actually visualize brain development even at the molecular level, beginning to see how the brain connects and the role of both genetics and experience and how that happens across both prenatal and postnatal life.

Just in the last year, we have seen just—well, what I would call breakthrough technologies like CLARITY that give you the first transparent brain with the ability to look at three-dimensional neuroanatomy. We have got the imaging techniques that are giving us the most complete architecture of the developing brain. So this is really an extraordinary time. It is also extraordinary for the power of genomics, which is revolutionizing every area of medicine. Last—about 3 months ago, the American College of Medical Genetics and Genomics summarized where we are for autism. They concluded that, “Using current knowledge and technology, a thorough clinical genetics evaluation of patients with ASD is estimated to result in an identified etiology in 30 to 40 percent of individuals.” That's up from about 5 percent only 5 years ago. So there is incredible progress.

The good news is that both neuroscience and genomics together are actually helping us to begin to pinpoint where the environment must be taking its toll. And all of the evidence right now points to mid-gestation, second trimester. What the culprit is or the culprits, we still don't know. But it is because of those kinds of technologies and those kinds of approaches, just as any other area of medicine, we are getting those insights.

Just two other points to make before I finish. One is that there are some things unique to the autism field that I think really are helpful here. One is NDAR, National Database for Autism Research. It is a massive effort. We don't really have this in almost any other area except in parts of the cancer field. NDAR collects the data from over 70,000 subjects. Virtually every subject who is

enrolled in an NIH-funded research project, those data are standardized through a data dictionary and shared through the database so that they can be interrogated much more broadly by a wide community. Only in the last couple of months, we have seen the first fruits of that with people analyzing all of the imaging data from many of the different sources and coming up with some new insights. It is very exciting.

The last thing is the IACC, which is what we are here to talk about, and I will just leave my comments for later, but I think in spite of your concerns around whether this committee has done everything that it set out to do, there are some remarkable achievements, as was pointed out by your colleagues just 2 or 3 years ago, in another hearing in which this was used as a model of what could happen in other disease areas where we want to be able to coordinate research better. We have done that in the IACC. We have created some remarkable strategic efforts to show where the science should go, what we can do, and we have monitored that with great detail. So if you can find a better example, I would love to see it in the whole realm of biomedical research. But as far as I know and I have been involved with many, many different areas in my tenure at NIH, there is nothing quite like this. So I am delighted to answer your questions, talk more about each of these issues, but I did want to give you a sense of the excitement that we see from the scientific perspective.

Mr. MICA. Thank you, Dr. Insel.

[The statement of Dr. Insel follows:]

THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

Examining the Federal Response to Autism Spectrum Disorders

Witness before the
House Oversight and Government Reform
Subcommittee on Government Operations

Thomas R. Insel, M.D.
Director, National Institute of Mental Health

May 20, 2014

Introduction

Good morning Chairman Mica, Ranking Member Connolly, and distinguished Members of the Subcommittee. I am Dr. Tom Insel, Director of the National Institute of Mental Health (NIMH) at the National Institutes of Health (NIH). I have served as the Chair of the Interagency Autism Coordinating Committee (IACC), created by the Children's Health Act of 2000, re-established by the Combating Autism Act of 2006 (CAA), and reauthorized by the Combating Autism Reauthorization Act of 2011 (CARA), since my arrival at NIMH in 2002.

First, I'd like to thank you for the opportunity to share with you today some of the exciting progress we have seen since the passage of the CAA and the inception of the IACC. We at NIH are very grateful for the strong support that you in the Congress have always shown for NIH and the thousands of researchers around the country who are working to advance biomedical research in support of people living with a wide array of diseases, disorders and disabilities. As Chair of the IACC, I'd like to express the gratitude of all the Federal Agencies represented on the committee for your continued support for our efforts on autism spectrum disorder and related disabilities. I am here to provide an update on the Federal response to autism, including the work that has been done by the IACC to coordinate Federal activities and foster public-private collaboration, and to provide a snapshot of the considerable progress being made in autism research. More details on the specific programs and projects funded by the various Federal Agencies involved in the autism effort can be found in the recently submitted *Report to Congress on Activities Related to Autism Spectrum Disorder and Other Developmental Disabilities Under the Combating Autism Act of 2006 and Combating Autism Reauthorization Act of 2011 (FY2010-FY2012)*.

Background on Autism Spectrum Disorder (ASD)

Autism spectrum disorder (ASD – also referred to as “autism” interchangeably in this testimony) is a neurodevelopmental condition characterized by deficits in social interaction and social communication, along with restricted interests and repetitive behaviors— sometimes

accompanied by additional features such as intellectual disability or language impairments. With varying degrees of severity in these symptoms, autism is a heterogeneous condition that affects some with only mild impairments and others with profound disabilities. Like many other neurodevelopmental disorders, autism is thought to be caused by a combination of genetic and environmental factors—in this case, by genes and environmental factors that influence the development of the brain. Currently, there are only a small number of proven causes of ASD, including genetic mutations associated with several well-characterized genetic disorders such as Rett Syndrome, tuberous sclerosis and Fragile X, and other rare genetic syndromes. While each of these causative mutations is rare, the discovery of different rare mutations associated with ASD is increasing so quickly that in a recent report, the American College of Medical Genetics and Genomics (ACMG) strongly expressed their support for genetic testing to be routinely provided for individuals who have autism without a known cause, because currently available tests are likely to be able to identify a specific genetic mutation underlying autism symptoms in an estimated 30-40 percent of individuals. Identification of contributing gene mutations could result in benefits for the individual, including better targeted intervention strategies and awareness of additional health conditions for which he/she may carry an elevated risk.

Prevalence of ASD

The most recent report from the Centers for Disease Control and Prevention (CDC) estimates that one in 68 children (1.5 percent of eight-year-olds) in the United States has been identified with an ASD, which is an increase from the estimated prevalence of one in 88 (1.1 percent of eight-year-olds in 2008) reported in 2012. The data reported this year, for children who were eight years old in 2010, show that three major aspects of the picture of ASD have remained the same. First, ASD is almost five times more common among boys than girls – with one in 42 boys and one in 189 girls identified. Second, white children are more likely to be identified with ASD than black or Hispanic children. And third, most children with ASD are not diagnosed until after age four, even though ASD can be diagnosed as early as age two. Interestingly, this latest study emphasized an emerging trend. In the 2014 report, nearly half of children with an ASD were found to have average or above-average intellectual ability (an IQ of 85 and above) compared to only one third of children a decade ago. It could be that we are getting better at identifying these children, there could be a growing number of children with ASD and higher intellectual ability, or it may be a combination of the two.

Overall, does the upward trend in CDC prevalence estimates over the last several years represent a true increase in the number of children with ASD, or does it reflect more children with ASD being detected due to improvements in awareness, screening and other factors? The answer – it is possible that both contribute. Clearly, the numbers indicate that there is, and there will continue to be, an increasing need for services to address the wide variety of needs among children being diagnosed with ASD and progressing toward adulthood.

IACC Coordination Activities

As autism is a complex condition that impacts individuals and families across the lifespan and in all areas of their lives—including health, education, and service needs—a coordinated Federal response to address all of these areas is underway. The IACC was established by the Congress to coordinate efforts across multiple Federal departments and agencies as well as private organizations to support autism-related research and serve the autism community. The CAA outlines the membership of the IACC, composed of both Federal Agency officials and public members representing a variety of stakeholder groups within the autism community, including adults on the autism spectrum, family members of children and adults with ASD, leaders of national advocacy organizations, researchers, clinicians, educators, and other community providers. Participation of both Federal and public members on the IACC helps to ensure that a wide range of ideas and perspectives are represented in the committee’s deliberations.

The CAA charges the IACC with a number of tasks to facilitate coordination, such as developing and annually updating an interagency strategic plan for autism research, preparing an annual report summarizing the latest advances in autism research, monitoring and exchanging information about the wide array of autism-related activities being undertaken by Federal Agencies, providing a forum for public input on issues related to ASD, and providing advice to the Secretary of Health and Human Services (HHS) to help guide autism efforts. To fulfill this charge, the IACC released its first *Strategic Plan for ASD Research* in 2009, followed by annual updates that refined and expanded the original set of *Strategic Plan* objectives, and provided updates on progress that had occurred since the *Plan* was launched. Note that the IACC does not have a charge or a budget to implement research or services programs. As a Federal advisory

committee composed of Federal agency officials, private funders, and other community stakeholders, the role of the IACC is advisory in nature and is limited to coordination, monitoring, and providing advice to the Secretary of HHS regarding emerging issues and specific actions that may be warranted in order to better meet the needs of the community.

In 2013, the IACC undertook the most comprehensive review of the *Strategic Plan* to date, taking advantage of the extensive five-year portfolio analysis data collected by the Office of Autism Research Coordination (OARC) for the IACC. Detailed information available and accessible to the public through an online database about projects that have been funded, by both government and private funders on an annual basis, is vital for the autism field. Using portfolio analysis data, the IACC was able to provide a five-year accounting of the implementation of the *Plan*, tracking the number of projects funded and dollars committed toward each of the 78 individual objectives since the inception of the *Plan*. In this review, the committee found that, to varying degrees, progress has been made toward nearly all of the 78 objectives in the *Plan* in the past five years. Most of these objectives represent broad-based goals such as research on new diagnostic, therapeutic, or services approaches, requiring the support of multiple projects and the activity of multiple Federal and private funders.

In addition to the IACC's *Strategic Plan*, which has served as a guide for Federal Agencies and private partner organizations in planning their research activities, the committee has also been successful in fostering public-private partnerships to advance autism research and effect change in areas of critical need identified by the community. For example, in 2011, a mother of a child with autism from the Somali-American community in Minneapolis, Minnesota gave public comment at an IACC meeting, asking the committee to support research to understand if there might be a higher prevalence of autism in the Somali-American community in that city. The IACC responded to this community concern by fostering a collaboration between CDC, NIH, and the private autism organization, Autism Speaks to answer this question. The three groups collaboratively funded a project to examine the prevalence of autism among children of different ethnic groups in the Minneapolis area. Findings showed that, one in 32 Somali children in Minneapolis were identified as having ASD. This estimate is about the same as for White

children, but higher than for Black and Hispanic children in Minneapolis. Overall, the combined prevalence for the Minneapolis children was one in 48, which is higher than CDC's most recently published ASD prevalence estimate of one in 68. Somali children with ASD were also found to be more likely to have intellectual disability than children with ASD in all other racial and ethnic groups in Minneapolis (100 percent of the Somali-American children with ASD who had IQ records on file showed an intellectual disability in comparison to only 20-30 percent of children with ASD in other ethnic groups). The community in Minneapolis is now using these findings to make improvements for children and families.

Wandering behavior associated with ASD—the tendency for a child with ASD to wander away from a caregiver or safe place into an unsafe environment—has become a national issue in the autism community due to its often tragic outcomes, including accidental injuries and deaths. Children with ASD and other developmental disabilities are at higher risk of wandering away from caregivers and safe areas than are children without these conditions or with other cognitive disabilities. To address this issue, which also was first raised at the IACC through public comment, the IACC launched an effort to reduce the incidence of wandering-related injuries and fatalities by supporting the CDC to propose the adoption of a code intended to capture information about individuals, with any condition classified in the ICD, who wander. The intention was to provide a way to document and understand this behavior, and to support the development of approaches to reduce the risk of wandering-related injuries and fatalities. The measure was adopted and the code is now in use. Discussion at the IACC meeting also resulted in an IACC public member initiating coordination among private organizations to support a study to assess the prevalence as well as qualitative aspects of wandering behavior in the autism community using an established interactive virtual network (IAN – the Interactive Autism Network) of people with ASD and their families. The study, conducted within the short timeframe of a few months, resulted in the publication of an analytical report about the prevalence of autism-related wandering that helped raise awareness of the issue in the community and provided some initial figures to support the need for further research in this area. Many private organizations have mobilized to assist in efforts to raise awareness and provide tools and training to help keep children with ASD safe and to give needed support to families.

Research Highlights

With the coordination provided by the IACC and its *Strategic Plan*, NIH and other agencies within HHS and other Federal departments have been working collaboratively to tackle the challenges of supporting research on this profoundly complex condition. Investment in ASD research over the last decade has increased 90 percent to \$190 million in Fiscal Year 2014.

Some of the most important research investments related to ASD have not been specific to ASD but have created tools or resources for studying brain development, new insights about the immune system, or research on the microbiome that may transform ASD research. I'd like to share just a few examples of the scientific progress that has been made toward understanding autism and developing new clinical approaches over the past five years. This brief survey cannot do justice to the many areas, from immunology to social science, that are revealing new insights about ASD.

We're currently at a pivotal moment in the field of brain research as an explosion of new technologies enables scientists to analyze brain anatomy and function in ways that have never before been possible. At the same time, the world of autism research is also rapidly evolving. Since 2009, over 11,000 articles on autism research have been published in scientific journals—more than double the number published in the preceding five years. The increase in availability of large, shared data sets through venues such as the NIH's National Database for Autism Research (NDAR), which provides access to data from more than 70,000 research participants, with appropriate privacy protections, is enabling scientists around the globe to get involved in autism research. In fact, ASD research is on the cutting edge of data sharing in biomedical research as all NIH-funded scientists are expected to deposit clinical data in NDAR. This approach provides unprecedented transparency and access to accelerate scientific progress. And through the use of a global unique identifier (GUID) for each individual whose de-identified data is housed in the database, NDAR precludes duplication of data from a given individual who might be enrolled in multiple studies.

The technology advances that are revolutionizing neuroscience are rapidly being incorporated into the autism field, with the promise of greatly deepening our understanding of autism.

One ground-breaking new method developed by NIH-funded researchers, called CLARITY, takes intact postmortem human brain samples, donated with appropriate consent, and replaces the lipids (or fat) in the brain with a clear hydrogel, holding all of the brain structures in place, but making them transparent. Until now, access to deep brain structures could only be achieved by slicing the tissue into very thin sections, so cells and molecules were only studied in two dimensions. This new technique preserves the connections between neurons and between larger brain regions, enabling researchers to visualize actual brain structures in 3-D, down to the level of individual nerve fibers, neuronal cell bodies, their extensions, and even molecules. Applying CLARITY to a post-mortem brain sample taken from a person with autism revealed an unusual pattern of connectivity between neuronal structures. This technique will likely reveal a whole new level of information about connectivity in the autism brain, helping us to better understand the circuitry and neurochemistry underlying autism-related symptoms, and offering opportunities to develop novel interventions to enhance brain function.

Another project supported by the NIH that has had a recent and profound impact on autism research is the BrainSpan Atlas of the Developing Human Brain. This atlas provides a map of gene expression over the course of fetal and post-natal brain development. Two very recent studies examined groups of genes related to autism using this atlas. Previously, when studied in the context of the adult brain, these genes didn't appear to have anything in common except that they all were identified as genes that contribute to risk of developing autism. Researchers decided to examine the expression of these genes during development using the BrainSpan Atlas to find out whether they could discern any identifiable patterns – either spatial or temporal. Remarkably, when the gene expression patterns were studied in the developing brain using the database, these seemingly unrelated autism genes were revealed to have very important things in common; they were expressed in the same region of the brain at the same time, around the mid-point of fetal development. This reinforces the evidence that pregnancy/fetal development is a key window for the development of autism. Additional studies—such as a recent study from the

University of California at San Diego that found scattered patches of disorganized brain cells in the deep layers of the brain cortex in samples from children with autism—also converge on the second trimester of fetal development as a critical time-point in the development of autism, indicating that the origins of autism are present before birth.

If autism begins before birth, why are we making the diagnosis after age 3? A number of new scientific findings from prospective longitudinal studies are helping us make significant progress in the area of early identification. For example, NIH-funded researchers using eye-tracking technology determined that children who later go on to develop autism exhibit a distinct pattern of decline in eye contact with caregivers that is detectable between the ages of two to six months of age. In another study, in slightly older infants and toddlers with autism, from 14-42 months of age, the use of eye-tracking technology revealed pronounced differences in attention to social cues; when given a choice between watching a video of a friendly human face interacting with them versus one showing a moving geometric pattern, the children who eventually developed autism preferred to focus on the geometric pattern. Other studies have demonstrated that children who later develop autism show measurable differences in repetitive behaviors (such as hand flapping or rocking back and forth) and in visual attention to objects (“sticky attention” – in which children with ASD tend to stare at an object after picking up for a longer period of time than typically developing children) by the age of 12 months, as well as visible differences in the development and structure of the white matter tracts that connect different parts of the brain in infants at the age of six months. With these and other new findings, we hope that in the future it will be possible to design tests or biomarkers to help us identify children who are on the path to autism within the first year, opening the door to early interventions that can help reduce the severity of disabling symptoms.

Do we have effective early interventions? Recent studies have also begun to demonstrate that early behavioral interventions can have lasting positive effects. A randomized controlled trial of a treatment called Interpersonal Synchrony, in which a child is assisted in sharing both social actions and attention, showed that this technique enhances eye contact and social awareness, and that these skills can be applied to new situations. The fact that a child who receives this therapy

develops new social behaviors indicates that the brain is “plastic” or able to adapt and remodel itself to learn new skills and that behavioral therapy is actually changing the way that child’s brain processes social information. In another study, researchers evaluated children receiving the Early Start Denver Model therapy approach, or ESDM. ESDM focuses on social exchange, social attention, social engagement, and positive affect. Randomized trials have shown that this intervention results in significant improvement in IQ, language, and adaptive behaviors. Very compelling new evidence has also shown that this technique results in “normalized” patterns of brain activity, as measured by electroencephalography, and that these patterns correlate with improvement in behavioral outcomes. This suggests that ESDM is actually remodeling the brain to respond to social stimuli in a different way—perhaps by strengthening existing neuronal circuits or building new ones to compensate in areas where function is reduced—and this adaptation results in improved social behaviors.

Pharmacological treatments for autism are in earlier stages of development, but work has intensified in this area. In 2008, only six drug treatment clinical trials were underway. That number is now around 100. ASD is a relatively new area for clinical trials research. Working out the design and the appropriate outcome measures has been an ongoing discussion between NIH and FDA as well as with colleagues at Autism Speaks and scientists involved in ASD clinical trials in Europe. These discussions are helping us to improve trial design and ensure the highest rigor of science along with the best protection of participants. As the dialogue continues and ongoing clinical trials proceed, we expect to have more rapid progress on medications and other interventions for autism in the near future.

In order for a medical treatment to be effective, it must address the problem at hand. What we know as “autism” is really a collection of conditions, and the causes of autism are likely to differ from person to person. The ultimate goal for autism treatments is that they will soon be defined by biological indicators of the underlying cause, or biomarkers, which will help with both diagnosis and the development of effective treatments. Some of the remarkable findings we’ve already discussed have begun to define biomarkers of autism. Because of the potential for biomarkers to be such a powerful tool in efforts to identify autism early and address core

symptoms, several large national and international efforts to accelerate the discovery of autism biomarkers have been launched. The Foundation for the NIH manages the Biomarkers Consortium, which is a private-public partnership to identify and develop biomarkers to help prevent, diagnose, and treat a variety of conditions such as autism. The Biomarkers Consortium has organized a targeted search for and refinement of biomarkers for ASD, which will unite funding agencies, academic researchers, and pharmaceutical companies. The Consortium is also working with international partners from European Autism Interventions - A Multicentre Study for Developing New Medications, which is the largest single grant for autism in the world at over \$38 million, to focus discovery of autism biomarkers with the ultimate goal of creating effective and personalized treatments for autism.

NIH continues to support its Autism Centers of Excellence (ACE) program, which was expanded under the Combating Autism Act. The ACE program is composed of both individual research centers at a single institution and networks of research teams at different institutions working together to solve a common scientific problem. The ACEs are designed to conduct intensive and coordinated research programs into the causes of ASD and to develop and disseminate new interventions and treatments. In 2012, NIH made nine new ACE awards—three centers and six networks—to be funded over five years. In 2013, two additional networks were awarded. The newly awarded ACEs will address a variety of critical research areas, such as using brain imaging technology to chart brain development of children at risk for ASD; identifying potential environmental and familial factors that may confer autism risk; investigating sex differences in ASD; evaluating the effectiveness of widely-used treatments to improve social interaction and communication, including exploring mechanisms of verbal communication and new interventions for minimally verbal children with ASD; and developing effective in-school and at-home interventions for children with ASD.

Finally, I'd like to share an update on services research. Recent studies in this arena, as well as the most recent *IACC Strategic Plan Update*, have highlighted areas of significant services needs for people all across the spectrum, including the need for transition services and adult services that can provide much-needed supports once an individual ages out of the educational system.

Research has suggested that people with ASD are often under-employed due to difficulties in obtaining and maintaining meaningful employment, as well as due to income limits prescribed for those who receive Social Security Disability Insurance benefits. Health disparities and lack of adequate independent living opportunities for people on the autism spectrum are two other common themes in autism services research.

While services research is not the primary focus of the NIH mission, NIH does support a small number of autism services research grants, and recently launched a series of three initiatives to support research on services implementation across the lifespan, with the goals of addressing the challenges of improving outcomes for children, adolescents, and adults. The first initiative targets models for coordination of ASD identification, evaluation, and early intervention services for children with ASD within the first two years of life, including tests of the feasibility and effectiveness of interventions across settings. The second focuses on models to assist adolescents with ASD to transition to adult supports and services while preventing lapses in services and supports. The third addresses development of adult ASD service strategies that concern areas of employment and training, social relationships, physical and mental health, and independent functioning, including community housing and safety, alone or in combination, with the ultimate goal of improving behavioral, functional, and health outcomes. Awards for all three initiatives are expected in 2014.

Conclusion

As you can tell from this brief update, we have made a great deal of research progress since the enactment of the CAA in late 2006, fueled by increasing investments from the NIH annual appropriation each year and \$122 million from the American Recovery and Reinvestment Act of 2009 into the autism research effort in 2009 and 2010, shortly after the release of the original *IACC Strategic Plan*. Since reconstituting the IACC under the CAA in 2006, the committee has become an important focal point for Federal coordination and public input on Government autism activities. It has done this by holding frequent public meetings, providing data to the public via its website and publicly accessible Federal-private research project database, and regularly publishing detailed reports regarding Federal activities and research progress related to

the implementation of the *IACC Strategic Plan*. In addition, the NIH's internal Autism Coordinating Committee has played an important role in helping NIH institutes coordinate their efforts to ensure that areas of the *IACC Strategic Plan* that fall within the NIH mission are being covered, and to foster cross-institute collaborations and prevent duplicative efforts.

As a result of this investment in autism research and our intensive efforts to coordinate and to foster collaboration, over the past few years we have seen remarkable progress in autism research. We have made tremendous advances in our understanding of how autism unfolds during the course of early development, in the identification of factors that may be contributing to increased or decreased risk for autism, and in developing and testing new screening/diagnostic tools, treatments and interventions, and services approaches that can be used in a variety of populations and community settings.

With the availability of unprecedented tools and technologies, we are poised to make significant scientific discoveries that can be translated into the next generation of tools and services to improve the quality of life for people on the autism spectrum. With several promising early results, there is also a need for more replication to validate research findings. Continued focus on coordination and collaboration with external partners will be essential to help us achieve the objectives in the *IACC Strategic Plan*. With sustained support and continued public-private collaboration, the IACC and its members can continue to work steadily toward the eventual collective community goal.

I thank you for this opportunity to speak with you and look forward to addressing any questions that you may have.

Thomas R. Insel, M.D.
Director, National Institute of Mental Health

Thomas R. Insel, M.D., is Director of the National Institute of Mental Health (NIMH), the component of the National Institutes of Health charged with generating the knowledge needed to understand, treat, and prevent mental disorders. His tenure at NIMH has been distinguished by groundbreaking findings in the areas of practical clinical trials, autism research, and the role of genetics in mental illnesses. NIMH has a large autism research program, covering a wide variety of topics, from molecular mechanisms to research on services. The program emphasizes studies that will lead to improved and earlier diagnosis and the development of improved treatments. In addition to directing the NIMH, Dr. Insel chairs the Interagency Autism Coordinating Committee, a federal advisory committee appointed by the Secretary of Health and Human Services that provides advice and coordination to the federal autism research effort (since 2002). He has also served as Co-Chair for the NIH Blueprint for Neuroscience Research (since 2004) and the Acting Director of the NIH National Center for Advancing Translational Sciences (NCATS) (2011-2012). Currently, Dr. Insel is one of the leaders for the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) effort, a Presidential Initiative focused on developing new tools for understanding the brain.

Prior to his appointment as NIMH Director in the Fall 2002, Dr. Insel was Professor of Psychiatry at Emory University. There, he was founding director of the Center for Behavioral Neuroscience, one of the largest science and technology centers funded by the National Science Foundation and, concurrently, director of an NIH-funded Center for Autism Research. From 1994 to 1999, he was Director of the Yerkes Regional Primate Research Center in Atlanta. While at Emory, Dr. Insel continued the line of research he had initiated at NIMH studying the neurobiology of complex social behaviors. He has published over 250 scientific articles and four books, including the *Neurobiology of Parental Care* (with Michael Numan) in 2003.

Dr. Insel has served on numerous academic, scientific, and professional committees and boards. He is a member of the Institute of Medicine, a fellow of the American College of Neuropsychopharmacology, and is a recipient of several awards including the Outstanding Service Award from the U.S. Public Health Service. Dr. Insel graduated from the combined B.A.-M.D. program at Boston University in 1974. He did his internship at Berkshire Medical Center, Pittsfield, Massachusetts, and his residency at the Langley Porter Neuropsychiatric Institute at the University of California, San Francisco.

Mr. MICA. We will get back to questions, but we are going to recognize next Mr. Michael Yudin, and he is the acting assistant secretary for the Department of Education's Office of Special Education and Rehabilitative Services.

Welcome sir, and you are recognized.

STATEMENT OF MICHAEL K. YUDIN

Mr. YUDIN. Great. Thank you, good morning Chairman Mica, Ranking Member Connolly, Mr. Posey, members of the subcommittee. I appreciate the opportunity to speak with you today about the role of the Department of Education in providing supports and services to individuals with autism spectrum disorder.

The Department supports a wide range of activities in improving our knowledge of ASD, methods of instruction, vocational rehabilitation services, and the skills and qualifications of educators and service providers to ensure that individuals with autism, as well as all individuals with disabilities, enjoy equal opportunity, full community participation, independent living, and economic self-sufficiency.

The Department's primary role in supporting services to individuals with autism is through our funding administration and monitoring of the Individuals With Disabilities Education Act, or IDEA. When Congress reauthorized IDEA in 2004, it explicitly included autism in the definition of a child with a disability. My goal is to give you some more information about the kinds of autism supports and services that we are providing students and their families, to teachers, and the broader community under the provisions of IDEA.

So, as you know, IDEA serves a very broad range of disabilities and severity in order to ensure that their needs are met and that children are indeed successful. All children with disabilities receiving services under IDEA have an Individualized Education Program, or an IEP, which is developed by a team of stakeholders which must include the student's parents.

More than 30 years of research shows us that students with disabilities do better when they are held to high expectations and have access to the general curriculum. Today, a majority of students with disabilities spend most of their time in regular education settings. Therefore, we must ensure that both general education, general educators and special educators have the proper training and tools to provide evidence-based instruction so that students with disabilities have the opportunity to succeed in the general curriculum. IEPs must identify the necessary supports, accommodations, and related services for particular students with disabilities to succeed in the general curriculum, including speech, psychological or counseling services, occupational behavioral therapy, or the school health services that are particularly important to students with autism.

For older students, IEPs will also include transition services to ensure they are prepared for life after high school. It is particularly important to have students themselves participate in this transition planning, and to learn the self-advocacy skills that are necessary for students once they leave high school to fully participate,

meaningfully participate in their communities, enjoy competitive and gainful integrated employment.

For our youngest children, part C of IDEA, provides support for screening and early intervention services for children from birth through age 2 who have or may have disabilities or delays.

Mr. Connolly, you noted earlier that early screening is absolutely critical to early identification, and access to services and supports which can enhance children's learning and development, minimize developmental delays, and result in more positive outcomes in school and in life.

The Department also supports children with autism through the training of teachers, and related service personnel, providing support for technology development, assisting schools, districts, and States to identify, adapt, and sustain effective school-wide positive behavior interventions and supports, and helping parents and families access the necessary information and the tools to support their children's education.

The Department also plays a role in supporting adults with significant disabilities, including ASD, through the Vocational Rehabilitation Program. Through this program, State VR agencies, vocational rehabilitation agencies, provide a wide range of services designed to help persons with disabilities prepare for and engage in competitive integrated employment. Importantly, 35 percent of VR consumers of VOC rehab consumers are youth with disabilities. So, accordingly, the VR program works with schools to provide youth with critical transition services to ensure that they have the education and the skills to be successful in postsecondary education and employment. We know that individuals with ASD who participate in VR programs can be successful and enjoy higher rates of employment.

As I wrap up my testimony, I want to briefly mention our research efforts around autism. It is important to note that our research entities do not conduct biomedical or medical research. First, the Institute of Educational Sciences supports research on the development, implementation, and evaluation of interventions that are intended to improve education outcomes for students with ASD. We know that there are communication and social deficits associated with ASD, but we also know that kids do better in these areas when they have access to nondisabled peer models. Projects include interventions that target social and communication skill impairments that are core functions—that are core features of ASD; transition support for children entering preschool and for adolescents leaving high school; assistance for families and teachers working with children with ASD; and the development and testing of technology applications to support learning of students with autism.

And second, the National Institute on Disability and Rehab Research, otherwise known as NIDRR, supports research and related activities that generate new knowledge and promote its effective use to improve the outcomes of people with disabilities in the areas of community living, employment, and health, and functioning. Thank you so much for the opportunity to testify today. I'm happy to take any questions that you have.

Mr. MICA. Thank you, and we will get to them shortly.

[The statement of Mr. Yudin follows:]

TESTIMONY OF MICHAEL YUDIN, ACTING ASSISTANT SECRETARY
OFFICE OF SPECIAL EDUCATION AND REHABILITATIVE SERVICES (OSERS)
U.S. DEPARTMENT OF EDUCATION

Before the
House Oversight and Government Reform Committee, Subcommittee on Government
Operations

On

"Examining the Federal Response to Autism Spectrum Disorder"

May 20, 2014

Chairman Mica, Ranking Member Connolly, and Members of the Committee, thank you for the opportunity to provide you with information on the role of the Department of Education in providing services and supports to individuals with autism spectrum disorder (ASD), and other activities directed at improving our knowledge of ASD, methods of instruction, vocational rehabilitation services, and the skills and qualifications of persons who provide educational and other services.

Background

The medical categorization of autism and autism-related conditions was recently modified by the American Psychiatric Association (APA) in their revised Diagnostic and Statistical Manual (DSM-5). In the new DSM-5, the APA has combined multiple autism and autism-related categories and their diagnostic criteria from the DSM IV into one broader category of autism spectrum disorder. For the purpose of my statement today, when describing programs administered by the Department, please consider autism and ASD to refer to the same diagnostic category.

Individuals with Disabilities Education Act (IDEA)

The Department's primary role in supporting services to individuals with autism is through our funding, administration, and monitoring of special education programs under the IDEA. Autism is among the disabilities specifically enumerated in IDEA for defining a child with a disability.

Under Part B of the IDEA, all eligible children with disabilities are entitled to a free appropriate public education in the least restrictive environment possible. As you know, children with autism often have complex needs and require intensive supports. In order to ensure that their needs are met, all children with disabilities receiving services under Part B of the IDEA have an individualized education program (IEP), developed by a team of stakeholders, which must

include their parents. In students' IEPs, the team includes an assessment of the individual strengths and needs of the student, appropriate goals for the student, and the necessary supports and accommodations for that student to be successful.

Given that the majority of students with disabilities spend most of their time in regular education settings, identifying the necessary supports and accommodations for those students and ensuring that teachers have the proper training to implement those supports and accommodations is critical. IEPs may also identify related services for particular students with disabilities, including speech language pathology, psychological services, counseling, occupational therapy, or school health services that may be particularly important to students with autism.

For older students, IEPs will also include transition services. While these services are important for all students with disabilities, they are especially important for students with autism, who may experience greater difficulties in community living and obtaining competitive employment.

In addition to the services offered under Part B of the IDEA for children ages 3 through 21, Part C provides support for screening and early intervention services for children from birth through age 2 who have or may have disabilities or health problems, or a developmental delay. Early screening is critical to earlier identification of developmental concerns and access to services and supports, which can enhance children's learning and development, minimize developmental delays and disorders, and result in more positive outcomes in school and life.

Under Part C, families and teams of service providers develop individualized family service plans (IFSPs) that outline the necessary supports for children and their families. Services provided in conjunction with IFSPs under Part C are a valuable resource for parents, families, and children in helping identify children who may have autism and providing these children and their families with the early supports they need.

The Departments of Education and Health and Human Services recently partnered to launch Birth To 5: Watch Me Thrive! This initiative is a coordinated effort to encourage developmental and behavioral screening and support for children, families, and the providers who serve them.

The initiative includes: 1) a compendium of research-based screening tools that meet specific validity and reliability criteria; 2) User's Guides, designed for providers from multiple sectors that describe the importance of developmental and behavioral screening, how to talk to parents, how to select the most appropriate screening tool for the population served, and where to refer a child for services if a developmental concern exists; and 3) resources on general early child development and strategies to support children with developmental delays or disabilities.

Under the IDEA Part D programs, the Department also supports children with autism through training teachers and related services personnel, providing support for technology development, providing technical assistance to providers, and helping parents and families

access necessary information about the IDEA, their child's diagnosis, and how to navigate the educational system.

Grant Programs

From 2009 to 2013, the Department of Education funded 50 grants that focused on preparing personnel to support children with autism. Forty-one of those grants supported the training of individuals who will provide direct services to children with autism, such as speech-language pathologists, behavior specialists, school psychologists, and special education teachers. In total, during those five years, this program supported the training of approximately 2,700 personnel in providing services to children with autism. Nine other grants supported the training of educational leaders and faculty at the doctoral level. The 70 scholars supported under these grants will conduct research on autism and best practices and provide leadership at the local and State levels in supporting students with autism.

For faculty and staff already in service, the Department supports grants under the State Personnel Development Grant (SPDG) program to address state identified professional development needs. Currently, three states have identified a professional development need related to children with autism. Specifically, these grants focus on: (1) inclusion of children with autism in the general education environment; (2) literacy and behavior; and (3) early intervention and elementary education service providers.

Nationwide, the Department also supports over 110 parent centers that provide training and assistance to families of children with disabilities, including children with autism. Parent Centers provide a variety of services including one-to-one support and assistance, workshops, and publications. Centers in each state are also typically familiar with state and local autism resources, service providers, LEA-specific educational practices, and support groups.

The Department-funded National Professional Development Center on Autism Spectrum Disorders (NPDC) has over the last six years, provided resources, professional development, and technical assistance to help address state-identified needs for personnel in special education, related services, early intervention, and regular education. The Center helps personnel that work with infants, toddlers, and children with autism; and ensure that those personnel have the necessary skills and knowledge, derived from practices that have been determined through scientifically based research and experience, to be successful in serving children with autism and their families.

The IDEA Partnership has also developed the Autism Spectrum Disorder Toolkit, which contains materials and resources to assist individuals, organizations, and other stakeholders in understanding Autism Spectrum Disorder and implementing appropriate interventions and supports for individuals with autism.

The Center on Positive Behavioral Interventions and Supports (PBIS) gives schools, school districts, and States capacity-building information and technical assistance on identifying,

adapting, and sustaining effective school-wide disciplinary practices and provides resources on how to address and reduce challenging behavior.

Data from the Office of Civil Rights show that students with disabilities are more than twice as likely to receive an out-of-school suspension as their non-disabled peers and we know that students with autism may be at increased risk of bullying and harassment or may present behavioral problems of their own, often connected with communications difficulties or problems reading or processing social cues and responses from other students.

The PBIS framework provides a school-wide approach that has been shown to have success in reducing the incidence of these problems. Additionally, the Department has issued guidance to States in the form of Dear Colleague letters, most recently on August 20, 2013¹, to ensure all school districts provide all children with positive, safe, and nurturing school environments in which they can learn, develop, and participate.

Vocational Rehabilitation (VR)

Programs authorized under the Vocational Rehabilitation Act also play a role in assisting individuals with ASD. The Department's VR State Grants program supports VR services to individuals with disabilities, including eligible individuals with ASD, through formula grants to State VR agencies. These agencies provide a wide range of services designed to help persons with disabilities prepare for and engage in gainful employment.

The VR State Grants program is a required partner in the one-stop service delivery systems under section 121 of the Workforce Investment Act (WIA). Program services are tailored to the specific needs of the individual through an individualized plan for employment (IPE). The program may provide a variety of services, such as vocational evaluation, counseling, mental and physical restoration, education, vocational training, job placement, rehabilitation technology, and supported employment services. Priority is given to serving individuals with the most significant disabilities. Autism is identified in the Rehabilitation Act as a significant disability. Thus individuals with autism and other significant disabilities receive priority for services if a VR agency must implement an "order of selection" due to resource constraints.

In FY 2013, State VR agencies reported that slightly over 10,000 of the 341,000 individuals whose service records were closed that year after receiving services had a primary or secondary impairment as a result of autism, 57 percent of whom obtained an employment outcome. As compared to all individuals served by the VR program, individuals with autism are slightly more successful in obtaining employment as compared to the employment outcome rate of 53.6 percent for all individuals.

¹ <https://www2.ed.gov/policy/speced/guid/idea/memosdcltrs/bullyingdcl-8-20-13.pdf>

Individuals with ASD are also provided assistance through protection and advocacy and client assistance programs authorized by the Rehabilitation Act and administered by the Department. Activities conducted under the Protection and Advocacy of Individual Rights program include support of State protection and advocacy systems to protect the legal and human rights of individuals with disabilities of all ages through individual advocacy and legal representation, as well as systemic advocacy designed to bring about changes in policies and practices for the benefit of groups of individuals with disabilities.

Research

The Institute of Education Sciences (IES) is the primary education research arm within the Department. Within IES, the National Center for Special Education Research (NCSE) supports research on the development, implementation, and evaluation of interventions that are intended to improve education outcomes for students with ASD. NCSE has funded roughly 35 research projects focused on children with ASD. Projects funded by NCSE include interventions that target social and communication skill impairments that are core features of ASD, transition support for children entering preschool and for adolescents leaving high school, assistance for families and teachers working with children with ASD, and the development and testing of technology applications to support learning of students with autism.

The National Institute on Disability and Rehabilitation Research (NIDRR) is a component of the Office of Special Education and Rehabilitative Services in the Department of Education. NIDRR supports research and related activities that generate new knowledge and promote its effective use to improve the outcomes of people with disabilities in the areas of community living, employment, and health and functioning.

In the last few years, NIDRR has funded 10 grants that focused on issues related to autism spectrum disorder, including several grants to identify methods of facilitating the transition of youth and young adults with autism to employment or post-secondary education. NIDRR's funding has also supported several awards that examine how technology (such as online instruction) can be used to help individuals with autism live successfully in the community. NIDRR has a strong programmatic interest in community integration which is particularly important to individuals with autism and their families.

Neither IES nor NIDRR conduct strictly medical or biomedical research on autism.

Interagency Collaboration

The Office of Special Education and Rehabilitative Services (OSERS) represents the Department of Education on the Interagency Autism Coordinating Committee (IACC), authorized by the Combatting Autism Act. Through this Committee Federal agencies share information on their autism research to advance our body of knowledge and avoid the potential for unnecessary duplication of research.

Conclusion

I appreciate the opportunity to share with you a summary of the Department of Education's activities with respect to autism. I would be pleased to respond if you have any questions.

Biography of Michael K. Yudin

Acting Assistant Secretary for Special Education and Rehabilitative Services

Michael K. Yudin is currently the Acting Assistant Secretary for the Office of Special Education and Rehabilitative Services (OSERS) at the U.S. Department of Education. He serves as the principal adviser to the Secretary on matters related to the education of children and youth with disabilities, as well as employment and community living for youth and adults with disabilities. The mission of his office is to provide leadership to achieve full integration and participation in society of people with disabilities by promoting inclusion, ensuring equity, and creating opportunities for people with disabilities.

Yudin also served as Principal Deputy Assistant Secretary for the Office of Elementary and Secondary Education (OESE). In this role, he helped lead the formulation and development of policy designed to promote academic excellence and ensure equitable opportunities for educationally disadvantaged students in K-12 education. Yudin served as Acting Assistant Secretary for Elementary and Secondary Education from June 2011 to May 2012.

Prior to joining the Department, Yudin spent nine years in the United States Senate, serving as legislative director for Senator Jeanne Shaheen of New Hampshire, senior counsel to Senator Jeff Bingaman of New Mexico, and HELP Committee counsel to Senator Jim Jeffords of Vermont. In these roles, he assisted in developing, promoting, and advancing a comprehensive legislative agenda related to education, children and families, disabilities, and poverty. Working for senior Members of the HELP Committee, Yudin helped draft, negotiate, and pass various pieces of legislation, including the *No Child Left Behind Act*, and *IDEA 2004*. He also worked on the reauthorizations of the *Rehabilitation Act of 1973*, *Head Start*, the *Carl D. Perkins Vocational and Technical Education Act of 2006*, and the *Higher Education Act*.

Before joining the Senate, Yudin served as an attorney at the Social Security Administration and at the U.S. Department of Labor for nearly ten years. In these positions, he provided legal advice on various policy initiatives, including social security, disability, employment, and welfare reform. He also served as director of employment policy for two leading national disability organizations: the ARC of the United States and United Cerebral Palsy (UCP).

Mr. MICA. We will now recognize Marcia Crosse, and she is the health care director for the U.S. Government Accountability Office. Welcome and you are recognized.

STATEMENT OF MARCIA CROSSE, PH.D.

Ms. CROSSE. Thank you, Chairman Michael—Mica, Ranking Member Connolly, Mr. Posey, and members of the subcommittee. I'm pleased to be here today as you examine the Federal Government's response to autism spectrum disorders. My remarks today are based on GAO's November 2013 report on Federal autism activities and reflect information we included in our April 2014 report on overlap and duplication in Federal programs. And I request that my full written statement be entered into the record.

Mr. MICA. Without objection, so ordered.

Ms. CROSSE. Thank you. From fiscal year 2008 through 2012, 12 Federal agencies awarded at least \$1.4 billion to support autism research and other autism-related activities. Funding multiple studies in the same research area can be appropriate and necessary, for example, for purposes of replicating or corroborating prior research results. And multiple agencies can provide a variety of expertise. However, the involvement of multiple agencies can also make it challenging to identify gaps and efficiently allocate resources across the Federal Government.

The Combating Autism Act directed the Interagency Autism Coordinating Committee, or IACC, to coordinate HHS autism activities and monitor all Federal autism activities. The Combating Autism Act also required the IACC to develop and annually update a strategic plan for autism research. This plan is organized into 7 research areas that encompass a total of 78 specific objectives.

We identified over 1,200 autism research projects funded by Federal agencies in the 5-year period we examined. We found that 84 percent of these projects had the potential to be duplicative because they focused on the same objectives in IACC's strategic plan as other projects. That is, each of the agencies funded research in areas that were also funded by other agencies. For example, for one of the 78 research objectives, there were five agencies funding 20 separate autism research projects. Having multiple projects related to one objective does not necessarily mean that there is duplication. However, given that all of the projects on an objective share a common purpose, this raises the possibility that one or more projects were duplicative.

The IACC performs a valuable role in monitoring Federal autism activities and coordinating the activities sponsored by HHS. However, we believe that the IACC and Federal agencies may have missed opportunities to coordinate and reduce the risk of duplicating efforts and resources. We found that the IACC was hindered by limitations in the data it had collected. The data were outdated, inconsistent, incomplete, and not tracked over time. Our analysis across multiple years found that some objectives had more autism research projects funded than were suggested in the strategic plan, whereas other objectives were not funded by any agency, raising the potential for unrecognized gaps.

In our November report, we recommended that HHS improve IACC data to enhance coordination and monitoring. HHS disagreed

and stated its efforts were already adequate. However, we note that the updated strategic plan that IACC released last month includes multiyear data on research projects and funding which we believe will assist the committee.

Lastly, we found that, apart from Federal agencies' participation in the IACC, there were limited instances of agency coordination and monitoring. Some agencies lacked formal policies or procedures for checking research funded by other agencies or for identifying if agencies were funding similar projects led by different investigators. We recommended in our November report that the agencies improve their coordination. The agencies supported improved coordination, but most disputed that duplication occurs. We agree that more information on the specific projects funded within each objective would need to be assessed in order to determine actual duplication. However, neither the agencies nor the IACC has undertaken such a review.

In summary, we continue to believe the recommendations we have made are warranted and actions are needed. As established in GAO's recent duplication work, it is important for agencies that fund research on topics of common interest, such as autism, to monitor each other's activities to minimize the potential for the inefficient use of Federal resources.

Mr. Chairman, this completes my prepared remarks. I would be happy to respond to any questions you or members of the subcommittee may have.

[The statement of Ms. Crosse follows:]

United States Government Accountability Office



Testimony
Before the Subcommittee on
Government Operations, Committee on
Oversight and Government Reform,
House of Representatives

For Release on Delivery
Expected at 9:00 a.m. ET
Tuesday, May 20, 2014

FEDERAL AUTISM ACTIVITIES

Funding and Coordination Efforts

Statement of Marcia Crosse
Director, Health Care

GAO Highlights

Highlights of GAO-14-613T, a testimony before the Subcommittee on Government Operations, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Autism—a developmental disorder involving communication and social impairment—is an important public health concern. From fiscal years 2008 through 2012, 12 federal agencies awarded at least \$1.4 billion to support autism research and other autism-related activities. The Combating Autism Act directed the IACC to coordinate HHS autism activities and monitor all federal autism activities. It also required the IACC to develop and annually update a strategic plan for autism research. This plan is organized into 7 research areas that contain specific objectives.

This statement is based on GAO's November 2013 report, GAO-14-16, with selected updates. It discusses federal autism activities, including (1) the extent to which federal agencies fund potentially duplicative autism research, and (2) the extent to which IACC and agencies coordinate and monitor federal autism activities. GAO analyzed agencies' data and documents, and interviewed federal agency officials.

What GAO Recommends

GAO recommended in November 2013 that HHS improve IACC data to enhance coordination and monitoring. HHS disagreed and stated its efforts were already adequate. GAO also recommended that DOD, Education, HHS, and NSF improve coordination. The agencies supported improved coordination, but most disputed that duplication occurs. GAO continues to believe the recommendations are warranted and actions needed.

View GAO-14-613T. For more information, contact Marcia Crosse at (202) 512-7114 or crossm@gao.gov.

May 20, 2014

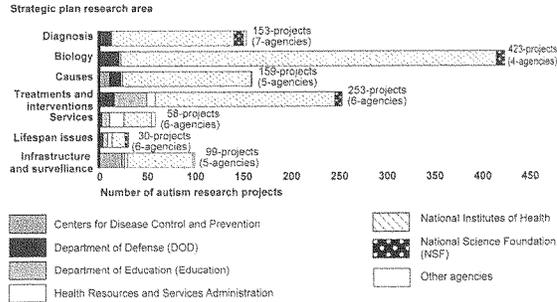
FEDERAL AUTISM ACTIVITIES

Funding and Coordination Efforts

What GAO Found

Eighty-four percent of the autism research projects funded by federal agencies had the potential to be duplicative. Of the 1,206 autism research projects funded by federal agencies from fiscal years 2008 through 2012, 1,018 projects were potentially duplicative because the projects were categorized to the same objectives in the Interagency Autism Coordinating Committee's (IACC) strategic plan. Funding similar research on the same topic is sometimes appropriate—for example, for purposes of replicating or corroborating results—but in other instances funding similar research may lead to unnecessary duplication. Each agency funded at least 1 autism research project in the same strategic plan objective as another agency and at least 4 agencies funded autism research in the same research area.

Number of Federal Agencies' Autism Research Projects Funded, by Research Area, Fiscal Years 2008 through 2012



Source: GAO analysis of data from the Interagency Autism Coordinating Committee (IACC) and federal agencies that funded autism research.

Note: Thirty-one of the 1,206 projects funded by federal agencies from fiscal years 2008 through 2012 are not included in this figure because they were not categorized to a specific research area. At the time of GAO's review, DOD had not submitted data on its fiscal year 2012 research projects, and therefore they were not included in this figure. The "other agencies" are: Administration for Children and Families, Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Environmental Protection Agency, and the Substance Abuse and Mental Health Services Administration. Not all of these "other agencies" necessarily funded projects in every research area.

The IACC and federal agencies may have missed opportunities to coordinate and reduce the risk of duplicating effort and resources. GAO found that the IACC is not focused on the prevention of duplication, and its efforts to coordinate the Department of Health and Human Services' (HHS) autism research and monitor all federal autism activities were hindered by limitations with the data it collects. Apart from federal agencies' participation on the IACC, there were limited instances of agency coordination, and the agencies did not have robust or routine procedures for monitoring federal autism activities.

Chairman Mica, Ranking Member Connolly, and Members of the Subcommittee:

I am pleased to be here to discuss our recent work examining federally funded autism activities. Autism is a complex developmental disorder that begins during early childhood, characterized by impaired social interactions, problems with verbal and nonverbal communication, and repetitive behaviors, or by severely limited activities and interests.¹ The most recent estimates from the Centers for Disease Control and Prevention (CDC) indicate that at least 1 in 68 children in the United States have been identified as having autism. There is no single known cause of autism and there is no known cure. However, research shows that early intervention and treatment services can greatly improve a child's development.

A variety of federal agencies are involved in responding to this important public health concern. From fiscal year 2008 through fiscal year 2012, 12 federal agencies spent a combined total of approximately \$1.4 billion on autism activities: \$1.2 billion on autism research, such as research to identify the causes of autism, and \$200 million on other autism-related activities, such as training to help health care professionals better identify and diagnose autism.² Most of these 12 agencies are members of the Interagency Autism Coordinating Committee (IACC). The IACC is a federal advisory committee composed of federal and nonfederal members.³ The Combating Autism Act of 2006 (CAA) required the IACC to coordinate all autism activities within the Department of Health and

¹What is commonly known as autism is a group of disorders known as autism spectrum disorder that can range from mild to more severe in their symptoms. In this statement, the term "autism" is used to refer to autism spectrum disorder.

²The 12 agencies are the Department of Defense (DOD); Department of Education (Education); Environmental Protection Agency (EPA); National Science Foundation (NSF); and 8 agencies within the Department of Health and Human Services—Administration for Children and Families (ACF), Administration for Community Living (ACL), Agency for Healthcare Research and Quality (AHRQ), CDC, Centers for Medicare & Medicaid Services (CMS), Health Resources and Services Administration (HRSA), National Institutes of Health (NIH), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

³Federal members of the IACC are from DOD, Education, ACF, ACL, AHRQ, CDC, CMS, HRSA, NIH, and the Food and Drug Administration. The IACC nonfederal members represent individuals with autism and parents of children with autism; as well as members of the autism advocacy, research, and service-provider communities.

Human Services (HHS) and monitor federal activities related to autism across the federal government.⁴ To fulfill these requirements, the IACC holds meetings and has issued several reports including a strategic plan for autism research, which the CAA requires the IACC to develop and annually update. The strategic plan is organized into seven research areas with specific short- and long-term research objectives, and contains a total of 78 objectives.⁵ The IACC also issues an annual Autism Spectrum Disorder Research Portfolio Analysis Report. This report is organized by the same seven research areas and includes information on research projects funded by federal and nonfederal entities related to autism, including budget information, for a single fiscal year.⁶ The National Institutes of Health (NIH)—an agency within HHS—created the Office of Autism Research Coordination (OARC) to provide administrative support to the IACC. On behalf of the IACC, OARC periodically collects data from agencies on the autism research projects they fund, helps agencies categorize this research to the specific strategic plan objectives, and prepares the portfolio analysis, which includes this data.

Having multiple agencies fund research in the same area can be appropriate and necessary—for example, for purposes of replicating or corroborating prior research results. It can also be advantageous to be able to draw on different expertise found in multiple agencies. One such advantage is that agencies may be better able to tailor research or other programs to suit their specific missions and needs. However, the involvement of multiple agencies can also make it challenging to identify gaps and efficiently allocate resources across the federal government.

My remarks today will focus on two areas: (1) the extent to which federal agencies fund potentially duplicative autism research and other autism-related activities, and (2) the extent to which the IACC and agencies coordinate and monitor federal autism activities. My remarks are based

⁴Pub. L. No. 109-416, § 3, 120 Stat. 2821, 2827 (2006). The IACC and other autism activities authorized under the CAA were reauthorized through fiscal year 2014 under the Combating Autism Reauthorization Act of 2011. Pub. L. No. 112-32, 125 Stat. 361 (2011).

⁵The seven research areas are diagnosis, biology, causes, treatment and interventions, services, lifespan issues, and infrastructure and surveillance.

⁶At the time we did our work, the most recent portfolio analysis was published in July 2012 and contained information on research funded in 2010. The IACC also has a companion database to its portfolio analysis, which allows users to view and search projects included in the portfolio analysis.

primarily on our report, released in November 2013, entitled *Federal Autism Activities: Better Data and More Coordination Needed to Help Avoid the Potential for Unnecessary Duplication*.⁷ For this report, we collected data on the research federal agencies funded, including funding amounts, from fiscal years 2008 to 2012 through database searches, review of related documentation, interviews, as well as through the use of data that agencies submitted to OARC.⁸ To determine potential duplication in autism research, we identified research projects that were categorized to the same strategic plan objectives. For projects that were not categorized to a specific objective, but were categorized to one of the seven research areas, we assessed duplication based on whether they were categorized to the same research area. Determining that projects were categorized to the same strategic plan objective or research area suggests potential—but not actual—duplication. Determining actual duplication for research projects would require a more extensive review and was beyond the scope of our study. Additionally, we collected data on non-research activities funded by federal agencies from fiscal years 2008 through 2011, and assessed whether there was actual duplication of these activities using the framework we established in our previous work. This framework considers duplication to have occurred when two or more agencies fund the same activities that target the same users.⁹

To assess the extent to which the IACC and agencies coordinate and monitor federal autism activities, we reviewed IACC documents, including the strategic plan, and interviewed OARC officials and officials from 10 federal agencies and select nonfederal IACC members. We assessed the IACC's and agencies' coordination and monitoring activities against criteria established by our prior work. These criteria include key practices for interagency coordination and collaboration, and federal internal control standards related to communicating with external entities, including other

⁷GAO, *Federal Autism Activities: Better Data and More Coordination Needed to Help Avoid the Potential for Unnecessary Duplication*, GAO-14-16 (Washington, D.C.: Nov. 20, 2013).

⁸At the time of our review, DOD had not submitted data on its fiscal year 2012 research projects. As a result, our review did not include data on DOD's fiscal year 2012 autism research.

⁹See, for example, GAO, *2013 Annual Report: Actions Needed to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-13-279SP (Washington, D.C.: Apr. 9, 2013).

federal agencies, and measuring progress on organizational efforts, such as those established through strategic plans.¹⁰

We conducted the work on which this statement is based, and made selected updates in May 2014, in accordance with generally accepted government auditing standards.¹¹ Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Further details on our scope and methodology are included in our November 2013 report.

The Majority of Federally-Funded Autism Research Had the Potential to Be Duplicative

Of the 1,206 autism research projects funded by federal agencies from fiscal years 2008 through 2012, 84 percent—or 1,018 projects—had the potential to be duplicative because the projects were categorized to the same strategic plan objectives or research areas.¹² We found that each of the 11 federal agencies that funded autism research during this period funded at least 1 autism research project in the same strategic plan objective as another agency.¹³ In many instances, 3 or more agencies funded research projects under the same objective. For example, 5 agencies awarded approximately \$15.2 million for 20 autism research projects related to one objective. This objective was to test methods to improve dissemination, implementation, and sustainability of evidence-based interventions, services, and supports in diverse community settings. Four agencies awarded approximately \$4.1 million for 8 autism research projects to develop at least two individualized community-based interventions to improve quality-of-life or health outcomes for the

¹⁰See, for example, GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, GAO-12-1022 (Washington, D.C.: Sept. 27, 2012), and GAO, *Standards for Internal Control in the Federal Government* GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999).

¹¹Our updates were limited to reviewing certain publically available information, such as the most recent strategic plan released by the IACC.

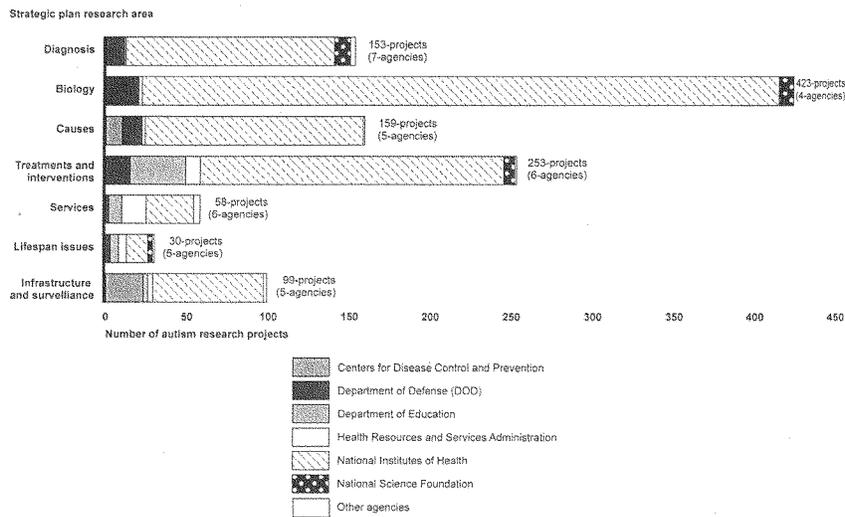
¹²Our findings suggest potential, not actual duplication. Thirty-one projects could not be assessed for potential duplication.

¹³ACL, within HHS, did not fund autism research from fiscal year 2008 through fiscal year 2012; ACL funded one non-research autism-related activity during this time period.

spectrum of adults with autism. Funding autism research on the same topic may be appropriate and necessary—for example, for purposes of replicating or corroborating results—but in some instances, funding similar autism research may lead to unnecessary duplication and inefficient use of funds.

Most agency officials we spoke with said that they consider the research funded by their agencies to be different than autism research funded by other agencies; however, we found that each research area included projects funded by at least four agencies. For example, the diagnosis research area included projects funded by seven different agencies. The most commonly funded projects were in the area of biology (423 projects), followed by treatment and interventions (253 projects), and causes (159 projects). NIH funded a majority of the autism research projects in five of the seven research areas. (See fig. 1.)

Figure 1: Number of Federal Agencies' Autism Research Projects Funded, by Research Area, Fiscal Years 2008 through 2012



Source: GAO analysis of data from the Interagency Autism Coordinating Committee (IACC) and federal agencies that funded autism research.

Note: Thirty-one of the 1,206 projects funded by federal agencies from fiscal years 2008 through 2012 are not included in this figure because they were not categorized to a specific research area. At the time of our review, DOD had not submitted data on its fiscal year 2012 research projects, and therefore DOD's fiscal year 2012 autism research projects were not included in this figure. The agencies included as "other agencies" in each research area are: Administration for Children and Families, Agency for Healthcare Research and Quality (AHRQ), and Substance Abuse and Mental Health Services Administration in diagnosis; Environmental Protection Agency in causes; AHRQ in treatments and interventions; AHRQ and Centers for Medicare & Medicaid Services (CMS) in services; AHRQ in lifespan issues; and CMS in infrastructure and surveillance.

Five agencies that funded non-research autism-related activities from fiscal years 2008 through 2011—Administration for Community Living (ACL), CDC, Department of Defense (DOD), Department of Education (Education), and the Health Resources and Services Administration (HRSA)—funded activities that were not duplicative. HRSA and Education both funded training activities related to autism. HRSA's activities included training health care professionals, such as pediatric

practitioners, residents, and graduate students, to provide evidence-based services to children with autism and other developmental disabilities and their families. The activities also included training specialists to provide comprehensive diagnostic evaluations to address the shortage of professionals who can confirm or rule out an autism diagnosis. Education's training activities focused on the education setting; for example, to prepare personnel in special education, related services, early intervention, and regular education to work with children with disabilities, including autism. Additionally, DOD and ACL both funded a publicly available website to provide information on services available to individuals with autism. DOD's website was developed for military families to provide them with information on the educational services that are close to specific military installations in select states, while the ACL website is broader by focusing on all individuals with autism and other developmental disabilities, their families, and other targeted key stakeholders concerned with autism. Finally, we determined that CDC is the only agency funding an awareness campaign on autism and other developmental disabilities. CDC's *Learn the Signs. Act Early.* campaign promotes awareness of healthy developmental milestones in early childhood, the importance of tracking each child's development, and the importance of acting early if there are concerns.

The IACC's and Federal Agencies' Efforts to Coordinate and Monitor Federal Autism Activities Were Limited

We noted in our November 2013 report that the IACC and federal agencies may have missed opportunities to coordinate federal autism activities and reduce the risk of duplication of effort and resources. Although the CAA requires the IACC to coordinate HHS autism activities and monitor federal autism activities, OARC officials stated that the prevention of duplication among individual projects in agency portfolios is not specified in the CAA as one of the IACC's statutory responsibilities and therefore is not a focus of the IACC. OARC officials stated that it was up to the individual federal agencies to use the information contained in the IACC's strategic plan and portfolio analysis to prevent duplication. Officials from three federal agencies—CDC, DOD, and NIH—told us that they use the strategic plan and portfolio analysis, which are key documents used by the IACC to coordinate and monitor federal autism activities, when setting priorities for their autism programs and to learn of autism activities conducted by other agencies. OARC officials acknowledged that the IACC could choose to use data from the portfolio analysis as the basis for specific recommendations regarding areas where interagency coordination could be increased, but to date this has not occurred. OARC officials stated that they do not consider it to be their responsibility to review the data that they collect on behalf of the IACC for

duplication or for coordination opportunities. Instead, they said that they fulfill their role in assisting the IACC in its cross-agency coordination activities in other ways, such as by facilitating interagency communication and gathering information.

In our November 2013 report, we recommended that the Secretary of Health and Human Services direct the IACC and NIH, in support of the IACC, to

- identify projects through their monitoring of federal autism activities—including OARC’s annual collection of data for the portfolio analysis, and the IACC’s annual process to update the strategic plan—that may result in unnecessary duplication and thus may be candidates for consolidation or elimination; and
- identify potential coordination opportunities among agencies.

HHS did not concur with our recommendation. The agency stated that such an analysis by the IACC to identify duplication would not likely provide the detail needed to determine actual duplication, and that the role of the IACC should not include identification of autism-related projects for elimination. We agree that further analysis would be needed to identify actual duplication. While the strategic plan objectives, which represent broad and complex areas of research, are useful to identify the potential for unnecessary duplication, we believe that such identification is worthwhile as it can effectively lead to further review by the funding agencies to ensure funds are carefully spent. Agencies can review specific project information to confirm whether research projects associated with an objective are, for example, necessary to replicate prior research results. While funding more than one study per objective may often be worthwhile and appropriate, this type of analysis by agencies would help provide assurance that agencies are not wasting federal resources due to unnecessary duplication of effort. Further, such an analysis could help identify research needs—such as research that is needed to complement or follow-up prior research, or research that requires further corroboration—and move autism research forward in a coordinated manner. We also question the purpose of using federal resources to collect data, if the data are not then carefully examined to ensure federal funds are being used appropriately and efficiently.

Further, we found that the IACC’s efforts to coordinate HHS autism research and monitor all federal autism activities were hindered due to limitations with the data it collects. For example, the guidance and

methodology for determining what projects constitute research, and therefore should be included in the portfolio analysis, has changed over the years. As a result, the projects included in the portfolio analysis have varied. Such inconsistency makes it difficult to accurately determine how much an increase in the funding of autism research was due to an actual increase in research versus the inclusion of more projects in the analysis. Additionally, the portfolio analysis and strategic plan contain limited information on non-research autism-related activities, and the IACC did not have a mechanism to collect information on such activities.

In our November 2013 report, we made recommendations that the Secretary of Health and Human Services direct the IACC and NIH, in support of the IACC, to

- provide consistent guidance to federal agencies when collecting data for the portfolio analysis so that information can be more easily and accurately compared over multiple years; and
- create a document or database that provides information on non-research autism-related activities funded by the federal government, and make this document or database publicly available.

HHS did not concur with these recommendations. HHS emphasized that, when collecting data for the portfolio analysis, it has balanced the need for consistency with the need to be responsive to feedback from the IACC and from those participating in the portfolio analysis. While we agree with HHS that it is important to be responsive to feedback and make adjustments to guidance as necessary to improve data collection, we believe that annual changes of the type we observed are not productive. Guidance should be developed so that accurate, consistent, and meaningful comparisons of changes in federal funding of autism research can be made over time and used to inform future funding decisions. Additionally, HHS commented that information on non-research autism-related activities was publicly accessible through a report to Congress that the CAA, and its reauthorization in 2011, required of HHS. While this document could be a starting point from which the IACC could begin to regularly catalog non-research autism-related activities, we believe that having a document or database that contains current and regularly-updated information on these activities is an important aspect of fulfilling the IACC's responsibility to monitor all federal autism activities, not just research.

We also reported in November 2013 that the data used by the IACC was outdated and not tracked over time, and therefore not useful for measuring progress on the strategic plan objectives or identifying gaps in current research needs. Although the IACC did not examine research projects over time, our analysis found that, when looking across multiple years, some agencies funded more autism research projects than were suggested in the associated strategic plan objective, whereas other objectives were not funded by an agency.¹⁴ Recently, in April 2014, the IACC released an update of its strategic plan. This plan included the number of research projects funded from fiscal years 2008 through 2012 under each objective, and the corresponding funding amounts, which may help identify those objectives that have received more funding than others. Although OARC collected specific information on the more recently funded projects—those funded in fiscal years 2011 and 2012—this information was not included in the plan. Detailed project information is needed to effectively coordinate and monitor autism research across the federal government and avoid duplication.

Lastly, we found limited instances of coordination among federal agencies, apart from participation on the IACC. We also found that agencies did not have robust or routine procedures for monitoring federal autism activities. While 5 of the 10 agencies with which we spoke stated that they monitored federal autism activities by searching databases or websites, these searches were narrowly focused or undefined, and some agencies lacked formal policies or procedures for staff to follow. For example, some agencies conducted federal database searches to ensure that a principle investigator was not receiving funding from another agency for the same project; however, these searches would not identify whether agencies were funding similar projects led by different principal investigators.¹⁵ After our November 2013 report was released, HHS informed us that NIH program officials use a database for detection of duplication of scientific content across research applications to help identify similar projects led by either the same or different principal investigators. Although the use of this database may be helpful, HHS did

¹⁴For example, while one objective recommended launching 3 projects related to underlying biological pathways of genetic conditions related to autism, 72 projects were funded from fiscal years 2008 through 2012.

¹⁵Principal investigators are typically individuals designated by the applicant organization, such as a university, to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award.

not provide information indicating that NIH has policies requiring program officials to actually search this database before awarding each research grant. Several agency officials also stated that they rely on their peer reviewers, other experts, and project officers to have knowledge of the current autism research environment. As established in our recent duplication work,¹⁶ it is important for agencies that fund research on topics of common interest, such as autism, to monitor each others' activities. Such monitoring helps maximize effectiveness and efficiency of federal investments, and minimize the potential for the inefficient use of federal resources due to unnecessary duplication.

To promote better coordination among federal agencies that fund autism research and avoid the potential for unnecessary duplication before research projects are funded, we recommended that the Secretary of Health and Human Services, the Secretary of Defense, the Secretary of Education, and the Director of the National Science Foundation (NSF) each determine methods for identifying and monitoring the autism research conducted by other agencies, including by taking full advantage of monitoring data the IACC develops and makes available. DOD concurred with our recommendation to improve coordination among federal agencies, and comments from Education, HHS, and NSF suggested that these agencies support improving the coordination of federal autism research activities. However, Education, HHS, and NSF disputed that any duplication occurs. We agree that more information on the specific projects funded within each objective would need to be assessed in order to determine actual duplication. However, the fact that research is categorized to the same objectives suggests that there may be duplicative projects being funded. During the course of our work, Education, HHS, and NSF did not provide any information to show that they had reviewed research projects to ensure that they were not unnecessarily duplicative.

Chairman Mica, Ranking Member Connolly, and Members of the Subcommittee, this concludes my prepared statement. I would be pleased to respond to any questions that you may have.

¹⁶See for example, GAO, *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8, 2014) and GAO-13-279SP.

**GAO Contact and
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Acknowledgements**

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Marcia Crosse is a Director for the Health Care team at the U. S. Government Accountability Office (GAO). She is responsible for overseeing GAO evaluations in the areas of biomedical research, bioterrorism, disease surveillance, HIV/AIDS, medical product safety, organ transplantation, and pharmaceutical regulation, among other issues. She began her GAO career in the Program Evaluation and Methodology Division in 1983 where she applied comprehensive evaluation methods to a wide range of assignments. Since joining GAO's health care group in 1996, she has led a variety of assignments on public health issues. She has received multiple awards in her GAO career, including the Distinguished Service Award. She received her bachelor's degree from the College of William and Mary. She holds both a master's degree and a doctorate from the University of North Carolina at Chapel Hill.

Mr. MICA. Well, we will start right in.

I guess Mr.—Dr. Insel, Ms. Crosse gave a pretty critical review of efforts to eliminate duplication. She said there had been some steps taken, but in fact, that data was incomplete, out of date. There have been some improvements. Do you want to take a minute and respond generally to her comments?

Dr. INSEL. Well, you know, I think the general comment for me, it is a little ironic because one of the last hearings I was at on the Senate side, I sat with Senator Shelby and he wondered why we weren't doing more to replicate the science that NIH supports. There is a real concern because of recent reports that not enough replication has been done, particularly on the basic science that is funded by the Federal Government. And so the NIH generally, under Dr. Collins, has taken on an increasing rigor, increasing replication campaign. And so our goal very much is to increase, not decrease duplication. We want to make sure that more people are working on the same problems, that we are bringing all of that data together, and that we can ensure that any findings, such as the recent finding about the disorganization in the cortex that was found in children who had died with autism, so it was a post-mortem study, badly needs to be replicated. We just need to have someone else trying to do almost precisely the same study with other material to find out whether that, in fact, can be replicated.

In a world in which, to my mind, this is all hands on deck, we need to have 10 times as many people working here across several agencies, I think being concerned about duplication, being concerned—thinking of that as the problem is just chasing the wrong rabbit down the wrong hole. That is not the issue right now. I can't imagine, actually, a less relevant problem to the issues that we are all facing. We know so little about this disorder. The key now is, how do you get the fuel into this engine with all of these excited scientists, fantastic technologies we have to get this done, and to get some answers? And if Congress comes forward and says, You know, you are doing too many experiments, or too many people are working on this. We don't know if it is being done in the right way. We don't know if everybody is maybe doing the same experiment in two different places as if that's a problem, when we are telling you is, in science, that a precisely what we need. We need more people working on the same problems and, to the extent possible, using exactly the same techniques to see if we get the same answers.

Mr. MICA. Well, again, GAO is highly critical. They said we have had 1,200 of these projects in 5 years. It doesn't appear that your agency has sorted out—well, also, the Interagency Autism Coordinating Council has not, and one of the reasons it was formed was to avoid duplication of effort, try to make certain that the dollars are spent. If it is similar research, and it's—that in fact, it is justified, but the last criticism you had that you still have not undertaken, duplicative review process, which would sort out any of the repetitive studies that you are saying are so important. How do you respond to that last comment that was made?

Dr. INSEL. So it's a great question, and I think it's really thinking about keeping in mind what a coordinating committee does for us, and you could see our strategic plan where we have gone through

this extensive monitoring, as GAO has noted. This is about strategy. It is about high-level planning and figuring out where the priorities should be. Questions about whether funding could be duplicated, how that funding gets distributed, these are tactical questions, and we have an entire staff, not on the IACC. There is a whole program staff. I have 65 in my own institute. That is their job. So for every grant that comes in, they go deeply into, has this been funded before? Is this person being funded by someone else to do the same work? Is there a possibility here that this is redundant and doesn't need to be taken on? So it is a question that gets answered, but not through the IACC. That's not part of the charge, nor is it in the coordinating committee that would even have access to the kind of data that you would need, which is pre-award data, so the IACC has a good view of what has been funded.

The question you are bringing up, and what I think GAO is concerned about, is a tactical question about, how do you ensure before you fund the next grant, what we would call pre-award state, that something doesn't, in fact, get awarded that isn't necessary. So we have an entire process for that. HHS responded in their response back to GAO that the reason we don't need to get the IACC to do this is we already have a large staff doing this.

One other question that just in terms of the response, as was pointed out, out of the 78 objectives, there were 4 that actually never got funded by any agency; 74 did and were met to a greater or lesser extent. And it may interest you to know that one of those four was actually a recommendation from the IACC that the agencies develop a way to ensure replication research, that we actually find a mechanism to ensure that the agencies are supporting identical research across agencies to get replication or, as you might call it, duplication. That was never funded because we couldn't figure out a way to get anybody to actually support that. But it, again, runs exactly counter to what you are seeing as the problem, we are seeing as an essential need. I can't put it in any starker terms than that.

Mr. MICA. Well, you also alluded to the kinds of investments being made, and then you cited two specific areas where you saw that there were either—well, first of all, you said how vital brain research is. Obviously, it is important, and then a couple of breakthroughs in genomics—is that the proper pronunciation? And then neuroscience, would be the two areas I think you identified as some—getting some promising results. Is that correct? The most promising?

Dr. INSEL. That's correct.

Mr. MICA. Okay, and you spend about \$161 million for research. There's other aspects of this, some NIH, \$21 million for CDC surveillance and research efforts, that's a little different. Then we get to the HHS folks. They do research on occasion, and other things.

Dr. INSEL. Department of Ed.

Mr. MICA. Pardon?

Dr. INSEL. Department of Education.

Mr. MICA. Department of Education, I'm sorry. But again, to the pure science, and the two most promising areas of the \$161 million, how much is going into those two areas?

Dr. INSEL. Well, I would have to actually take a moment to look up specifically what those numbers would be for autism.

Mr. MICA. Half, 20 percent, 10 percent.

Dr. INSEL. Probably around half would be going into that additional funding for interventions, development for biomarkers, for a whole range of other clinical kinds of studies that NIH supports.

Mr. MICA. Well, my dad used to say, it is not how much you spend; it is how you spend it. And again, we are not in the position of evaluating science or the research that is conducted. We are getting a critical report and fairly pointed from GAO. Did you want to respond to anything, Ms. Crosse?

Ms. CROSSE. I would like to respond, thank you. We have certainly no objection to duplication that is undertaken knowingly and intentionally in order to replicate or validate research results.

That is not what we were seeing. We were seeing, not just within an agency, but across agencies because there were always at least four different agencies funding research in each one of these areas, that there was not the kind of coordination that we think is essential to ensure that in this very important area funds are not being wasted on efforts that have already been undertaken by other agencies, and perhaps in a more rigorous manner.

For example, the National Science Foundation, when we first went to them, denied that they were funding any autism research. They are not a member of the IACC, and their information had not been included in previous strategic reports from the IACC. However, it was very simple for us to identify over 30 projects focused on autism that NSF was funding. They were not engaged in coordination with NIH, with the Department of Education, with HRSA.

Mr. MICA. I don't mean to interrupt, but did they have authority as the coordinating—under their coordinating charter to look at and also determine whether there is duplication?

Ms. CROSSE. They certainly have authority to obtain information. The IACC is charged with coordinating all autism activities across the Federal Government to gather information on all activities.

Mr. MICA. They didn't look at NSF?

Ms. CROSSE. Not in the earlier years we examined. In the subsequent years, at the time that we were undertaking our work, the IACC was beginning to contact them and in their more recent report has included information on the National Science Foundation.

Mr. MICA. So that is improving. But it gets back to your last point, which was that they were not conducting duplicative review overall within—and that should be one of the primary purposes of the IACC, right?

Ms. CROSSE. Well, we believe that since they have been charged with coordinating and obtaining information on all activities, that that should include all of the agencies that are conducting research. And you know, that was a primary example, but I think that, you know, to indicate that there is no room for improvement, I think it is not valid. We certainly found room for improvement. We are not—we are not making the charge that they are not doing anything.

Mr. MICA. I don't want to put words in your mouth, but you said that some of this has turned around since you undertook your re-

view, and since we have had a report in November and then to Congress in April.

Ms. CROSSE. We see some improvement. However—

Mr. MICA. It is still—

Ms. CROSSE. We still believe there is room for improvement.

Mr. MICA. Do you want to respond, Doctor?

Dr. INSEL. I would love to find somebody who does it better. I would just like to see the example. I think it is really helpful to put all of this in some context. And the reason why I keep harping on the—this being the wrong rabbit going down the wrong hole, is that when you compare autism to AIDS, it is really quite extraordinary. So as you said, Chairman Mica, that \$160 million is being spent in 2012. It is a little bit more than that. But that is basically the autism figures, and you also, both of you cited the enormous public health cost and economic cost. AIDS affects about a million people in the United States. Do you want to guess what the AIDS' budget is for research at the NIH? It is \$3 billion. We are talking about \$160 million for a disorder that affects at least as many children as are affected by—as are affected with AIDS in the entire country.

Mr. MICA. Well, the question here is—I don't mean to interrupt—you have got 12 agencies now identified with \$1.4 billion over 4 years. Is that the correct amount?

Ms. CROSSE. Yes, Chairman Mica, that's the amount.

Mr. MICA. We are trying to make certain that—again, you have a pretty critical report, not, again, maybe most recently, within the last 12 months or so, but—

Dr. INSEL. Let me contest that a little and push back. You know, I think the report says there is a potential for duplication in 84 percent of the research, and they looked at over 1,000 examples. I actually, couldn't find a single example where there was true duplication. It is a little bit like if I said, on your subcommittee, there is a potential for corruption. That's a sort of, you know, presumptive, pejorative comment, without actually any evidence to the fact that here is an example where something was wasteful.

Mr. MICA. Well, and let me go to Ms. Crosse, and then we will get to Mr. Connolly afterwards.

Mr. CONNOLLY. By the way, I'm sure Dr. Insel just meant with the exception of those present.

Dr. INSEL. Absolutely, absolutely. Those present are not considered either in a pejorative or a presumptive way to be guilty as charged. But this is the problem with the terminology of saying "potential," because it suggests that there is a problem when people looked and actually haven't found it.

Mr. MICA. But I think she is saying a potential and identified specifically the NSF, and then you wanted to respond.

Ms. CROSSE. Well, we did find some instances, but we were not, let's be clear, we were not looking for actual duplication. We did not undertake the kind of detailed review of the scientific hypotheses, of populations being studied, and the methods being used for each and every one of over 1,200 studies. That was not our charge, and that is not what we undertook. We were looking to see, as has all of GAO's recent work on overlap and duplication and fragmentation in Federal Government programs, to see whether or

not multiple agencies are undertaking similar work on similar populations. And we found that to be the case.

We did have brought to our attention, a small number of actual duplications that was—studies that were occurring, but that's because individuals in those agencies volunteered those to us. Our—so to say that we looked and didn't find it is—didn't find it is inaccurate. We were not undertaking the kind of review that we believe the agencies should be responsible for doing when they are putting out Federal dollars.

Mr. MICA. Well, I have gone over my time. The whole purpose of this hearing, again, is to look at the critical report and see what we think is going on, and then try to make certain that there are corrections in the programs.

Let me yield right now to Mr. Connolly.

Mr. CONNOLLY. Thank you, Mr. Chairman.

And this is going to be a spirited conversation. That is great.

Ms. Crosse, let me begin with you. Is your expertise scientific research?

Ms. CROSSE. I am not trained as a scientist. I'm a social scientist.

Mr. CONNOLLY. So you are familiar with the scientific method?

Ms. CROSSE. I am.

Mr. CONNOLLY. Have you looked at Federal research dollars in comparable audits on breast cancer?

Ms. CROSSE. I have not.

Mr. CONNOLLY. AIDS?

Ms. CROSSE. No.

Mr. CONNOLLY. Prostate cancer?

Ms. CROSSE. No. We have not been requested to do such work.

Mr. CONNOLLY. I am not asking that question, Ms. Crosse. I am asking about your experience.

Ms. CROSSE. No, we have not.

Mr. CONNOLLY. So you don't have any basis other than this, apparently, for this whole idea of duplication?

Ms. CROSSE. I have a basis for how GAO examines duplication across Federal programs. I do not have similar—

Mr. CONNOLLY. Ma'am, you don't have—ma'am, you do not have any basis, based on what you just said to me and your experience, and this audit, to claim that you come here with expertise on duplication of research allowing you to opine whether this particular set of research, in fact, stands out because there's 84 percent of 1,200 projects at risk of duplication. That is a pretty explosive charge, whether you want to admit it or not, that plays right into the narrative in this body that taxpayer dollars are just constantly being wasted.

And when you say that, GAO, you risk legitimate scientific research that can affect people's lives. And that is a very heavy burden when you come here and assert what you assert based on virtually nothing.

It is okay to say there is room for improvement. There is a risk of inefficiency. That is true. And we want to explore that. But to go much beyond that is what Dr. Insel is objecting to. And I think he has a point, based on the expertise you don't bring to this table.

Ms. CROSSE. Sir—

Mr. CONNOLLY. Yes.

Ms. CROSSE. — I believe that what we did say is there is room for improvement. There is the potential for duplication.

Mr. CONNOLLY. I am very well aware of what you said. I heard your testimony, and it was repeated by Dr. Insel, and it was repeated by the chairman. And what you are doing is playing into the hands of those up here, whether you intend to or not, who actually want to cut back on Federal resources because all Federal spending is bad. The Federal Government can't do anything well. And so what you are putting at risk with that kind of statement is legitimate research.

Now, maybe there's duplication. Let's examine that. Is duplication, per se, bad? I thought I heard you say in your testimony not necessarily.

Ms. CROSSE. I said that if it's undertaken intentionally, with the purpose—

Mr. CONNOLLY. Oh, it has to be intentional?

Ms. CROSSE. Well, I think if duplication is occurring without knowledge that it's occurring, and without an examination of whether or not the results that are achieved are similar or different, then you haven't advanced the science. It is just happening. And it is not—it is not being recognized. I think that is a different situation. And that's one that I would be concerned about.

Mr. CONNOLLY. Well, okay. I seem to recall that some very key scientific research sometimes happens even accidentally, through mistakes. I seem to recall a mold that produced antibiotics. I think if GAO were around at that time, you would have criticized them for having a messy lab. And you would have been right. But scientific research isn't always a pure, pristine, clean, nonduplicative process. And there may be lots of different reasons for giving similar research grants to see what they come up with, because your lab may be different than his lab. Your approach may be different. You may have a slightly different angle that actually leads to dramatically different results. That's how science sometimes works. And sometimes it is a dead end. And when you look back at it retroactively, you go, What a waste of money. But they didn't know at the beginning, and the effort was an honest one to begin with. Now, there may be some research that is, you know, frankly, not particularly legitimate, and who knows why they got the grant and so forth. But in terms of the scientific endeavor, given the mission we have here, you know, I think Dr. Insel's point is let a thousand flowers bloom. In this case, let 1,200 flowers bloom. The risk of inefficiency has to be outweighed with the potential for discovery, for dramatic breakthroughs, not only in detection, but in treatment. And so it's a risk weighing kind of thing, the scientific method. And it doesn't always lend itself neatly to green eyeshade audits, Ms. Crosse.

Ms. CROSSE. Mr. Connolly, we did not make recommendations for any cuts in Federal funding. We made recommendations for improvement and a more thoughtful and knowledgeable approach to managing the research enterprise across a range of agencies that are working in the same area.

Mr. CONNOLLY. Ms. Crosse, I accept that.

And I hope Dr. Insel accepts that as a helpful, broad generalization of good management. But you went beyond that. There is

something almost insidious in suggesting that 84 percent of 1,200 research projects over a 5-year period are at risk of duplication. That goes far beyond recommending good management principles. That insinuates that there is something there though we haven't cited it. And that's Dr. Insel's point. And all right, you didn't look at it. But that is sort of an indictment hanging out there by implication. And I accuse you, I accuse the GAO of being irresponsible when you do that. That is not helpful to scientific endeavor, and it actually damages a very important research component of the Federal Government that's very small compared to other diseases. Because one of the problems we have, Dr. Insel made the point, you know, frankly sometimes up here, why do research dollars go to particular conditions or illnesses? Frankly, lobbying. It's not based on the prioritization of who suffers from it or, you know, how pervasive it is, or even a careful cost-benefit analysis. It's often based on public pressure. And that's how democracy works. But in this case, we are talking about a very small amount of Federal research dollars. And it seems to me the real issue here is actually getting more resources to this scientific endeavor, not fewer.

But I repeat, I think it is irresponsible of GAO to make that kind of statement. The first statement is fine. The second one is insidious. And I don't think you have the qualifications, quite frankly, to make that kind of statement.

Ms. CROSSE. Mr. Connolly, I respectfully disagree. I believe our statement was pointing out the portion of the research where there is room for examination.

Mr. CONNOLLY. No, ma'am, you said 84 percent of 1,200 research projects are at risk of duplication.

Ms. CROSSE. Have the potential.

Mr. CONNOLLY. Based on what?

Ms. CROSSE. Because they are—

Mr. CONNOLLY. You didn't look at them. You didn't come up with a conclusion that we looked at this, this, this, this, compared it, and it's quite clear there is rampant duplication and inefficiency, and you didn't need to do it that way. You didn't come to that conclusion.

Ms. CROSSE. Because 84 percent of the projects are overlapping across agencies, that was the basis for our conclusion.

Mr. CONNOLLY. Does that mean they are not coordinating?

Ms. CROSSE. We found room for improvement in coordination.

Mr. CONNOLLY. Well, okay. There is always room for improvement, even at GAO, Ms. Crosse.

Ms. CROSSE. Yes, sir.

Mr. CONNOLLY. But the only example I thought I heard you say here today was NSF, because it's outside the penumbra of the IACC, and it was doing its own thing.

Ms. CROSSE. That's not the only instance where we believe improvements in coordination could occur. We think that that was a clear—the clearest example.

Mr. CONNOLLY. Okay. Give us another one.

Ms. CROSSE. We thought—for example, we found frequent meetings between HRSA and CDC to discuss their research proposal and excellent coordination. However, AHRQ did not take HRSA's

advice that the work they were funding was duplicative with work HRSA had already funded. That was an example.

Mr. CONNOLLY. Did you conclude, based on your examination, that taxpayer dollars were wasted?

Ms. Crosse. We did not.

Mr. CONNOLLY. Thank you.

Dr. Insel, you want to talk a little bit about the scientific method? And are you concerned at the implied duplication and overlap that might mean that dollars—that there is an opportunity cost, that dollars could have been better focused or targeted but weren't? I guess that's what we are supposed to conclude from this broad generalization from the GAO.

Dr. INSEL. Well, I am going to rise to defend Ms. Crosse a little bit, because after all, her organization—

Mr. CONNOLLY. This isn't personal, Ms. Crosse, but it's about—

Ms. CROSSE. I understand.

Mr. CONNOLLY. Listen, I have been working on and off up here since 1979. And GAO is a wonderful organization, does great work. But there are times when GAO can't see the forest for the trees because they bring a green eyeshade approach to something, forgetting the mission, and not bringing in expertise—they can't to every endeavor—but they need to be a little more humble about that sometimes in their methodology. And in this particular case, I am bothered, I am really bothered by this report, because I think it can do real damage in the current climate up here. It plays right into the hands of the wrong narrative: So we are wasting dollars; we don't need to be investing more. Not that that's GAO's intention. But even GAO can try now and then to avoid being politically tone deaf in a context, especially when something as important as autistic research is at stake. That's my point.

Dr. Insel, sorry.

Dr. INSEL. I am not sure I have anything to add, Mr. Connolly.

Mr. CONNOLLY. I was asking you the previous question, and you decided to defend Ms. Crosse, and I was telling you you didn't need to. But maybe we can return to the subject at hand, which is, are you worried, though—I mean does she make a point, does the GAO make a point that there is duplication that worries you, overlap that worries you, lack of coordination that worries you because it's diverting really precious resources that could have been better targeted? Are there examples in your mind as the head of the IACC?

Dr. INSEL. I have a long list of worries, but none of them are on it, none of the things you just mentioned.

Mr. CONNOLLY. Why not?

Dr. INSEL. Because there are so many more pressing problems that we are facing. Again, I go back to the fact that we know so little about this disorder. We know the prevalence is increasing, as both of you have said. And really, this issue is to me a complete side bar. This is not a place to focus.

Mr. CONNOLLY. Okay. But put yourself in the position, for a minute, of a lay person who sincerely may be concerned and share your concern about let's try to get to the heart of this, and better understand it, and to be able to develop more effective interventions and, ultimately, hopefully, prevention even. And I hear a report that 84 percent of your 1,200 projects over 5 years are at risk

or potential duplication. That doesn't concern the head of the IACC, that some of those projects may in fact be duplicative? Because that's the implication.

Dr. INSEL. As I said at the outset, I am looking for duplication. That is what I think is actually essential to the scientific process.

But that is not to say that there aren't ways we can do things better. The IACC is not perfect. We are always looking for input from outside groups. I would say that this particular investigation, because that's what it was over a period of I believe 2 or 3 years, at some point began to actually interfere with the very thing we were trying to do. My own staff, I at one point asked them how much time is this taking? And this ran into hundreds of hours, 20 or more meetings. I mean, it is just an extraordinary burden for people looking for something that, ultimately, frankly, they never found. And what you have is a report that ends up saying there is a potential for duplication.

Mr. CONNOLLY. And I will add, but I mean, is it not true that, sadly, a lot of scientific research, especially in the medical field, ends up at dead ends with the best of intentions?

Dr. INSEL. That's the way science works. If you knew the answer, you wouldn't have to do the experiment.

Mr. CONNOLLY. Thank you.

Thank you, Mr. Chairman.

Mr. MICA. Well, just to state for the record Mr. Connolly consumed 13 minutes. And I consumed about 10 and a half. I just want to add a couple of things here, and I will count it against time. Then we will go to Mr. Woodall.

Mr. Woodall, we are doubling the time for members on the panel.

And then we will get to Mr. Posey next. Let me just say a couple of things clarifying. First, I asked the question if this was just—if this was a report—I am not that familiar with all of the history of this issue. But the study was actually mandated by a public law, 111-139. It wasn't a request of Members. Is that correct?

Ms. CROSSE. The report that we issued in April, where we included information on our November report, was mandated by law. But our original report issued in November was requested. It was requested by Senators Coburn, Ron Johnson, Mike Lee, and Robert Menendez.

Mr. MICA. Okay.

Ms. CROSSE. And it was at their initiative that we undertook this.

Mr. MICA. I just wanted to get the genesis of the study that was—that you were requested to do. That's the first thing. Secondly, I don't want anyone to think that this hearing was organized or its purpose is to cut funding for autism. If there was wasteful money or something uncovered and that was an issue—I think what we wanted to do, again, I was startled by the April—no, April of this year, yes, and the 2013 report. So when an agency makes a statement like that, that does get her attention. So that's part of the purpose of the hearing. And if we aren't spending money where we are getting the most results, and there was an agency set up in 2006 to try to better coordinate those efforts, then we may have issues. And that's why we are doing this hearing. We want every dollar to be as effective as possible. My side of the aisle,

too, Mr. Connolly, we have put—Mr. Gingrich, when we took over, we doubled, almost doubled some of the money for research. And I am one of the individuals who feels that you can't—if it is properly applied and you are doing the research, then look at the billions you could save, the agony, the heartache for these families and these individuals that are affected. So I just want the record to clearly reflect this isn't any attempt to cut funds, or to, again, do away with research that is needed. So, with that, let me—

Mr. CONNOLLY. And Mr. Chairman?

Mr. MICA. Yeah.

Mr. CONNOLLY. Can I just point out for the record that my friend has now matched, if not exceeded, my time.

Mr. MICA. That is exactly what I intended to do. You are not going to get an extra minute out of me.

Mr. CONNOLLY. You have always been fair. Thank you.

Mr. MICA. I always try to be fair. I learned from my first year in Congress from a Democrat Member who treated me with fairness and equality, that I would repeat it even if it required me to buy Preparation H.

Mr. CONNOLLY. And it is also important to note that the chairman's brother was a wonderful Democratic Member this of this body from Florida.

Mr. MICA. We all have our issues.

Mr. Woodall, you are recognized.

Mr. WOODALL. Thank you, Mr. Chairman.

I appreciate the time. And I appreciate you pointing out that this is not a hearing about reducing autism funding; this is a hearing about making sure that every penny counts. I don't know who represents an area that is not full of moms and dads who want answers and want to make sure that every penny is being spent effectively.

And candidly, to Mr. Connolly's point, Dr. Crosse, when you have explosive things that come out in a report, I would argue that that GAO report has done more to focus the discussion on autism research and whether or not there are enough dollars there or not as anything. I have not seen the negative undercurrent. I have seen the very positive persuasion. But more importantly, whether doing your work and reaching your conclusions helps the autism research cause or hurts the autism research cause, GAO is not tasked with sorting that out.

GAO is tasked with sorting out the answer to the question that in this case four Senators asked and a law mandated. And I hope that the takeaway will never be that if there is a political point that you can make that you should make it, or if there is an end that you can justify, you should justify it. We rely on GAO to share the good and the bad and the ugly. And I am grateful to you all for the work that you do.

To that end, thinking about those hundreds of hours that you all invested, Dr. Insel, I kind of think of that as the price of admission. I always hate to see dollars wasted on compliance. That is something that we fight on a regular basis in my part of the world. But when you are talking about \$1.4 billion over a series of years, folks do want some accountability. And folks at home don't understand why DOD is working on part of this issue, and DOE is working on

part of this issue, and NIH is working on part of this issue. Understanding that accountability is a part of what we all do, using this as the model, Dr. Crosse has been criticized for making an observation but not recommending solutions. You made an observation about the time involved. Is there a solution to that?

Dr. INSEL. It is essential that people, when they have a question, look at the evidence. I wouldn't contest that for a moment.

But what I would contest is the importance of looking at all the evidence. Parts of the report are simply inaccurate or incomplete. There has been an enormous work on looking at the accountability within the autism research funding stream. So we have this recent report, which is really an accountability report of our strategic plan that looks at every single objective, finds out how much was spent over every year, where the money has gone, how does that map onto what was planned. So none of that, by the way—all of that was available last year. It has only recently been published, but GAO saw that. This was presented at the public meetings that the IACC held. Somehow that failed to make it into the report.

Mr. WOODALL. Well, my experience is, and yours may be similar, the report Congress does on its own success generally turned out pretty good. Turns out we think pretty highly of the work that we do. The work that outside groups do on our success sometimes don't come back quite as optimistic. I look at that report, it looks like it was prepared in-house. Is there a similar document that you would hold out as the be all, end all of outside examination of the IACC's work?

Dr. INSEL. That's a great point. And it is important to realize that the IACC isn't inside, it isn't outside; this is made up of a whole range of stakeholders. By the way, they virtually never agree on anything, either with respect to autism or with respect to anything else. So this is their best attempt to take an honest accounting and evaluation of how the funding agencies had done. Half of this group, nearly half, are actually non-Federal members. Most of them family members, some people with autism itself. They are hardly cheerleaders for either the IACC or for the Federal agencies.

Mr. WOODALL. Mr. Chairman, I don't want my time to expire without asking unanimous consent to enter the statement of Don Mueller in the record.

Mr. MICA. Without objection. And you still have 5 minutes remaining.

Mr. WOODALL. Thank you, Mr. Chairman.

Don is the executive director of the Marcus Autism Institute, which is down in my part of the world. And I brag about the work that they do all the time. In fact, our school system that I represent, largest school system in the southeastern United States, has slots prepaid down there because of the work that they do and the importance of being able to find those limited resources available when we need them. Because there are not enough—there are not enough opportunities for folks to seek that help. But as I was reading your testimony, Doctor, I couldn't help but notice a reference to some eye-tracking technology that sounded a whole lot like some of the things that I brag about coming out of the Marcus Institute. Am I right about that, or am I just a proud public servant bragging about the scientists and folks in his district?

Dr. INSEL. You have every right to brag. That is a spectacular group doing fantastic work and actually is probably the group that will open up this opportunity to diagnose autism before the first year. That is a game changer.

Mr. WOODALL. When we think about the dollars that go into it, and I appreciate what GAO did to help folks to get their minds around the many different baskets that dollars can go into, candidly the dollars that we spend on palliative care aren't all that inspiring to me. The dollars we spend on game-changing science, there is not a man or woman in my district who wouldn't say, Rob, I will write the check, to tell me that what we are doing is making a difference. Tell me that it's going to be a game changer, and I will write the check tomorrow to do more. I think so often when I have conversations with lay people about autism, it is a conversation about treatment of symptoms, not a conversation about changing a life. And if we can use this opportunity and others to publicize it, celebrate it, get folks excited about it, again, there is just no limit to the power of the American people to invest in ideas that will change the future. To Mr. Connolly's point, yes, folks are worried about government waste. And the potential duplication is something that folks have on their mind. But we would not have the opportunity to talk about the ideas that we celebrate, we wouldn't have an opportunity to talk about the successes, at least not in this forum, but for the laws mandating a report, the Senate's requested report.

And I am grateful that we have had that time. Let me ask you, Dr. Crosse, director of health care, you have heard Mr. Connolly's criticisms of what I would call the standard GAO process, right? This is what we fund you to do. Hearing those concerns, knowing that, generally, as we look around this room, this is a group of folks who all agree on the goal and who all want to get to that goal as soon as possible, is there a tool that the GAO does not have in its quiver? Is there an arrow that is not in the quiver that you would have liked to have had to do something different in this report? Or did you do this report right the first time given the mandate, and you would do it the exactly the same way again?

Ms. CROSSE. I believe that we did exactly what we were requested to undertake, and that aligned with the mandate we have been given and the approach that is being used to look at fragmentation, overlap, and duplication that can occur across the Federal Government. If it has come across as tone deaf, that certainly is not our intention. We try to be very clear, and we try to be very precise in what we say and in what we don't say. And again, we did not call for reductions in funding. We did not say that dollars being spent on autism research were wasteful.

Mr. CONNOLLY. Would my friend yield?

Mr. WOODALL. Be happy to yield.

Mr. CONNOLLY. I thank my friend. I just note for the record that GAO, we rely on GAO a lot, so sometimes GAO, they are fallible, too. They don't speak ex cathedra. I recall a situation where GAO reported that there were 56 Federal financial literacy programs. And that went viral. They were wrong. There were not. They had to go back, and they admitted that, well, actually, maybe there

were 12 or 13, but the damage was done. That's the concern I have. I thank my friend.

Mr. WOODALL. Always looking for those areas of agreement. And certainly, this research is one of those. I think Mr. Connolly is absolutely right when he talks about the power of—that lobbying has in making these decisions. I will tell you, Dr. Insel, when constituents come and ask for an earmark or a plus-up in this area of NIH or that, I always tell them that we have tried to hire the absolute finest folks that the world has to offer. And if you believe that a lawyer trained out of the University of Georgia has more to offer scientific research than the best minds on the planet, I am happy to start making those decisions. But our goal is to find the very best folks, put them in positions of responsibility, then take every penny that we can find to dedicate in that direction, and allow those folks who see where those areas of opportunity are to dedicate those dollars appropriately. I am grateful to the coordinating work that you do. I know you can be doing many, many other things with your time. But none that would have a greater impact on the men and women that I serve back home in Georgia. And I am grateful to you for it.

Dr. INSEL. Thank you, sir.

Mr. WOODALL. Mr. Chairman, I yield back.

Mr. MICA. Thank the gentleman. Mr. Massie, did you have any questions at this time?

Mr. AMASH. Amash.

Mr. MICA. Mr. Amash. I don't know why I did that.

Mr. AMASH. No, I yield back to you, Mr. Chairman.

Mr. MICA. Thank you. There is a distinct difference between the two members. And I apologize.

Then we will go to Mr. Posey, who had unanimous consent to participate.

Mr. POSEY. Thank you, Mr. Chairman.

And Dr. Insel, let me say that I think you are a good man, you are well qualified for the job, and you have good intentions. And I hope that this discussion about the direction it is going is not something that you are taking personally. You know. Some folks, and I am one of them, believe that the government and the scientific community has made a strategic error by mostly focusing on genetics-only research. I am just finishing up my opening statement here, basically. It seems NIH is clinging to outdated paradigms, and IACC leadership for some reason or reasons has obstructed progress in researching the environmental initiatives that are actually listed in the IACC's own strategic plan. Those have been underfunded, while genetics have been funding at around threefold the recommendation. I am interested in knowing what, if any, changes Congress and the parents can expect to see from the IACC.

Dr. INSEL. Well, thank you, Mr. Posey. If I can, just to put this in context, because often there is some confusion about what we mean when we use the term genetics or genomics. Just put autism aside for the moment. Again, you look at disorders that we study that are major public health problems that we know have a very clear environmental cause, lung cancer, asthma. Those are two pretty good examples. If you looked into the NIH funding for those,

it is heavily dominated by genomics. Now, we know there is an environmental cause for lung cancer, and we know the same for asthma. So what are we doing studying genomics? The reason is because in 2014, genomics isn't about necessarily just finding a cause, it is a tool. It is the engine for discovery. It has given us a way to faster, better, and cheaper figure out mechanisms of disease. And sometimes that takes us in ways and places we had never expected to go. But to say that we—

Mr. POSEY. My time has run out here. Are mostly the studies that they were talking about being redundant on genomics, do they have the same goals? Do they have the same metrics? Are they being measured by the same metrics? Are they using the same techniques?

Dr. INSEL. I am not sure that I am aware of projects that were thought to be redundant on genomics. In the area of genomics, everything that we do, not just in the United States, but around the world, filters into a single site called the database of Genotypes and Phenotypes, dbGaP. And so all of that has to be standardized to use exactly the same techniques and to provide the same kind of data.

Mr. POSEY. Thank you. Your job is, you know, much broader than simply autism. And in the last 4 years, you were not only director of the National Institutes of Mental Health, but also the acting director of the newly formed National Center for Translational Medicine. Realizing there is only so many hours in a week, a day, I am curious about how much of your actual time outside of IACC meetings do you spend singularly focused on autism?

Dr. INSEL. That's a great question. My wife asks me that quite a bit, actually, because the hours are there, but on the percent basis, it's not at this point the majority of my time. I have lots of other things that I am responsible for. I have to say that part of the reason I have focused as much as I have on autism for the National Institute of Mental Health is because increasingly we think about this as the prototype. Today we think about schizophrenia, bipolar disorder—

Mr. POSEY. Would you say it's an hour a week, 4 hours a week?

Dr. INSEL. Oh, no, no, no. It has got to be more than that. I would have to actually sit down and look at my calendar. But it probably tracks pretty well with our funding commitments. It is probably about 10 percent of our funding. And I suspect it is about 10 percent of my time.

Mr. POSEY. Okay. And if you find differently, if you would send the committee back—

Dr. INSEL. I will be happy to provide something for the record.

Mr. POSEY. One of the findings of the GAO was the potential for duplicative research, which has been a big topic up here today. Who at the NIH actually makes the final funding decisions on autism research grants?

Dr. INSEL. It is certainly not the IACC. It is the institute directors at the NIH, who are responsible for their own budgets. In this case, there are six different institutes that have some commitment to autism. Five of them are on the IACC.

Mr. POSEY. Would you send me a list of them and their names and—

Dr. INSEL. Absolutely. We will provide that for the record.

Mr. POSEY. And their budget amounts?

Dr. INSEL. Yes.

Mr. POSEY. Is there a coordination between NIMH, the Child's Health Institute, and other centers and institutes on what will and won't be funded?

Dr. INSEL. Yeah. There's a separate parallel group called the ACC, the Autism Coordinating Committee, which is made up of the program officers at each of those institutes, those and others as well, deafness as well. They get together on a regular basis, at least once a month. They hash through their portfolios, both what they have and what's coming in, and make decisions about what the funding should look like going forward.

Mr. POSEY. Thank you. Will you send me a list of all those players and who they represent?

Dr. INSEL. Absolutely. We will do that for the record.

Mr. POSEY. I know that before the final decision there is a review by experts of grant applications. The IACC members do not have grant review authority the way that a typical advisory body for centers and institutes do. It was announced on April 29th in the Federal Register that the National Institute of Child Health and Human Development, Special Emphasis Panel, Outcomes in Autism Spectrum Disorders, Mechanisms and Needs Assessment would be meeting on May 6th in a closed door meeting to review grants. I am wondering who serves on this and other special emphasis panels that review the body of autism grant applications at the NIH.

Dr. INSEL. There are two tiers of review at the NIH. One is the one you just described, which is the level of usually scientific experts, but sometimes public members as well, to look at scientific merit for the grants that come in, and to rank them. The second tier is it then goes to a body called the advisory council. And each institute has one of these. They go through that entire list with people from program, look at both scientific merit, public health needs, and also programmatic balance, and help the institute director to make a final decision about what should get funded.

Mr. POSEY. Thank you. Would you please provide me in writing the name and staff position so I can kind of get that straight on a chart?

Dr. INSEL. Right. We can lay that out for you. Would you like it for the institutes that handle autism research?

Mr. POSEY. Everybody that touches it.

Dr. INSEL. So that would be the members of council for each of those institutes. It is actually public record.

Mr. POSEY. Both layers, yeah.

Dr. INSEL. Well, so I should just clarify that the review committees, of which there are several, in this case the one that you reference is what is called a special emphasis panel.

Mr. POSEY. Correct.

Dr. INSEL. So that's put together for just this particular review on this particular request for applications. We can certainly provide you with those names. Those are, of course, public. But we will get you that for all of the recent requests for applications. We just had three for NIMH, and we will make sure you have those names.

Mr. POSEY. Thank you. It just wasn't in our package. And so it may be available, but you know, you can put your finger on it in 5 minutes, and it would take my staff 5 days just as a practical matter.

Dr. INSEL. It is not worth 5 days. We will get it to you.

Mr. POSEY. Okay. Would you please provide that list their bios and CVs and financial disclosure forms?

Dr. INSEL. And again, all of that is public record for government employees. And at the institute, directors and council members, all of that is available. For members of special emphasis panels, I would have to check to find out whether they are vetted in the same way in terms of their financial disclosures. I believe they are, but I would actually have to look at that. And we will let you know that for the record.

Mr. POSEY. Okay. Thank you. Are there any parents of individuals with autism included in the review process?

Dr. INSEL. Well, at NIMH, we have had a tradition of doing that, all the way from our—the ARRA funding, where they were a large part of the review, to now having generally a member of—usually a parent who sits on our council. At this point—or sometimes it is actually a person affected by the disorder. The most recent parent of a person with autism was Portia Iversen, who sat on the NIMH council until about 2 years ago. This rotates around. So the other public members, I don't know that right now—we do have one parent of a person with autism, but that is not something that is public. But the people are chosen to serve partly to provide that kind of perspective. Now this is at the high level. This is at the council level that is making the final decisions on an advisory basis.

Mr. POSEY. Yeah. Somebody from Autism Speaks, for example, what would be their odds of being on that review panel?

Dr. INSEL. So for that first level, tier one, scientific review, there is—if they don't have a conflict with applications coming in, we are always looking for people who can bring scientific expertise to that discussion. At the second level, at the higher tier, Portia Iversen was the founder of Cure Autism Now. So that is somebody who was deeply involved in the advocacy community. So, again, NIMH covers many disorders. It is not just about autism. But we have tried to make sure there is someone with an autism focus on the council so that those grants get a very careful look.

Mr. POSEY. Okay. Have there been any discussions of public grants to balance out the private sector grants?

Dr. INSEL. That's a terrific question. And it's something we haven't talked about so far. But as the NIH funding has gone down about 25 percent over the last decade in terms of purchasing power, we have been fortunate that there has been an increase in private investment. Simons Foundation, Autism Speaks, the Autism Science Foundation, those three really making a difference and helping to buffer what has been a very difficult period for the NIH. The way that that gets coordinated is through the IACC. So we would love to have members or leadership from each of those private groups on the IACC. They have been there until recently. Rob Ring was just appointed from Autism Speaks. But he has not attended any of the meetings. That will happen. Because of turn-

over at both Autism Speaks and Simons Foundation, we have lost their representation. But that is going to be repaired very quickly.

Mr. POSEY. Good. I am glad to hear that.

My time has expired, Mr. Chairman. I hope we do another round.

Mr. MICA. Well, I am not sure how much additional time we will have.

I had a couple of questions.

Mr. Turner, did you have anything at this point? He has just joined us.

Mr. TURNER. No.

Mr. MICA. Let me just ask a couple of questions I didn't get to before. And I was trying to look at, again, the most promising areas. And I talked about the neuroscience, and how do you pronounce it?

Dr. INSEL. Genomics.

Mr. MICA. Genomics. I had heard you mention some research, maybe I was wrong, about the second trimester. Could you elaborate on that? Is that another promising area?

Dr. INSEL. Well, as Congressman Posey pointed out in his opening remarks, there is virtually no expert who would doubt that environmental factors are important for autism. We don't know yet exactly what those are. And that has got to be a major focus going forward. The few that we do know about do point us towards the second trimester as the point at which they act. So whether it's drug exposure, sometimes prematurity, other events, other kinds of exposures, even one that has been purported for pollution, when you map those factors onto development it is not post-natal, it is not early prenatal, it is really right in that period around 12 to 24 weeks that we are most concerned. But what is it? You know, it's probably many things. And how do we get our hands around that? And how do we help people to know what to avoid when they are carrying a baby at risk? Those are the questions that we haven't yet answered.

Mr. MICA. Well, one of the things that if you could provide us for the record, I would just like to have in the record, and I would ask you some of the money we are spending in the more promising areas, maybe you could just give us a little breakdown of estimates in the most promising areas for the future. I think that's important to establish for the record. And then, again, we want to direct as many additional funds to where you have the promising research or results. So, again, if you wouldn't mind providing that.

Then you started talking about data collection. And I guess you are getting better at it. And what is it, NDAR?

Dr. INSEL. Yes, sir.

Mr. MICA. How old is that data collection system?

Dr. INSEL. NDAR was started I believe in 2005, just built as an infrastructure. It has taken a while to grow it. We are up to over 70,000 individuals with an ASD diagnosis, and millions, actually over billions of records. We are just seeing the first fruits of that as people—

Mr. MICA. And how much money are you spending on data collection?

Dr. INSEL. It costs us about \$3 million to build it. It is about a million dollars a year to—

Mr. MICA. Is that adequate? Again, your sampling is somewhat small, 70,000, considering the population. And then the data collection I guess has become more sophisticated. Did you all look at that, Ms. Crosse?

Ms. CROSSE. We did not look at that, no.

Mr. MICA. But I think that's also important, building an accurate database. But if you could, again, provide to the committee any information on where we might make improvements if we don't have enough funds for data collection and we aren't expanding that base of knowledge. I think those are my questions, follow-up questions at this point. It is just important that—you talked about the kinds of investments. And we want to make certain that we are investing properly, that if we don't have the coordination that we need, that we achieve that.

Dr. INSEL. Again, sir, just to make sure we are clear on this, I would push back against the sense that we don't have sufficient coordination. I don't think that's the problem. And as I said at the outset, I don't know that there is any disease area that does it better than autism. The problem is we just don't have enough—

Mr. MICA. It's also been held up as a model, too, of what we have done with the IACC. But again, we have some differing of opinion, and that's what the hearing is about today, and making certain that we are targeted and focused adequately. Mr. Connolly.

Mr. CONNOLLY. Thank you, Mr. Chairman.

I just have two follow ups. One quick question for Dr. Insel. Ms. Crosse pointed out that NSF is not part of the IACC, and kind of was doing its own thing. Why isn't it part of IACC, and shouldn't it be?

Dr. INSEL. It would be great if they were. They feel that their mandate is in basic science, that autism is a clinical problem, and this is outside of their lane. The fact is they work on issues, like robotics, that we think could be extremely helpful for the autism community. We—outside of the IACC, we have a lot going on with NSF. In fact, we have joint funding efforts with them in computational science and other areas.

Mr. CONNOLLY. And here I do credit GAO, Ms. Crosse pointed out initially they said, no, we are not doing any autism research, and GAO discovered, well, actually they were doing about 30, I think you said. So it just seems to me, Mr. Chairman, that's something we may want to follow up on. I am not sure it ought to be NSF's decision whether or not they are part of the IACC.

Dr. INSEL. Love to have your help on that. That would be terrific.

Mr. CONNOLLY. I think that is a follow up, definitely, Mr. Chairman, if you want to work together on that.

Mr. Yudin, just one question. I have known lots of families who have autistic kids. And you know, for 14 years, I was in local government and helped finance and oversee the 12th largest school district in the United States. And you talked about the best policy is try to integrate these kids into the general curriculum. And that's a noble goal. But practically, most teachers have no training whatsoever in dealing with autistic kids. And it can be very challenging. There are all kinds of issues, depending on the spectrum.

So what are we doing to provide that kind of training so that teachers are not afraid, not intimidated, not wanting to avoid this

integration in the general curriculum? Because if that's the goal, the key is teachers who are trained and familiar and embrace that goal, too.

Mr. YUDIN. Thank you, sir. That's a fantastic question. We know that research shows that kids with disabilities do in fact do better when they have access to the general curriculum and they are held to high expectations. You know, as you noted, as everyone knows, autism spectrum disorder is in fact, you know, kids have autism on the spectrum. So there is a range of severity, a range of individual needs, interventions, services, and supports, you know, across that spectrum. We have invested in a number of efforts in research-based strategies, such as positive behavior interventions and supports, PBIS is what it is known, and it is a school-wide effort that sets a framework for behavior. It sets clear expectations for behavior. Teachers are trained on it. Parents are trained on it. The school cafeteria workers are trained on it. Bus drivers are trained on it. And if implemented with fidelity, has fantastic outcomes that address a number of areas around behavior, around office referral, around suspensions, around attendance, around engagement, and ultimately around academic support. So I would start with that framework. That is a solid research base that is really making a difference in classrooms all across the country. What it also then does is frees up specialists, whether they are special ed. teachers, or counselors, or psychologists to then really work with kids that do have more intensive behavioral needs. We support a technical assistance center on intensive interventions that works with States and districts to provide those research-based tools and strategies.

Mr. CONNOLLY. Thank you, Mr. Chairman.

Mr. MICA. Mr. Posey.

Mr. POSEY. Thank you, Mr. Chairman.

And, you know, please don't mistake me for advocating that we abandon genetic or genomic research. My question was just why the environmental-based research was funded at much less than the recommendation, and the genetic research was funded at three times more than the recommendation. What would you recommend to improve the relevance of research funded by NIH to families?

Dr. INSEL. Can I get you to unpack that question a little bit to get some sense of—

Mr. POSEY. All right. How many of the therapies currently that are typically used by the autism community have been evaluated by NIH research grants?

Dr. INSEL. There is a robust cohort of efficacy trials looking at a variety of interventions, both behavioral and biomedical interventions, pharmacological, and devices. But as you probably know, the range of what is being used in the community is vast. And in the absence of anything that seems to truly work in randomized control trials that has been shown to be effective and rapid and accessible, people are reaching for all kinds of things. So we do have effective behavioral interventions. At this point, in 2014, remarkably, we have no pharmacological treatment for the core symptoms of autism. And that is extraordinary.

Mr. POSEY. Yeah. Okay. Some years ago, NIH staff informed this committee that a chelation study would be conducted to evaluate its benefits in children who test for high levels of heavy metals like

lead, mercury, and cadmium. Do you know if that was ever conducted?

Dr. INSEL. I know that there was a proposal to do such a study in the NIMH intramural program. And my recollection of that, this is many years ago, was that it did not make it through the Institution Review Board process, that the IRB felt that it was difficult to do that study under the ethical constraints based on the information they had.

Mr. POSEY. Okay. The previous question about the research grants. Could you also give us a list of those?

Dr. INSEL. I am sorry, just to clarify the question about research grants, a list of—

Mr. POSEY. On therapies currently typically used by the autism community. You said there were a number of them.

Dr. INSEL. Yes. Absolutely. And again, all of that information is also in this tome that has recently come out that looks at the accountability of the strategic plan. I should, because I didn't respond directly to your question about the proportion of the budget that's going to genetics versus environment, in the realm of looking at environmental risk factors, more than half is either on the environment, specifically on gene environment interactions, or epigenetics, which is a mechanism by which the environment would have that impact. So that's in excess of \$30 million that go into that area.

Mr. POSEY. Okay. And this is just out of curiosity. Has NIH, NIMH, or NIH funded studies looking at the use of vitamin B6 in children with autism? Are you aware of that?

Dr. INSEL. I would love to take a look at that for the record and let you know. I don't know offhand of such a study.

Mr. POSEY. There is a question of why there haven't been studies of whether autism prevalence is higher in children who received versus did not receive one of the seven vaccines administered in the first year of life, and how you can legitimately state that vaccines don't cause autism studies until the actual studies are conducted. And I am not saying you, I am saying anyone, you know. That's not a personal statement. You know, put aside all the criticisms about how to do the study, where do you come down on that?

Dr. INSEL. Well, this may be, again, a place where GAO might have suggested that there has been some duplication. There has been an enormous amount of focus on this topic over a long period of time. I have never counted the number of studies, but I know that there is a—even today yet another report out, a large meta analysis out of the University of Sidney looking at 10 different projects that have looked specifically at this question about the role of vaccines and, again, comes up completely empty handed. There is just no evidence there. So how much more needs to be done there, how much do you want to continue to bang away at that question? Personally, I think the environment is an important factor here, but it is probably going to be prenatal, not in the first or second year of life.

Mr. POSEY. Well, are you aware of any studies that we have done that have not been tarnished by the touch of Poul Thorsen that conclusively have done a blind study of vaccinated versus unvaccinated?

Dr. INSEL. Well, those are two different questions. There has been an enormous amount of epidemiological work, not just in the United States but around the world. And part of what the report out of Sidney describes is that effort. The question about doing a prospective vaccinated versus unvaccinated clinical trial came up at our previous hearing. And I think that's going to be a tough one to get through an Institution Review Board, to tell parents in a random way that you are not going to be allowed to vaccinate your children.

Mr. POSEY. Okay. Let's stop it right there. Because every time we have ever talked about doing one of those studies, some idiot in the media says I am suggesting that children intentionally don't get vaccinated. And I don't know that anybody ever has ever proposed that. But there are plenty of children whose parents will not allow them to be vaccinated. There are plenty of cultures where children are not vaccinated. And there are other reasons children are not vaccinated. And there are children who take large doses of vaccination, and children whose parents decide to have them take one vaccination at a time to avoid thimerosal. And I have not been able to ascertain that there has actually been a legitimate study done that wasn't tainted by the touch of the international colossal scumbag Poul Thorsen.

Dr. INSEL. Well, perhaps I can reassure you a little bit on that score. I agree with you that there are a lot of parents today who are choosing not to vaccinate. And that does provide maybe the unenviable opportunity to ask, does that matter? We are trying to do that through a very large study of 35,000 families with autism in a very large health care system where some of the families have decided, when they have a child with autism, not to vaccinate their next child. And the question will be, does that—two questions, actually. A, does that make a difference? Does that next child have a greater or lesser possibility of developing autism if they are not vaccinated? And the second question is, are they more likely to develop preventable medical illnesses as a result?

I guess the other question I keep wondering for myself, since we have already done this, we don't have the data yet, but we will very soon, is will—if the results come out negative again, will people accept that answer?

Mr. POSEY. Absolutely. If it's a transparent, bona fide study, I think no matter where people fall on the issue, what side, they would be relieved at a credible, transparent conclusion. Yes, I think everyone would be relieved, regardless of what the results are. They just want to see a straight arrow, bona fide examination, study, and conclusion. And I don't think they want anybody to invent anything. I mean, I have had—I have talked to, you know, hundreds of mothers personally. And I am sure there's thousands and maybe millions that I haven't talked to who have said, you know, my child, usually a little boy, was absolutely perfectly normal until the day after he got his vaccinations. And through a related career, I have got a little bit of experience with mercury. And, you know, I know that if we find mercury in our fish, we shouldn't eat them. And I think that the spectrum causes are very wide. I think this is one of them. I think genetic-enhanced foods are one of them. I mean, we changed genetics of what we eat and don't ex-

pect it to change our genetics? I mean, there are so many things. I think pollution goes into it. I mean, we know that it harms children who eat lead pipes. I mean, clearly, the children who have eaten lead off the pipes, it has harmed the children. I mean, there is a lot of reasons for it. But one heavy reason that I hear often about is the thimerosal in the vaccinations.

And I think it would be great if the government, who is here to do good things for people, would take that off the table. But not in a way that we met, and we did this and we did that, but in a very public way, and a very transparent way. You could I think remove that question forever with just one decent, highly qualified, respected study.

Dr. INSEL. Sir, if you will permit me, as soon as we get the data in a form that has been accepted for publication, I would love to sit down with you and go through them. And we can do that one to one.

Mr. POSEY. I look forward to it.

Dr. INSEL. And let you see what that looks like. I am interested to see it myself. And we will know that I think in the next 3 months.

Mr. POSEY. Thank you.

Mr. Chairman, you let me go over a little bit. Thank you very much.

Mr. MICA. Thank you. Thank you, Mr. Posey, for attending and participating. And I also want to thank our three witnesses for their participation, testimony today.

Without objection, we are going to leave the record open for an additional 7 days. And we have additional questions that we will be submitting to some of the witnesses for responses for the record.

There being no further business, I do want to thank everyone again for participating. Raised a lot of important issues that looked at some of the study results from GAO and heard testimony from the IACC representative. And again, sorting through this and making certain that we are doing the best possible with taxpayer dollars is our goal. And hopefully, we can get closer to finding both the cause and prevention and help a lot of people who have had to struggle through the terrible problems brought about by autism. So with that, there being no further business before the Government Operations Subcommittee, this hearing is adjourned. Thank you.

[Whereupon, at 11:05 a.m., the subcommittee was adjourned.]

APPENDIX

MATERIAL SUBMITTED FOR THE HEARING RECORD

Statement of Ranking Member Gerald E. Connolly (VA-11)
Subcommittee on Government Operations
Committee on Oversight and Government Reform
Examining the Federal Response to Autism Spectrum Disorders
May 20, 2014

Mr. Chairman, thank you for holding today's hearing to examine the Federal Government's response to autism spectrum disorders (ASD), with a focus on strengthening the Interagency Autism Coordinating Committee's (IACC) efforts to coordinate and monitor Federal ASD research initiatives and treatment activities. On behalf of the millions of Americans and their families living with ASD, it is my hope and expectation this morning that our expert panel of witnesses will engage in a productive discussion aimed at identifying shared principles around which all stakeholders can coalesce and build on to ensure Federal ASD activities are carried out in the most efficient and effective manner possible.

The Centers for Disease Control and Prevention (CDC) estimates that 1 in 68 children in the United States are living with ASD. This is clearly a serious public health challenge, as millions of individuals must battle daily with symptoms that vary greatly in severity and scope, but often involve impaired social interactions, problems with verbal and nonverbal communication, and repetitive behaviors.

According to the CDC, it is estimated to cost at least \$17,000 more per year to care for a child with ASD compared to a child without ASD, with costs arising in the form of medical and nonmedical expenses, ranging from medicines, therapies, and special education; to caregiver time and adult housing. A recent National Institutes of Health (NIH) study concluded, "The economic burden associated with ASD is substantial and can be measured across multiple sectors of our society," and calculated that the total societal costs of caring for children with ASD exceeded \$9 billion in 2011.

In passing the Combating Autism Act of 2006, and subsequently reauthorizing the Act in 2011, Congress began to address the rising rate of ASD and established the IACC to coordinate all efforts within the Department of Health and Human Services (HHS) concerning ASD. According to the IACC charter, "The Committee's primary mission is to provide advice to the Secretary of Health and Human Services on matters concerning autism spectrum disorder and to facilitate the efficient and effective exchange of information on autism activities among the member agencies in order to enhance coordination of autism-related programs and activities."

Creating the IACC was an important first step in ensuring that the Federal response to ASD responsibly leverages taxpayer dollars to engage in a systematic and comprehensive approach to autism research and treatment activities across government, academia, and the private sector. However, based on GAO's recent reviews of the IACC, which concluded that, "better data and more coordination needed to help avoid the potential for unnecessary duplication," I am concerned that the Federal Advisory Committee Congress established to coordinate Federal ASD activities is, according to GAO, relying on data that is, "outdated, not tracked over time, inconsistent, and incomplete." Of course, we must recognize that GAO only addressed *potential* duplication of Federal ASD activities.

(OVER)

As GAO has consistently and transparently stated in these same reports, “Determining actual duplication for research projects would require a more extensive review of voluminous and scientific data, and was beyond the scope of this study.” Further, HHS makes a fair point in noting that duplication, in and of itself, is not necessarily a negative characteristic with respect to effectively conducting scientific research activities.

I look forward to learning more about what the IACC plans to do to enhance the reliability and usability of its data. Specifically, I want to examine how all stakeholders will work together to improve the quality of IACC data to enhance coordination and monitoring of Federal autism activities, and how the Departments of Defense, Education, HHS, and the National Science Foundation will better coordinate ASD research activities to ensure we get the most “bang for our buck” from finite taxpayer resources.

As the U.S. Government Accountability Office (GAO) will testify today, researchers have yet to identify the root causes of autism and there are no known cures. Thus, it is absolutely vital that we sustain our Nation’s robust commitment to funding Federal scientific research that may enhance our knowledge of the disease and improve treatment options for individuals coping with ASD.

It is important to note that additional hearings and legislation, if necessary, may be beneficial in spurring Federal efforts to improve our utilization of Federal ASD research dollars. However, we must all recognize that our ultimate success in realizing breakthrough discoveries, treatments, and therapies, will depend on the dedicated work of our highly-skilled Federal employees at NIH, HHS, and CDC.

Congress would be penny wise and pound foolish to continue degrading and demoralizing these Federal workers through harmful pay freezes and arbitrary workforce cuts. After all, it is these very same dedicated career civil servants that Congress has tasked to carry out the mission of implementing these ASD research initiatives.

In closing, if there is one singular principle that we all can embrace, surely it is that no family or child should be forced to face living with ASD alone – particularly when we know that early detection and intervention can make a dramatic difference in the quality of life for an individual living with ASD. I look forward to hearing about how we can improve the efficiency and effectiveness of the Federal response to ASD, and want to thank our witnesses for participating in today’s important hearing.

-END-

GAO Highlights

Highlights of GAO-14-613T, a testimony before the Subcommittee on Government Operations, Committee on Oversight and Government Reform, House of Representatives

Why GAO Did This Study

Autism—a developmental disorder involving communication and social impairment—is an important public health concern. From fiscal years 2008 through 2012, 12 federal agencies awarded at least \$1.4 billion to support autism research and other autism-related activities. The Combating Autism Act directed the IACC to coordinate HHS autism activities and monitor all federal autism activities. It also required the IACC to develop and annually update a strategic plan for autism research. This plan is organized into 7 research areas that contain specific objectives.

This statement is based on GAO's November 2013 report, GAO-14-16, with selected updates. It discusses federal autism activities, including (1) the extent to which federal agencies fund potentially duplicative autism research, and (2) the extent to which IACC and agencies coordinate and monitor federal autism activities. GAO analyzed agencies' data and documents, and interviewed federal agency officials.

What GAO Recommends

GAO recommended in November 2013 that HHS improve IACC data to enhance coordination and monitoring. HHS disagreed and stated its efforts were already adequate. GAO also recommended that DOD, Education, HHS, and NSF improve coordination. The agencies supported improved coordination, but most disputed that duplication occurs. GAO continues to believe the recommendations are warranted and actions needed.

View GAO-14-613T. For more information, contact Marcia Crosse at (202) 512-7114 or crossm@gao.gov.

May 20, 2014

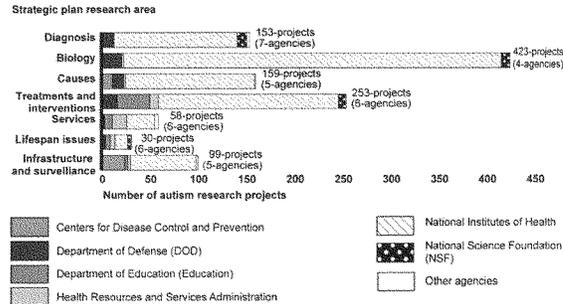
FEDERAL AUTISM ACTIVITIES

Funding and Coordination Efforts

What GAO Found

Eighty-four percent of the autism research projects funded by federal agencies had the potential to be duplicative. Of the 1,206 autism research projects funded by federal agencies from fiscal years 2008 through 2012, 1,018 projects were potentially duplicative because the projects were categorized to the same objectives in the Interagency Autism Coordinating Committee's (IACC) strategic plan. Funding similar research on the same topic is sometimes appropriate—for example, for purposes of replicating or corroborating results—but in other instances funding similar research may lead to unnecessary duplication. Each agency funded at least 1 autism research project in the same strategic plan objective as another agency and at least 4 agencies funded autism research in the same research area.

Number of Federal Agencies' Autism Research Projects Funded, by Research Area, Fiscal Years 2008 through 2012



Source: GAO analysis of data from the Interagency Autism Coordinating Committee (IACC) and federal agencies that funded autism research.

Note: Thirty-one of the 1,206 projects funded by federal agencies from fiscal years 2008 through 2012 are not included in this figure because they were not categorized to a specific research area. At the time of GAO's review, DOD had not submitted data on its fiscal year 2012 research projects, and therefore they were not included in this figure. The "other agencies" are: Administration for Children and Families, Agency for Healthcare Research and Quality, Centers for Medicare & Medicaid Services, Environmental Protection Agency, and the Substance Abuse and Mental Health Services Administration. Not all of these "other agencies" necessarily funded projects in every research area.

The IACC and federal agencies may have missed opportunities to coordinate and reduce the risk of duplicating effort and resources. GAO found that the IACC is not focused on the prevention of duplication, and its efforts to coordinate the Department of Health and Human Services' (HHS) autism research and monitor all federal autism activities were hindered by limitations with the data it collects. Apart from federal agencies' participation on the IACC, there were limited instances of agency coordination, and the agencies did not have robust or routine procedures for monitoring federal autism activities.

STATEMENT OF DONALD J. MUELLER
Executive Director, Marcus Autism Center
Vice President, Operations, Children's Healthcare of Atlanta

Hearing on Examining the Federal Response to Autism Spectrum Disorder
Government Operations Subcommittee
House Committee on Oversight and Government Reform
May 20, 2014

On behalf of the Marcus Autism Center, I am pleased to provide the Subcommittee our thinking about the societal and public policy ramifications of the research on Autism Spectrum Disorders (ASD) taking place at our Center and elsewhere in the Nation.

Marcus Autism Center is a not-for-profit organization and subsidiary of Children's Healthcare of Atlanta that treats more than 5,500 children with autism and related disorders a year. As one of the largest autism centers in the U.S. and one of only three National Institutes of Health (NIH) Autism Centers of Excellence, Marcus Autism Center offers families access to the latest research, comprehensive evaluations and intensive behavior treatments. With the help of research grants, community support and government funding, we aim to maximize the potential of children with autism today and transform the nature of autism for future generations. We also benefit greatly from our ongoing partnerships with other stakeholders in the ASD community, including Autism Speaks and other groups and institutions.

We are very grateful for the support provided by NIH to our researchers, who are led by our Director, Dr. Ami Klin, whose overarching research strategy has two main areas of focus— early detection and early intervention. This will be accomplished, in part, by further developing the science described in Dr. Klin's recent article in *Nature*.¹ In this publication, Dr. Klin is able to identify signs of autism present already in the first 2 to 6 months of life, thereby opening a window for even earlier diagnosis and intervention in the future. This can create significant societal and economic benefits because we know that you can reduce the lifetime cost of autism by as much as two-thirds if a child can access evidence-based early intervention. When one considers that current projections are over \$3 million in such lifetime costs for one person, and you think about the two million or more Americans who are or will be diagnosed with ASD, you can see the value proposition inherent in emphasizing research that will lead to the earliest possible diagnosis and intervention.

As you continue to review the federal response to autism and federal spending priorities, I want to share with you a concern that we have shared with officials at the U.S. Department of Health and Human Services and the U.S. Department of Education in recent months, which is that in the near future, special education funding under the Individuals with Disabilities Act (IDEA) and resources allocated to states under the Maternal and Child Health (MCH) block grant program will not likely keep up with the increasing early diagnosis of young children with ASD.

¹ "Attention to eyes is present but in decline in 2–6-month-old infants later diagnosed with autism" (W. Jones and A. Klin, *Nature* 504, 427–431, 19 December 2013).

For almost 40 years, IDEA has mandated that children with disabilities receive a free appropriate public education to meet their unique needs and prepare them for further education, employment, and independent living. Of particular note is that IDEA Part C recognizes the particular need for identifying and reaching very young children with disabilities and provides guidelines concerning the funding and services State and local governments should provide for children from birth through 3 years of age.

At present, IDEA is by no means fully funded. Over the years, Congress set a maximum target for the federal contribution to special education spending at 40 percent of the estimated excess cost of educating children with disabilities. Currently it funds less than half of that obligation. At the same time, we have seen fairly flat funding for IDEA Part C in recent appropriations bills, with federal funding for the Part C program this year (\$438 million) roughly the same or slightly lower than Fiscal Years 2009-2012. Similarly, the MCH Block Grant, which permits HRSA to allocate funds to states for a wide variety of purposes, including ASD screening and professional training, has been constrained in recent years, going from \$656 million to \$634 million in the current fiscal year.

At the same time that we are witnessing essentially flat federal funding of these programs that are so critical to ASD children and their families, we are seeing exponential growth in the number of children diagnosed and significant strides in scientific research that permits earlier and earlier diagnoses and interventions.

For example, in March, the Centers for Disease Control reported that an estimated 1 in 68 children are being identified with Autism Spectrum Disorder, a figure roughly 30% higher than the estimate for 2008 (1 in 88) and roughly 60% higher than the estimate for 2006 (1 in 110) and more than twice as frequent as the 1 in 150 children estimated in 2000. From the research conducted by internationally prominent researchers such as our Dr. Ami Klin, we now understand that children with autism can be diagnosed as early as eighteen months old, and as noted earlier could possibly one day soon receive a diagnosis as early as six months. As noted above, the recent study by Dr. Klin and Dr. Warren Jones of our Center published in Nature received international attention because if one can identify a child who is likely to be clinically diagnosed with ASD as early as six months, it means that intervention and treatment can start earlier than ever previously thought possible. This could dramatically improve the quality of life for children with autism, permit them to have more fulfilling and productive lives, and could substantially lower the costs associated with their education and health care.

With new advances in scientific research relating to autism, it is important that federal agencies charged with providing special education as well as health care funding are sufficiently aware of and taking into account that the average age of diagnosis could in the very near term drop from ages 4 and 5 to toddlers and younger. IDEA and to some extent the MCH Block Grant are failing to keep up with existing needs of the populations they were designed to cover and we expect that as earlier diagnoses occur increasingly throughout the nation, without a concerted effort by Congress and the Administration, funding will continue to fall behind in covering the needs of children with autism and other special needs.

Along these lines, although this Committee does not have primary legislative jurisdiction for legislation reauthorizing the Combating Autism Act, I would like to share my concern that the current Act insufficiently prioritizes early diagnosis research and implementation of tools that will lower the average age of early identification. If the government fails to facilitate the earliest intervention possible, it will adversely impact lifelong quality outcomes and will miss the opportunity to reduce significantly the costs of autism. In addition, IDEA Part C funding is insufficient for autism early intervention. For example, the Early Intervention system in Georgia is funded thru IDEA block grants. Right now in Georgia, I am advised that children receive 1-2 hours per week of therapy, which falls far short of the 20 hours/week of intensive therapy that evidence has shown is necessary on average. Accordingly, the federal response to autism should include amending the Combating Autism Act to prioritize and increase funding for early identification and intervention under age of 5 and should also require consistency among States in autism identification tools used to reduce the age of diagnosis. To the extent that Congress is unwilling to increase IDEA Part C block grant funding levels, HRSA should receive an increased authorization for early intervention spending, which would provide early intervention providers with additional hours of service they could offer to children with autism and related disorders.

Lastly, the federal response would be more efficient if Congress amends the Combating Autism Act to provide that the area of implementation science/healthcare delivery system research will be a greater focus of research funded via this law. Given the varied growth in reimbursement platforms for autism service delivery and the interdependence of service delivery upon various public infrastructures, it is critical that the government fund research on health care access, use, disparities and adherence; comparative effectiveness; quality of care; the impact of policies on clinical practice (and vice versa); and the overall patient care experience.

I can't over-emphasize the importance of the value proposition of early intervention. The negative associated disabilities of autism are not inevitable. If we can identify children early and provide evidence-based interventions, we can save our children from a lifetime of support. This is a good use of our resources, as it will ultimately reduce the cost of services needed to support these children and their families for years to come. Aligning our financial allocations with the scientific discoveries and service delivery is not only good for our society, it's good business.

Thank you for the opportunity to share our views on the federal response to Autism Spectrum Disorder.



**Testimony Submitted to the Record to the
House of Representatives
Committee on Oversight and Government Reform
Subcommittee on Government Operations
Hearing of May 20, 2014**

Examining the Federal Response to Autism Spectrum Disorders

By most measures, the federal response to autism is failing the autism community and the American people at large. If the federal response to autism spectrum disorders was adequate, we could point to a national policy on autism, a national strategy for prevention and treatment, as well as providing services and education across the lifespan for autism. To date, these do not exist.

If the federal response to autism was adequate, our public health agencies would have embraced the community, listened to the parents and scientists, and acknowledged the reality that about 50 percent of autism is related to environmental factors. They would have gotten serious about investigating these factors and educating parents and parents-to-be about how to avoid exposure. If the federal response to autism was adequate we would see the available resources effectively invested to obtain the answers we need. This has not occurred.

If the federal response to autism was adequate, by now, we would be seeing the prevalence numbers begin to decrease. Rather than decrease, the autism prevalence rates have continued to rise, to a new and even more alarming rate of 1 in 68 in children born in 2002, up from 1 in 150 in children born in 1992.

For almost 15 years, SafeMinds has been coming to legislators and asking you to engage in active oversight on the issues surrounding the epidemic increase in the prevalence of autism.

In July 2000¹, representatives of SafeMinds presented to the House Government Reform Committee the paper, *Autism, a Novel Form of Mercury Poisoning*² outlining similarities between the symptoms of mercury poisoning and autism spectrum disorders. At the time, we called for an immediate recall of thimerosal-containing vaccines given to children. The then Chairman, Dan Burton, wrote to Health and Human Services Secretary Shalala asking for an immediate recall, a request that was also rejected. At least two Citizen's Petitions to the Food and Drug Administration (FDA) were submitted from concerned organizations but not acted on.

In September 2004, Lyn Redwood, RN, MSN of SafeMinds testified at a hearing³ "It has been five years since the Public Health Service (PHS) and the American Academy of Pediatrics (AAP) first announced that thimerosal should be removed from vaccines. At that time, taking the appropriate position of caution, the PHS and AAP announced to the public and practitioners: "...because any potential risk is of concern, the Public Health Service (PHS), the American Academy of Pediatrics (AAP), and vaccine manufacturers

¹ (2000) Mercury in Medicine-Are We Taking Unnecessary Risks? Serial No. 106-232. Washington, DC, Government Printing Office.

² Bernard, S., et al. (2001). "Autism: a novel form of mercury poisoning." *Med Hypotheses* 56(4): 462-471.

³ (2004) Truth Revealed: New Scientific Discoveries Regarding Mercury in Medicine and Autism. Serial No. 108-262. Washington, DC, Government Printing Office.

agree that thimerosal-containing vaccines should be removed as soon as possible.”... we could not have imagined that in 2004 thimerosal would still be in vaccines and that the government agencies tasked with protecting the public would have failed to take aggressive action to get the mercury out and protect our nation’s children. We could not have imagined that they would, instead, have focused their energies on avoiding or hiding the truth that is before them, and in doing so undercut the public’s trust while continuing to put babies at risk for mercury injury.”

In November 2012⁴, Mark Blaxill of SafeMinds testified, “In the face of a national emergency, government agencies, especially CDC and NIH, have performed poorly and behaved badly. We need accountable, new leadership on autism at the NIH and the CDC. ...We need to stop investing in the autism gene hunt and identify what has changed in the environment that could have possibly injured so many children. We need to conduct independent research into the great unmentionables, mercury and vaccines, connections that we’ve documented in the earliest cases.”

SafeMinds provided three reports⁵ to the Committee regarding autism and associated issues. We are including the 2012 SafeMinds statement on the Federal Response to Autism with this current statement as this data remains relevant and ask that this statement and all its attachments be included in today’s hearing record and transcript.

In 2000, SafeMinds and the entire autism community wanted to remove mercury in vaccines from the autism equation as quickly as possible so that we might move on to addressing other factors. Even after 85 years in the market place, there is no scientific evidence to validate a safe exposure level for thimerosal, yet the FDA continues to allow it to be injected into pregnant women and infants. Mercury in all its forms is a potent toxin that can harm the brain, kidneys and heart. Like lead, it has no place in products we consume, use in our homes, or in any of our medicines.

In December 2012, SafeMinds published the Summary of Supportive Science Regarding Thimerosal Removal⁶ which provided an in depth resource on the body of research on thimerosal, rather than the handful of studies that federal authorities suggest validate its safety. The whole body of evidence supports removal of thimerosal from vaccines and all FDA-regulated products.

⁴ (2012) 1 in 88: A Look into the Federal Response to Rising Rates of Autism Serial No. 112-194. Washington, DC, Government Printing Office

⁵ SafeMinds provided 3 reports to the Oversight Committee in November 2012: (1) Autism, a National Emergency A SafeMinds Report on the Federal Response <http://www.SafeMinds.org/government-affairs/documents/SafeMinds%20Autism%20Nov%202012.pdf>; (2) Poul Thorsen, MD, PhD – CDC Researcher -Fugitive From Justice <http://www.SafeMinds.org/government-affairs/documents/Thorsen%20Background%20Report%20-%20Nov%202012.pdf>; (3) A Review of the Vaccine Injury Compensation Program - Is Justice Being Served? <http://www.SafeMinds.org/blog/2013/04/07/the-house-committee-on-oversight-and-government-reform/documents/SafeMinds-vicp-report-final5.20.12.pdf>

⁶ <http://www.SafeMinds.org/research/docs/Thimerosal%20Science%20Summary%20Dec%202012.pdf>

It has been 14 years since we first asked for thimerosal to be removed from vaccines, but pregnant women and infants are still exposed to mercury through vaccines. How long must the American people wait for totally neurotoxin free vaccines?

Integrity, Accountability and Transparency: The challenges and frustrations that members of Congress have expressed about obtaining information from this Administration on issues ranging from the Benghazi attack, Fast and Furious, and the implementation of the Affordable Care Act and the Bush Administration on War on Terror interrogation techniques and weapons of mass destruction are alarmingly similar to what we have been dealing with for almost 15 years in Republican and Democratic administrations alike. Compounding those frustrations for the autism community is the reality that we are managing the care of an individual with autism, we are bullied in the media and misrepresented as 'anti-vaccine' simply for asking for safer vaccines.

Representatives of various agencies of the Department of Health and Human Services have come before Congress and repeatedly, since 2000, denied any correlation between exposure to mercury, and/or vaccine injury and the onset of autism, even when their own data show otherwise. We now know from independent research that at least 83 families were compensated through the Vaccine Injury Compensation Program whose child suffered brain injury from vaccine reactions and developed autism.⁷ Congress never heard about these families from the individuals managing this program. Even when made public, there is a rejection of the truth.

If one reviews the transcript from the November 2012 hearing and the agencies' responses to questions, you find that most of the questions were not actually answered. In one partial response, the CDC reported back to the Committee that they have chosen not to retract the studies conducted by Dr. Poul Thorsen. This key player in the Danish research continues to live and work in Denmark more than three years after his US Federal indictment on 22 counts of money laundering and fraud. The CDC has grossly misrepresented his access to the data and his role in the Danish studies for fear that their house of cards created to defend their position on thimerosal and autism will collapse around them.

If Congress were willing to make it a priority, getting to the truth about the federal response to autism and all of the underlying factors could warrant a special committee. Autism affects over a million US children and has many issues of misconduct, malfeasance, waste, fraud and abuse.

Imbalance in Funding: Since the 2012 hearing, the Government Accountability Office issued a report⁸ in which eighty-four percent of the autism research projects funded by federal agencies had the potential to be duplicative. This conclusion mirrors the frustrations expressed by many within the autism community that there is inadequate

⁷ <http://digitalcommons.pace.edu/cgi/viewcontent.cgi?article=1681&context=pehr>

⁸ <http://www.gao.gov/assets/660/659147.pdf>

coordination of research and an imbalance in research funding between genetics and environmental factors. Valuable time and precious resources have been lost because of a refusal to address environmental factors aggressively.

Two recent studies confirm what parents have been telling Congress and the NIH all along – that their child’s autism is related to one or more environmental factors. A study out of Sweden published in the *Journal of the American Medical Association*⁹ looking at more than 14,000 children with autism spectrum disorder found an equal risk contribution from genetics and environmental factors. A second study¹⁰ conducted at Stanford, which was the largest population-based twin study of autism using contemporary standard of diagnosis of autism found that environmental factors common to twins explain about 55% of the risk of autism. The authors of the study stated, “Although genetic factors also play an important role, they are of substantially lower magnitude than estimates from prior twin studies of autism.”

Legislative Solutions: SafeMinds has joined forces with other autism organizations to form the Autism Policy Reform Coalition (APRC). We are organizations in service of people with Autism who are coming together for the purpose of proposing meaningful legislation that will make a difference in the lives of those with Autism - their families, physicians, communities, and our nation. The following organizations are represented as APRC: National Autism Association (NAA), Generation Rescue, Talk About Curing Autism (TACA), Autism is Medical (AIM), Autism Trust U.S.A., D.A.I.R. Foundation (Defending Academic Integrity and Research), SafeMinds, Thinking Moms Revolution (TMR).

APRC’s policy requirements for support of CAA reauthorization include:

1. Creating an Office of National Autism Policy Coordination, in the Executive Office of the President, modeled on the structure and purpose of the Office of National Drug Control Policy. This office would develop, implement, and evaluate a measurable, national strategy on all non-DHHS aspects of Federal autism policies and practices — including wandering, victimization, education, employment, housing, and other relevant issues. The Office would be directly accountable to Congress, the President, and most importantly, autism community stakeholders and all taxpayers.
2. Creating an Office of Autism Research at the National Institutes of Health (NIH), modeled on the highly-successful Office of AIDS Research. This would put budgetary accountability into the Strategic Plan for Autism Research, and reorient NIH research priorities away from further disproportionate spending on basic science and genetics. The office would promote more proportionate spending on

⁹ Sandin S, Lichtenstein P, Kuja-Halkola R, Larsson H, Hultman CM, Reichenberg A. The Familial Risk of Autism. *JAMA*. 2014;311(17):1770-1777. doi:10.1001/jama.2014.4144.

¹⁰ Hallmayer J, Cleveland S, Torres A, et al. Genetic Heritability and Shared Environmental Factors Among Twin Pairs With Autism. *Arch Gen Psychiatry*. 2011;68(11):1095-1102. doi:10.1001/archgenpsychiatry.2011.76.

environmental factors research, prevention, and translational research aimed at improving the quality of life of those facing autism.

3. Mandating research by HRSA on best practices for medical treatment of people with autism, including development of special population standards of care for co-occurring medical conditions associated with autism such as gastrointestinal, seizure and metabolic disorders.
4. Requiring meaningful parent advocate involvement in the planning of all government autism activities, modeled on the input structures existing in the Department of Defense (DOD) CDMRP program.
5. Improving the CDC's epidemiology on autism by improving the methods used to assess prevalence rates, expanding the states and ages reported, and speeding up the reporting.

About SafeMinds

SafeMinds was founded in 2000 with an ultimate goal to find the truth about the mercury-autism hypothesis. Our founders published the landmark paper, "Autism, A Novel Form of Mercury Poisoning." SafeMinds is the driving force pushing forward science that links environmental factors, such as mercury, to autism. We have sponsored approximately \$1.5 million in research related specifically to mercury and adverse neurological outcomes. This level of financial commitment establishes SafeMinds as the largest private, non-profit organization funding mercury and autism-related research.

We believe that the epidemic of childhood autism and the disabilities that accompany autism will end when our environment, food, and health care products are universally safe and non-toxic. SafeMinds works for justice, accountability and integrity in science and public policy as a means for preventing these disabilities in future generations. We educate and empower people, focus on prevention and fund research to find treatments that will lead to recovery for those living with autism.

Autism Spectrum Disorders are complex conditions, affecting individuals to varying degrees. Those living with autism, or caring for someone with autism have many needs, which the Federal government plays a major role in providing. We need to more effectively join forces in policy, planning and research to ensure that the needs across the life span are met.

Attachments

2012 Autism Report

Responses from Michael K. Yudin, Acting Assistant Secretary
Office of Special Education and Rehabilitative Services (OSERS)
U.S. Department of Education

To Representative Posey (FL-8) Questions for the Record
Received on June 2, 2014

From the May 20, 2014 Hearing
Before the
House Oversight and Government Reform's Subcommittee on Government Operations
on
"Examining the Federal Response to Autism Spectrum Disorders"

Submitted to the Subcommittee on July 2, 2014

1. At what age do individuals with disabilities like autism 'age out' of the education system?

Response:

The Individuals with Disabilities Education Act (IDEA) requires States, as a condition of receiving IDEA Part B grants, to ensure that a free appropriate public education (FAPE) is made available for children with disabilities, including those with autism and other intellectual and developmental disabilities. Entitlement to FAPE begins at a child's third birthday and runs through age 18. States have the option to make FAPE available to students for ages beyond 18 until a student turns 22, as determined by State law or practice. Beyond age 21, some states continue to provide secondary education for children with disabilities, though such services are not provided under the auspices of IDEA.

In addition to services at the primary and secondary level, youth and adult individuals with disabilities, including individuals with autism, are eligible for career and technical education and adult education programs, facilitated by reasonable accommodations provided under Section 504 of the Rehabilitation Act. Individuals with autism served under the Department's vocational rehabilitation program have a higher rehabilitation rate than individuals in the program generally.

- a. Given the dramatic increase in autism prevalence, do you believe that communities across the country are able to provide transition services?

Response: Comprehensive and effective transition services for children in all disability categories are in great demand. We believe that there are shortages in specialized personnel trained to provide transition services and limitations in capacity at the local level. We are dedicated to supporting the training of personnel in providing transition services and, in 2014, are supporting grants under the Special Education Personnel Preparation program to do so. In addition, we are providing support across a number of programs to support the establishment of a new national technical assistance center focused on providing technical assistance to States and localities. This technical assistance will promote effective transition services for youth with disabilities and support states and localities in fostering cooperation between schools and vocational rehabilitation agencies, to help ensure that youth leaving the secondary education

system have the resources they need to obtain competitive employment or succeed in postsecondary education.

The Department has also requested \$100 million in fiscal year 2015 to support Results Driven Accountability Incentive Grants, which would help support States as they identify and address critical needs in improving results for children with disabilities, including supporting local agencies in improving the supports for individuals transitioning into college and careers.

In addition to transition services-related grants and technical assistance, the Department is also a leader, along with the Social Security Administration, in the PROMISE (Promoting Readiness of Minors in Supplemental Security Income) grant initiative, which seeks to identify best practices to support youth with disabilities and their families who receive supplemental security insurance to become self-sufficient. The Department of Education is also working with the Departments of Labor, Health and Human Services, and the Corporation for National and Community Service on Performance Partnership Pilots, which could enable States, localities, and/or Tribes to test innovative, cost-effective, and outcome-focused strategies to achieve significant improvements for disconnected youth, many of whom also are youth with disabilities. Disconnected youth are those youth ages 14-24 who are neither in school nor employed. In many cases, they face the additional challenges of being homeless, in foster care, or involved in the justice system. The Department of Labor has also awarded over \$81 million to 26 states since 2010 through its Disability Employment Initiative (DEI) to improve education, training, and employment opportunities and outcomes of youth and adults who are unemployed, underemployed, or receiving Social Security disability benefits, by refining and expanding already identified successful public workforce strategies. Seven DEI projects have selected youth, including transitioning youth, as their focus.

- b. Do you see a role for local charities, churches and businesses in addressing transition services, employment, and job training for individuals with autism?

Response: Non-profit and social service organizations can provide critical support to individuals with disabilities, including individuals with autism, and their families. These organizations, as well as for-profit businesses, often operate as related services providers for families, school districts, or vocational rehabilitation agencies, either using their own funding or on a fee-for-service basis.

They also play a key role in expanding services such as supported employment, where demand has recently exceeded the supply of services funded through Federal grants, and are often providers of specialized job training and employment services such as work evaluation, work adjustment, and workplace skills training. Many of our transition services related grantees often partner with non-profit organizations in local communities. Many local charities and faith-based organizations host job clubs, community convenings that play an important function in helping unemployed community members find a new job, and manage the challenges associated with unemployment.

- c. Does the Department have information regarding individuals with autism who go on to college, graduate school, and/or technical schools and complete their education?

Response: Yes, according to data from the National Longitudinal Transition Study-2, 43.9 percent of students with autism in the study enrolled in some type of postsecondary education. Information is available at: http://www.nlts2.org/reports/2011_09_02/nlts2_report_2011_09_02_complete.pdf

2. One of the greatest challenges for states and federal policy makers is forward planning for the breadth of services that will be needed for adults with autism – everything from housing, to transition services, to employment and training program and Medicaid. Is the Dept. of Education able, and if so, will the Department begin providing to the public on an annual basis a state-by-state breakdown on the number of individuals who ‘age out’ of the education system?

Response: The Department annually collects and publicly reports the number of students with disabilities, ages 14 through 21, who exited special education because of reaching the maximum age for receipt of special education services. These counts are collected and reported by primary disability category, race/ethnicity, gender, and limited English proficiency status. For example, in 2011-12, 847 students with autism, ages 14 through 21, exited special education because of reaching the maximum age for receipt of special education services in the U.S., Outlying Areas, and Freely Associated States. This represents approximately 4 percent of the total number of students with autism, ages 14 through 21, who exited special education in 2011-12.

In comparison, 10,806 students with autism ages 14 through 21 (approximately 46 percent), exited special education by receiving a regular high school diploma in the U.S., Outlying Areas, and Freely Associated States. The state-level counts of students with disabilities, ages 14 through 21, who exited special education because of reaching maximum age for receipt of special education services in 2011-12 are published at: <https://explore.data.gov/Education/2011-2012-IDEA-Part-B-Exiting/7mdz-8ya4#column-menu>.

3. The CDC recently published a study regarding the prevalence of autism. Not all of the states in the study were able to obtain school data, which may have skewed the outcomes. (The 1 in 68 number increases to 1 in 58 when the states without education data were removed from the calculation.) What is the Department of Education doing to cooperate with these studies? How can we improve this cooperation?

Response: The decision to provide access to educational records as part of a CDC surveillance study is a state and local educational agency decision. The Department of Education has no authority to mandate participation in a study conducted by another agency.

The CDC does not collect data directly from the Department (although it has access to the data published pursuant to Sec 618 of IDEA)

We note that the Department collects the number of children with disabilities, ages 3 through 21, who are identified with a primary disability of autism at the school, district, and state level on an annual basis. IDEA autism data is an actual census of children who have been individually evaluated under the detailed procedures spelled out at 34 CFR Part 300, and been found to require special education and related services. The state-level counts of children with autism,

ages 3 through 21, in 2012 are publicly reported at: <https://explore.data.gov/Education/2012-IDEA-Part-B-Child-Count-and-Educational-Envir/5t72-4535>.

The Department does not publicly report the school and district level counts of children with autism.

4. With such a dramatic increase in the numbers of those with autism in the school system, what additional resources are needed by schools – i.e. speech and language therapist, occupational therapists, additional aids in the classroom, communication assistive devices? Are school systems having troubling finding adequately trained personnel to fill these slots? Are their special federal education grants for these specialized careers?

Response: States are in the best position to report on the resource needs of their schools. Each year, the Department funds grants to support the training of special education and related services personnel under the Personnel Preparation program. In FY 2013, the program supported 246 such grants preparing personnel at the master's and doctoral level in special education and related services, in addition to supporting 47 grants to institutions to improve the quality of their preparation programs.

5. One of the great tragedies in the autism community is the issue of wandering and elopement. All too many children wander away from homes, schools, and other care providers and end up dying from drowning. Please explain what schools should do to insure this does not occur?

Response: Wandering can happen under any type of school supervision, and in any school environment, but particularly where there are unlocked doors, open spaces (such as playgrounds), and during classroom transitions or student transportation. It is important, therefore, that teachers and other school staff are aware of this behavior, are trained to detect it, and have systems in place to deal with the problem.

School safety personnel should be alerted and trained to emphasize that their duties include two-way supervision of school perimeters both physically and through monitoring alarms and surveillance systems. Keeping potential wanderers in school is a multi-layered responsibility that extends beyond just classroom teachers and instructional aides.

School emergency, safety, or "all risk" plans should include special consideration for the safety of students with disabilities, including those with autism. There should be protocols for immediate communication with local law enforcement agencies if a student is missing and those agencies should have been briefed on the special characteristics of students with autism and their probable behaviors. Emergency plans can also prioritize attention to high risk environments near schools – ponds, rail lines, notable traffic hazards, and dangerous equipment near schools can be assessed and can often be fenced, alarmed, or physically barricaded. Schools should work within the community to identify and reduce environmental risks.

School health and wellness coursework for students often includes safety training, including water safety, and the training should be accessible to students with disabilities, including autism.

Response from Dr. Thomas R. Insel
Director, National Institute of Mental Health (NIMH)
Chair, Interagency Autism Coordinating Committee (IACC)
National Institute of Health
U.S. Department of Health and Human Services

To Representative Posey
Representative from Florida
U.S. House of Representatives

Hearing on:
“Examining the Federal Response to Autism Spectrum Disorders”

- 1. Following up on our discussion at the May 20th hearing, you indicated that you would provide me with additional information on the following: A list of those at NIH who make the final funding decisions for NIH’s Autism research grants, including their financial disclosure statements. A list of all of those serving on review committees that review autism-related grants, and including their financial disclosure statements.**

Response: The following response reflects the practice and policies of the NIH regarding funding decisions for grants. Several NIH Institutes and Centers (ICs) support research on autism spectrum disorder (ASD), including the National Institute of Mental Health (NIMH), the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), the National Institute of Environmental Health Sciences (NIEHS), The National Institute of Neurological Disorders and Stroke (NINDS), and the National Institute on Deafness and Other Communication Disorders (NIDCD). The director of the NIH Institute that is supporting the research award makes the final decision on the support of research grants. A list of the IC directors is available on the NIH website.¹

Prior to final funding decisions, all research applications, including those on autism, go through the NIH peer review process. The first level of review is carried out by a Scientific Review Group (SRG) composed of non-federal scientists who have expertise in relevant scientific disciplines and current research areas, and, where appropriate, community stakeholders. Autism grant applications received by the NIH are not reviewed by a single dedicated SRG, but instead are distributed across several SRGs according to the type of science they contain. This first level of review provides an assessment of scientific merit. The second level of review is performed by the Institute and Center (IC) National Advisory Councils or Boards. Under the Federal Advisory Committee Act, the Secretary selects the members of each Council or Board for their expertise, interest, or activities related to the IC’s research on particular areas of health, diseases, or conditions. Councils are composed of both scientific and public representatives. The Advisory Council makes recommendations regarding institute priorities and the merit of individual grant applications to the IC Directors, who make the final funding decisions.

¹ <http://www.nih.gov/icd/icdirectors.htm>

The NIH peer review system is mandated by statute (e.g., sections 492 and 492A of the Public Health Service Act). NIH policy is intended to promote a process whereby grant applications submitted to the NIH are evaluated on the basis of process that is fair, equitable, timely, and free of bias.

Information on the SRGs can be found on the NIH Center for Scientific Review website,² as can information about specific study sections.³ NIH posts rosters of the individuals who are members of SRGs, and an investigator is aware of the study section to which his/her institution's application has been referred.

The membership rosters of the Institute and Center Advisory Councils can be found on the home page website of each IC under "Advisory Council."⁴

Regarding your request for financial disclosure records, these forms contain an individual's personal and sensitive financial information, and this is not information that is releasable in a public document such as questions for the record. The appropriate NIH staff can work with your staff to identify the type of information that would be responsive to your inquiry.

2. **One of the biggest complaints from autism parents is the funding disparity between research investigating environmental factors and genetics research. During the hearing you discussed, genetics, genomics, and environmental factors. Please provide a layman's explanation of these three areas of causation research, how they are inter-related and what is known about pre-natal environmental exposures including medicines, household cleaners, and other common potential environmental factors that may contribute to a child's developing autism.**

Response: There is a subset of parents who feel strongly that the primary goal of autism research should be to identify a specific environmental cause. There are, however, many other community stakeholders who are more interested in other issues such as the development of effective treatments, or service provision for children, transition age youth and adults.

In Fiscal Year (FY) 2012, the most recent year for which NIH has a breakdown of autism research by risk factors, NIH supported approximately \$29 million in research toward understanding both genetic and environmental risk factors that may contribute to the development of autism spectrum disorder (ASD), as broken out by the chart below this answer. Of this total, approximately 28 percent supports research on genetic risk factors, while 72 percent supports research on: environmental factors (12 percent), gene-environment interactions (42 percent), and epigenetics research (18 percent).

NIH supports many studies investigating the contributions of environmental factors to ASD risk. These include the Childhood Autism Risks from Genetics and the Environment (CHARGE), Markers of Autism Risk in Babies Learning Early Signs (MARBLES), and the Autism Birth Cohort (ABC) Study of prospective autism risk in a large birth cohort in Norway, which are

² <http://public.csr.nih.gov/Pages/default.aspx>

³ <http://public.csr.nih.gov/StudySections/Pages/default.aspx>

⁴ A list of all the NIH Institutes can be found at, <http://www.nih.gov/icd/>.

using data from medical records, interviews, questionnaires, developmental assessments, and physical exams to explore a host of possible risk factors, focusing heavily on factors in the environment before, during, and after pregnancy. The CHARGE study has identified a number of possible risk factors that, combined with other genetic and environmental risk factors, may potentially contribute to the development of ASD, including: air pollution; maternal health conditions such as obesity, diabetes, and hypertension; and maternal influenza infections and fever. Importantly, these factors increase risk modestly, not in the 15-fold range linking smoking and lung cancer. In addition to its findings on risk factors, CHARGE investigators have reported that use of prenatal vitamins may serve as a protective factor, reducing the risk of having children with autism. Studies have also suggested that ASD risk is associated modestly with other prenatal and perinatal factors, such as preterm birth, advanced maternal and paternal age at conception and short inter-pregnancy interval. Associations between ASD and prenatal or perinatal exposure to air pollution or endocrine disrupting chemicals such as organophosphate pesticides and phthalates have also been identified. Scientific studies to date have not shown any link between vaccines and ASD.

DNA is the basic code for life. In humans, the DNA double helix consists of about three billion bases (nitrogen-containing compounds that serve as DNA building blocks). Less than two percent of this vast code is dedicated to genes, the sequences that code for proteins, the building blocks of all cells.

Genetics is the study of protein-coding genes, including their structure and function. Genomics is the study of the entire double helix of DNA (the genome), including all genes and their interactions as well as sequences between genes. The study of genes and genomes has been revolutionized by new technologies that have reduced the costs sequencing, or determining the order of bases in segments of DNA, by one million-fold and improved the speed and accuracy of finding mutations. As a result, today we have identified over 5,000 rare mutations that cause human diseases, an increase of 500 percent from a decade ago.

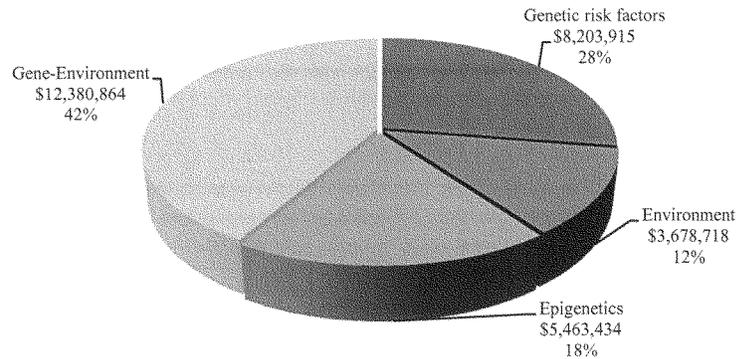
However, much of the research in clinical genomics today is focused on common variations in DNA sequence, not rare mutations in genes. Most of these common variations associated with human disease reside in the 98 percent of the DNA outside the protein-coding genes. These variations are often not direct causes of disease, but they confer risk or protection for many common human diseases, including Alzheimer's disease, hypertension, and diabetes.

Importantly, the tools of genomics research have become fundamental for modern biomedical science. Even for a disease like lung cancer, in which environmental causes are unequivocal, NIH is investing heavily in genomics to understand the mechanisms of disease. Indeed, it was genomic research that revealed the molecular lesions in lung and other cancers, providing targets for effective treatments. It is important to understand that in 2014, genomics offers our most powerful tools for understanding human disease and finding molecular targets for therapies, whether the cause is an environmental toxin (smoking) or a rare genetic mutation (cystic fibrosis).

The study of environmental causes or risk factors for most disorders has advanced less than genetics and genomics research, in part because the technologies and approaches for assessing

exposures during crucial periods of development have not advanced as far as the tools for sequencing DNA. While genomics technologies have improved dramatically, increasing in speed and capability and decreasing in cost per unit, the exposure assessments currently possible in many population-based epidemiology studies have not seen the same kinds of advances in the past few decades. Epidemiologists infer that environmental factors contribute to human diseases, generally based on statistical associations between exposures and increased risk for disease. In some cases, these associations have been so dramatic that straightforward statistical approaches have sufficed (*e.g.*, smoking increases the risk for lung cancer by 15-fold). For ASD, however, several environmental factors that modestly increase risk have been identified, but few large, prevalent environmental contributors have come to light in studies that have been done to date.

Total NIH funding on ASD risk factors in FY 2012 = \$29,726,931



Category descriptions:

Environment: Example projects include studies of environmental contaminants and toxins (such as household chemicals, pesticides, and pollution), maternal and paternal factors (e.g., age, folic acid intake, cholesterol), medications taken during pregnancy, and registries where many of these factors can be tracked simultaneously.

Epigenetics: Example projects include research on the mechanisms by which environmental factors (e.g., parental age, environmental toxicants) may influence risk for ASD.

Gene-Environment: These studies search for combinations of environmental risk factors and genetic susceptibility that increase the risk for ASD. This includes large epidemiological studies such as MARBLES, and studies which utilize animal models of ASD.

3. During the hearing we discussed the two recent studies regarding environmental factors. A study out of Sweden published in the *Journal of the American Medical Association*⁵ looking at more than 14,000 children with autism spectrum disorder found an equal balance between genetics and environmental factors. A second study⁶ conducted at Stanford which is the largest population-based twin study of autism using contemporary standard of diagnosis of autism found that environmental factors common to twins explain about 55% of the liability to autism. The authors of the study stated, "Although genetic factors also play an important role, they are of substantially lower magnitude than estimates from prior twin studies of autism." Why is NIH

⁵ Sandin S, Lichtenstein P, Kuja-Halkola R, Larsson H, Hultman CM, Reichenberg A. The Familial Risk of Autism. *JAMA*.2014;311(17):1770-1777. doi:10.1001/jama.2014.4144.

⁶ Hallmayer J, Cleveland S, Torres A, et al. Genetic Heritability and Shared Environmental Factors Among Twin Pairs With Autism. *Arch Gen Psychiatry*.2011;68(11):1095-1102. doi:10.1001/archgenpsychiatry.2011.76.

spending money on genetic autism research at a 6:1 ratio over environmental causation research?

Response: While both the Stanford study and Swedish study are methodologically strong, there is legitimate debate about the models used in both studies to define and estimate the relative contribution of environmental vs. genetic factors. What is becoming clear is that considering genetic and environmental risks separately as causes for ASD may not be the most productive approach. As the risk factors identified thus far only account for a small amount of heritability, it is most likely that the discovery of additional genetic and environmental risk factors, as well as a clearer understanding of gene-environment interrelationships, will be important for understanding the causes of ASD. The graph above illustrates the NIH risk factor portfolio as of FY 2012. Research relating to environmental risk factors is categorized under ‘**Environment**’ ‘**Epigenetics**’ or ‘**Gene-Environment**’ and makes up 72 percent (\$21,523,016) of the total NIH funding of risk factor research. Some research still focuses solely on genetic or environmental risk factors, but that is the minority of research and reflects that the scientific field increasingly believes that gene-environment interactions play a critical role in the development of ASD.

NIH has placed and will continue to place an emphasis on environmental as well as genetic risk factors, and in the translation of findings about risk factors into interventions research. Examples of current funding opportunity announcements (FOAs) that specifically solicit research on environmental and/or genetic risk factors are listed below. These include two new FOAs (PAR-14-203 and PAR-14-202) that were issued this year in response to NIH’s recognition that there is a need to stimulate additional research on environmental contributions to ASD.

Environmental Contributors to Autism Spectrum Disorders (R01) <http://grants.nih.gov/grants/guide/pa-files/PAR-14-203.html>

Environmental Contributors to Autism Spectrum Disorders (R21) <http://grants.nih.gov/grants/guide/pa-files/PAR-14-202.html>

Research on Autism Spectrum Disorders (R01) <http://grants.nih.gov/grants/guide/pa-files/PA-13-216.html>

Research on Autism Spectrum Disorders (R21) <http://grants.nih.gov/grants/guide/pa-files/PA-13-217.html>

Research on Autism Spectrum Disorders (R03) <http://grants.nih.gov/grants/guide/pa-files/PA-13-218.html>

- 4. How specifically do these findings alter the course of future grant funding for autism at NIMH and NIH? How specifically, will the NIH adjust research funding in response to these findings? Do you anticipate a greater percentage of research will be focused on environmental factors, not just in causation, but also therapeutic solutions?**

Response: The development of interventions from replicated findings of modifiable risk or causative factors is highly encouraged, but has been challenging to date, as it appears that there are multiple environmental factors that confer a modest risk, but no single environmental factor that is easy to target for large effect in terms of prevention. For example, environmental risk factors that have been identified and replicated in more than one study include prenatal maternal infection, preterm birth, advanced maternal and paternal age at conception, and short inter-pregnancy interval. These factors appear to modestly increase risk of having a child with ASD, but the factors are not easily modifiable for the population as a whole, and modifying such factors may not substantially alter risk for any single individual.

As noted above, NIH will continue to solicit rigorous research on environmental, epigenetic, and gene-environment causes of, or risk factors for, ASD. NIH currently has FOAs to solicit interventions research, including novel approaches based on findings of risk and causative factors; as such factors are discovered, funding mechanisms are in place to translate those findings into interventions:

Research on Autism Spectrum Disorders (R01) <http://grants.nih.gov/grants/guide/pa-files/PA-13-216.html>

Research on Autism Spectrum Disorders (R21) <http://grants.nih.gov/grants/guide/pa-files/PA-13-217.html>

Research on Autism Spectrum Disorders (R03) <http://grants.nih.gov/grants/guide/pa-files/PA-13-218.html>

Psychosocial/Behavioral Interventions and Services Research for Autism Spectrum Disorders <http://grants.nih.gov/grants/guide/pa-files/PA-11-283.html>

There are also Institute-specific FOAs that can support the development of novel interventions for ASD, based on emerging findings on risk factors, including those listed below:

Exploratory Clinical Trials of Novel Interventions for Mental Disorders (R21/R33) (RFA-MH-15-300) <http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-15-300.html>

Exploratory Clinical Trials of Novel Interventions for Mental Disorders (R33) (RFA-MH-15-301) <http://grants.nih.gov/grants/guide/rfa-files/RFA-MH-15-310.html>

First in Human Early Stage Clinical Trials of Novel Investigational Drugs or Devices for Psychiatric Disorders (U01) (PAR-14-107) <http://grants.nih.gov/grants/guide/pa-files/PAR-14-107.html>

Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders (R01) (PAR-14-153) <http://grants.nih.gov/grants/guide/pa-files/PAR-14-153.html>

Temporal Dynamics of Neurophysiological Patterns as Potential Targets for Treating Cognitive Deficits in Brain Disorders (R21) (PAR-14-158) <http://grants.nih.gov/grants/guide/pa-files/PAR-14-158.html>

5. During the hearing you stated that the NIMH did not follow through with doing a modern study on chelation therapy in children.

Response: The proposed study of chelation as a treatment for children with ASD was not approved by the Institutional Review Board (the board that provides ethics review of clinical protocols) at the NIH Clinical Center. The Board felt this study raised ethical concerns, as it involved significant risk for research participants without sufficient evidence of benefit because the therapy does not target a known causal mechanism for ASD. Chelation therapy has been approved by FDA for treating patients with acute heavy metal poisoning, but heavy metals have not been scientifically shown to play a role in ASD. Chelation therapy does involve significant risk to patients, as it can alter the levels of certain substances in the blood. Even when used under medical supervision, these products can cause serious harm, including dehydration, kidney failure, and death.⁷ While this risk is justified in the case of acute heavy metal exposure, where it is known that heavy metals are responsible for the illness and their removal by chelation can be a lifesaving treatment, in the case of the proposed chelation therapy trial for autism, the NIH Institutional Review Board did not feel that the potential for benefit outweighed the risks to children in conducting such a trial, so the trial did not go forward.

6. What are the methods of testing for heavy metals? Is one test more accurate than another?

7. What are the standard and complementary therapies available to treat children who test for high levels of lead, mercury, cadmium, arsenic, and other heavy metals?

Response to #s 6 and 7: These issues fall outside the purview of NIMH/NIH.

8. Dr. Insel, please acknowledge for the record, in your opinion, is it possible for a child to suffer brain injury as an adverse reaction to a vaccine and develop autism, or autism spectrum disorder, as a result of the brain injury?

Response: In my experience, children who manifest behavioral changes after brain injury are not diagnosed with ASD, but considered to have one of several neurological disorders, including traumatic encephalopathy. Numerous scientific studies to date have not shown any link between vaccines and ASD.

9. The rates of autism have increased from 1 in 2,500 to 1 in 68 in a quarter century. Are we at the point yet that the Administration will declare it a national emergency and treat it as one? Should President Obama do what President Clinton did with the

⁷ <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm229320.htm>

HIV/AIDS crisis and establish a White House Office of Autism Spectrum Disorders Policy and Planning?

Response: The Secretary of Health and Human Services has described ASD as an “urgent public health challenge.”⁸ The issue of White House offices is outside NIH's purview.

10. Dr. Insel, have you since being at the NIH, or prior to working at the NIH been asked to review medical files or related research for HHS in cases before the Vaccine Injury Compensation Program? Were you asked or did you review any information with related to the omnibus autism omnibus proceeding? If so, please provide details on the process, the extent of your review or involvement, and any information on the number of cases you were involved in reviewing.

Response: No, I have not reviewed or been asked to review such cases or information.

11. Dr. Insel, I have talked to many parents who have shared with me interventions that have worked for their children. Perhaps it was a diet change, supplement, eliminating certain types of foods, or addressing hormone levels. Some children with autism may have an underlying mitochondrial disorder or metabolic disorder. Frankly, we know that autism is a spectrum of disorders and different individuals are affected in different ways. Thus it is logical to assume that different interventions may work for some kids and not others. Given this, what specific steps has NIH done to (1) catalogue and investigate these different approaches and (2) initiate research to look at these different possibilities for causes and interventions?

Response: The IACC is cataloguing research projects across the Federal Government and private ASD research foundations, including research projects on interventions for ASD. The IACC is also planning a fall 2014 workshop that will explore several different conditions that co-occur with ASD, including psychiatric disorders, sleep and neurological disorders and metabolic and immune conditions, with the goal of identifying potential areas for further research.

Because ASD is a heterogeneous group of disorders without biomarkers for defining the subgroups, intervention trials have been challenging. In addition, in the absence of clear molecular targets as a basis for new drug design, most pharmaceutical companies have not become actively engaged in research and development of interventions for ASD. Though evidence-based behavioral treatments are available, in the absence of medications with proven efficacy from rigorous clinical trials, many parents are trying whatever they think will help, including supplements, diets, and other treatments that have never been rigorously clinically tested and proven to be effective. While there are many claims for powerful effects, the plural of anecdote is not evidence.

The NIH funds a broad portfolio of research on ASD interventions, including research on behavioral/social interventions, medications, and assistive technologies. Research on metabolic issues and etiologies for autism has included a recent study on a rare hereditary form of autism

⁸ Statement of Secretary Kathleen Sebelius for World Autism Awareness Day 2010. <http://wayback.archive-it.org/3926/20131018160841/http://www.hhs.gov/news/press/2010pres/04/20100401a.html>

that presents with epilepsy and intellectual disability and is caused by mutation of a gene that codes for the enzyme BCKDK (branched chain ketoacid dehydrogenase kinase), which prevents the body from breaking down the essential branched-chain amino acids leucine, isoleucine, and valine after eating food. When BCKDK is inactivated, individuals cannot maintain adequate levels of the above mentioned amino acids and they experience a deficiency. The problem can be addressed through amino acid supplementation in animals, but research is needed to determine whether supplementation can reverse the autism symptoms associated with this disorder in humans. In a separate study, preliminary findings have linked a rare form of autism with a gene defect that interferes with the body's ability to manufacture carnitine, an amino acid that helps convert fat into energy, suggesting that another form of autism also may be potentially amenable to treatment through nutritional supplements. Further work in this emerging field may yield new insights into the mechanisms of ASD and potential for novel treatments.

12. The Combating Autism Act has directed the NIH to spend over \$1.5 billion on autism research. Yet after close to 10 years you admit that you have come up with no new treatments for autism, and that the funded research has not prevented a single case of autism. What needs to change now so that we get better results for families, children and the taxpayers?

Response: In the Global Burden of Disease 2010 study, autism accounted for about four percent of the disability from all mental and substance use disorders (which in total accounted for 7.4 percent of all disability from medical causes). NIH has spent \$1.5 billion on ASD research over the past decade, with 63 percent of this being spent in the past five years. ASD biomedical research is still a nascent field. What needs to change going forward? We need biomarkers to stratify the ASD population for treatment studies. We need molecular targets for treatment development. We need to find environmental factors that are of sufficient import to permit preventive strategies.

13. Why does CDC's most recent autism surveillance cover children born in 2002, well over a decade behind, and only begins surveillance in a population born in 1992? Do you find this narrow focus of the population to be limiting in drawing conclusions regarding the overall affects of autism and possible contributing factors?

Response: This topic falls outside the purview of NIMH/NIH.

14. What is your response to the criticisms that the IACC is too heavily weighted with federal employees as members of the IACC and thus lacks accountability and responsiveness to the autism community?

Response: In 2012, 15 Federal members and 14 public members were appointed to the IACC. Currently, 14 Federal members and 16 public members sit on the IACC (please see list below). On September 30, 2014, the terms of the members listed below will expire. On October 1, 2014 HHS will issue an open call for nominations for members of the public who would like to be considered by the Secretary for potential service on the committee.

IACC Federal Members (2012- 2014)

1. Dr. Thomas Insel (IACC Chair and Director, National Institute of Mental Health)
 2. Dr. James Battey (Director, National Institute on Deafness and Other Communication Disorders)
 3. Dr. Linda Birnbaum (National Institute of Environmental Health Sciences)
 4. Dr. Coleen Boyle (Centers for Disease Control and Prevention)
 5. Dr. Francis Collins (Director, National Institutes of Health)
 6. Dr. Tiffany Farchione (Food and Drug Administration)
 7. Dr. Alan Guttmacher (National Institute of Child Health and Human Development)
 8. Laura Kavanagh (Health Resources and Services Administration)
 9. Dr. Donna Kimbark (Dept. of Defense)
 10. Dr. Walter Koroshetz (Deputy Director, National Institute of Neurological Disorders and Stroke)
 11. Sharon Lewis (Principal Deputy Administrator, Administration for Community Living)
 12. John O'Brien (Centers for Medicare and Medicaid Services)
 13. Asst. Sec. Linda Smith (Administration for Children and Families)
 14. Acting Asst. Sec. Michael Yudin (Dept. of Ed)
- *Former Member: Denise Dougherty – Administration for Healthcare Resources and Quality*

IACC Non-Federal Public Members (2012-2014)

1. Idil Abdull (Parent of a child with ASD; Co-Founder, Somali American Autism Foundation)
2. Dr. James Ball (President, JB Autism Consulting; Board Member, Autism Society)
3. Dr. Anshu Batra (Parent of 2 children with ASD; developmental pediatrician)
4. Noah Britton (Autism self advocate; Adjunct Professor, Bunker Hill Community College)
5. Dr. Sally Burton-Hoyle (Sister/legal guardian of an adult with ASD; Associate Professor of Special Education, Eastern Michigan University)
6. Dr. Matthew Carey (Parent of a child with ASD; Contributor, LeftBrain RightBrain Blog)
7. Dr. Jose Cordero (Dean, U. of Puerto Rico; pediatrician, epidemiologist)
8. Jan Crandy (Parent of an adult with ASD; Chair, Nevada State Autism Treatment Assistance Program)
9. Dr. Geraldine Dawson (Duke University Medical Center Professor; *formerly, Chief Science Officer, Autism Speaks*)
10. David Mandell (U. of Pennsylvania Associate Professor)
11. Dr. Rob Ring (Chief Science Officer, Autism Speaks)
12. Lyn Redwood (Parent, Coalition for SafeMinds Co-Founder)
13. Dr. Scott Robertson (Autism self advocate, Autistic Self Advocacy Network)
14. John Elder Robison (Autism self advocate; Scholar in Residence, College of William and Mary Neurodiversity)

- 15. Alison Singer (Parent of a child with ASD, sister/guardian of an adult with ASD; President, Autism Science Foundation)
- 16. Wendy Chung (Director of Clinical Research, Simons Foundation Autism Research Initiative)
 - *Former member: Dr. Dennis Choi (Simons Foundation Autism Research Initiative)*

15. Why is autism not being discussed and researched as an outcome of a disease of the immune system, and subsequent treatments being pursued by IACC?

Response: As a Federal advisory body, the IACC does not conduct or financially support research, so it cannot “pursue treatments.” The role of the IACC is to make recommendations to the HHS Secretary, including recommendations for research. In one of the objectives outlined in its Strategic Plan, the IACC has recommended research to explore “fever, metabolic and/or immune system interactions with the central nervous system that may influence ASD during prenatal-postnatal life.” In a recent review of progress toward achieving Strategic Plan goals conducted by the IACC, they found that this area of research has grown, with 26 projects (\$3 million) funded in FY 2012 across six funders including the NIH.

In its most recent assessment of Strategic Plan progress, the IACC noted that research on the potential relationship between the immune system and ASD has grown considerably over the past two years, resulting in several important advances. Immune cells and immune signaling molecules have been identified as playing an essential role in establishing stable connections between neurons during early brain development. In addition, studies are suggesting a vital role for the immune system in important brain processes such as learning and memory. Through general neuroscience research funding, NIH is supporting research to better understand the mechanisms by which immune cells and signaling pathways contribute to brain health and function. NIH is funding studies to elucidate the role of immune cells and molecular pathways in autism. For example, NIH-supported studies have shown that maternal antibodies targeting fetal brain proteins are present in a subgroup of mothers of children with ASD and in some children with ASD, and that in animals, these antibodies may alter neurodevelopment. Further research will be needed to determine whether or not these antibodies may have similar effects on development in humans.

16. Why has there been no follow up to the PACE law review paper, looking at how many of the VICP cases already paid out involving neurological injury have led to or included diagnoses of autism? What follow up has taken place, to connect the similarities of injury and presentation of injury to assess; 1) possibly successful treatments; 2) possibly trending predisposition to injury from vaccine, i.e. familial autoimmune disorders or mitochondrial dysfunction, exposures to particular medicines, or deficiencies of particular vitamins?

Response: This topic falls outside the purview of NIMH/NIH.

17. In a 2008 interview on CBS, former NIH Director Dr. Bernadine Healy called for a study of children who were developing normally and meeting their milestones and then

regressed into autism spectrum disorders? <http://www.cbsnews.com/news/the-open-question-on-vaccines-and-autism/>. What specific steps has NIH taken to investigate such cases of regression to identify possible shared experiences and risk factors?

Response: NIH continues to support rigorous research on the potential causes of, and associations between, ASD and developmental regression. For instance, an ongoing study within the NIMH Intramural Research Program is examining the possible associations between neuroimmune dysfunction and regression.⁹ Another effort is using data from 1200 patients from the Simons Simplex Collection, a repository of genetic and phenotypic data from children with ASD, to investigate the potential genetic causes associated with developmental regression in autism.¹⁰ And a large, national, longitudinal effort is examining how the interaction between genes and environmental factors may act as triggers for developmental regression.¹¹

18. It is my understanding that at least 45 children with autism have died following a wandering incident in just over two years. Parent groups brought this issue to the attention of IACC back in 2011. A safety subcommittee was established. The committee sent an official advisory letter to Sebelius alerting her to this deadly safety issue. What was her response to that letter? What follow up did the committee take? Why was the safety subcommittee disbanded so quickly?

Response: The IACC voted to form a Safety Subcommittee in 2010 (during the 2006-2011 authorization period) to address safety issues that affect individuals with ASD, including wandering—a behavior associated with ASD in which a child with ASD may have a tendency to wander away from a caregiver or safe place into an unsafe environment, where he/she is at risk of injury or accidental death. Children with ASD and other developmental disabilities are at higher risk of wandering away from caregivers and safe areas than are children without these conditions or with other cognitive disabilities. The IACC Safety Subcommittee held five meetings, the last two of which were joint meetings with the IACC Services Subcommittee because of the significant overlaps between the interests and membership of the two subcommittees. The Safety Subcommittee drafted a letter to the HHS Secretary regarding recommendations for addressing wandering, and submitted it to the full committee for consideration. The full committee deliberated and edited the content of the letter before voting to send it to then HHS Secretary Sebelius in February 2011. After the IACC sent its letter on wandering to the Secretary, recommending a number of actions related to the issue of ASD-related wandering behavior, the Secretary sent a response letter to the IACC on March 23, 2011. Both letters are posted on the IACC website.¹²

The letter recommended to the Secretary that a medical code for ASD-related wandering be adopted to provide a way to document and understand this behavior, and to support the development of approaches to reduce the risk of wandering-related injuries and fatalities. The IACC supported CDC's effort to implement this recommendation by proposing the adoption of a

⁹ Neuroimmunologic Investigations of Autism Spectrum Disorders (1ZIAMH002915-06).

¹⁰ Mutations Associated with Carnitine Deficiency: Risk Factor for Regression in ASD (1R03HD072102-01A1).

¹¹ The Charge Study: Childhood Autism Risks from Genetics and the Environment (3R01ES015359-05S1).

¹² http://iacc.hhs.gov/publications/2011/letter_wandering_020911.shtm and http://iacc.hhs.gov/publications/2011/iacc_response_letter_sebelius_wandering_032311.pdf.

code intended to capture within the health care system the information about individuals, with any condition classified in the ICD, who wander. The measure was adopted and the code is now in use, fulfilling the recommendation.

The IACC also recommended the collection of data on wandering. Discussion at the IACC meeting resulted in an IACC public member initiating coordination among private organizations to support a study to assess the prevalence as well as qualitative aspects of wandering behavior in the autism community using an established interactive virtual network (IAN – the Interactive Autism Network) of people with ASD and their families. The study, conducted within the short timeframe of a few months, resulted in the publication of an analytical report about the prevalence of autism-related wandering that helped raise awareness of the issue in the community and provided some initial figures to support the need for further research in this area. In addition, HRSA and CDC added questions about wandering to a survey instrument that they use in populations of children with special health care needs in order to capture more information about the prevalence of wandering in this population.

In July 2013, in order to foster coordination of activities between HHS and other Federal Departments on wandering, the IACC hosted a presentation by the Department of Justice (DOJ) and National Center for Missing and Exploited Children (NCMEC) at their quarterly meeting, where DOJ and NCMEC provided an update on their efforts to implement programming targeting ASD-related wandering. DOJ and NCMEC reported that they had implemented awareness and training programs for first responders, and they provided information to the IACC about lessons learned since they began focusing attention on recovering missing children with autism.¹³ Advocacy organizations also provided presentations on their efforts to raise community awareness, and provide tools and training related to wandering. The IACC continues to monitor this area for new developments and opportunities to facilitate interagency coordination efforts.

Following the effort on wandering, the IACC Safety Subcommittee worked jointly with the IACC Services Subcommittee on the issue of seclusion and restraint. The IACC was reauthorized on September 30, 2011, at which time HHS began the process of soliciting nominations of non-federal public members through an open call for nominations and then appointing a new set of non-Federal public and Federal members to serve on the IACC. When the new IACC began operating in July 2012, the committee voted to form a new Basic and Translational Research (BTR) Subcommittee and a new Subcommittee on Services Research and Policy (SRP) Subcommittee to serve the needs anticipated by the new committee. The committee did not vote to re-form the Safety Subcommittee, in part due to the substantial overlap between the previous Services Subcommittee and Safety Subcommittee. Instead, the issues formerly addressed by the Safety Subcommittee were subsumed under the new SRP Subcommittee. As mentioned earlier, the IACC has continued to monitor the issue of wandering, inviting input from the DOJ and NCMEC, as well as advocacy organizations at public meetings to keep the committee updated on wandering-related activities and needs.

¹³ http://iacc.hhs.gov/events/2013/slides_robert_lowery_070913.pdf

Enclosure

Response from Dr. Marcia Crosse

Director

Health Care

U.S. Government Accountability Office

To Representative Posey
Representative from Florida
U.S. House of Representatives

Hearing on:
"Examining the Federal Response to Autism Spectrum Disorders"

- 1. During the hearing, there were questions to your qualifications to conduct the study looking at the potential for duplicative research. Is it not true that you hold a PhD in social science and that you have an extensive background that more than qualifies you to lead such a study?**

Dr. Marcia Crosse has been with GAO for over 30 years and has served in GAO's Senior Executive Service as a Director in the Health Care Team since 2002. She holds a Ph.D. in social psychology from the University of North Carolina at Chapel Hill. She has led numerous GAO studies related to public health issues, including biomedical research, disease surveillance, HIV/AIDS, medical product safety, and pharmaceutical regulation. Dr. Crosse attended Harvard's Kennedy School of Government Program for Senior Executive Fellows and is the recipient of numerous GAO awards including the agency's Distinguished Service Award, Client Service Award, and Meritorious Service Award. More recently, Dr. Crosse has been named a *Samuel J. Heyman Service to America* award finalist for the 2014 Citizen Service Medal, in recognition of her work on public health. These awards are presented annually by the nonprofit, nonpartisan Partnership for Public Service to pay tribute to members of the federal workforce, recognizing individuals based on their commitment and innovation, as well as the impact of their work on addressing the needs of the nation. Dr. Crosse has also made presentations and participated in panel discussions in a variety of venues, including meetings sponsored by the Food and Drug Law Institute, the National Health Policy Forum, and the Pew Charitable Trusts.

Regarding GAO's examination of the potential for duplicative autism research it is important to note that the work we performed in preparing our 2013 report on which Dr. Crosse's statement was based, *Federal Autism Activities: Better Data and More Coordination Needed to Help Avoid the Potential for Unnecessary Duplication* (GAO-14-16), is part of a body of work GAO conducts to identify duplication, overlap, and fragmentation in the federal government. The intent of this body of work is to inform executive branch agencies and Congress of actions that can be taken

to improve the efficiency and effectiveness of government programs and activities.¹ GAO's 2013 report on autism research was also conducted in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings based on our audit objectives. We believe that the evidence we obtained provided a reasonable basis for the findings and conclusions presented in that report based on our audit objectives.

2. **There is much controversy regarding the quality and management of the research the CDC and other HHS institutions have funded regarding vaccine adverse events and thimerosal exposure. If asked, would the GAO be able to gather and evaluate the whole body of science as well as the internal discussions and unpublished data from HHS agencies, and information gathered by outside parties and provide Congress with an comprehensive analysis of the facts on the issue, whether the messaging we are getting from our public health authorities is 100 percent accurate?**

GAO audits and evaluates federal programs and activities, and the use of public funds, in support of Congress's legislative and oversight roles. Other agencies within the federal government have primary responsibility to conduct, fund, and evaluate scientific research to address public health issues. Given its role, GAO is best positioned to evaluate the processes, procedures, and methodologies that these agencies follow to carry out their activities, rather than conducting a comprehensive review of specific scientific findings as if it were in the position of a public health agency.

3. **You may be aware that a couple of years ago an outside organization conducted an analysis of compensated cases in the National Vaccine Injury Compensation Program and found at least 83 cases in which families were compensated when their child suffered brain injury or seizure disorders after immunizations and also had autism. If asked, would the GAO be able to conduct a thorough review of (1) compensated cases and determine how many cases have been compensated (and denied) in which the child suffered a brain injury or seizure disorder, and how many of those also developed autism, or autism like symptoms?**

GAO is currently conducting a review of the National Vaccine Injury Compensation Program (VICP) at the request of Chairman Issa. The objectives for that work include the following: (1) What are the current timeframes for processing VICP claims, and what factors are associated with longer claims processing timeframes? (2) What changes have been made in the vaccine injury table and what are the criteria for changing the table? (3) How have the funds in the Vaccine Injury Compensation Trust Fund been spent? (4) What is known about the experience of petitioners who have filed claims with the VICP? and (5) How has the Department of Health and Human Services informed the public of the availability of VICP? Due to limitations in the available data, GAO would not be able to conduct a thorough review to determine how many VICP cases have involved a child who suffered a brain injury or seizure disorder who also

¹See for example, GAO, *2014 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8 2014) and GAO, *2013 Annual Report: Actions Needed to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-13-279SP (Washington, D.C.: Apr. 9, 2013).

developed autism or autism-like symptoms. For example, according to Health Resources and Services Administration officials, who maintain a data system for the VICP, the available data for VICP cases includes the injury for which the petitioner seeks compensation under the program; however, it does not consistently include data on the individual's other medical conditions.

4. **In the report on autism, the GAO concluded “that the data used by the IACC was outdated, not tracked over time, inconsistent, and incomplete. These weaknesses limited the IACC’s ability to monitor its progress on its coordination and monitoring efforts--which, in prior work, GAO established as a best practice for inter-agency collaboration, as well as a federal internal control standard. In addition, these weaknesses limited agencies’ ability to use these data to identify coordination opportunities and avoid the potential for unnecessary duplication.” Is this failure to follow established best practices unique to the IACC management staff, or is it something you see with other organizations at the NIH?**

We have previously reported on NIH’s efforts to coordinate with other agencies conducting medical research. Our 2012 annual report on duplication, overlap, and fragmentation in the federal government discussed the potential for unnecessary duplication when multiple federal agencies fund research on the same topic.² Specifically, we pointed out that NIH could improve its coordination with the Department of Defense and the Department of Veterans Affairs, and officials at all three agencies acknowledged that duplication may sometimes go undetected. Consequently, GAO determined that the Director of NIH—as well as the Secretaries of Defense and Veterans Affairs—should improve information sharing and the ability of agency officials to identify possible duplication.³ In our duplication work, we have also identified the need for better coordination at other federal agencies conducting scientific research. For example, we found instances where the Department of Homeland Security and the Environmental Protection Agency lacked internal coordination processes to ensure that research activities were not overlapping or duplicative of each other. We also found that the U.S. Department of Agriculture did not have a documented, systematic process to monitor the extent to which research gaps were filled.

²GAO-12-342SP

³Further information on the agencies’ response to our recommendation can be found on our action tracker website at http://www.gao.gov/duplication/action_tracker/Health_Research_Funding/action1.



Written Testimony Provided for the
House Committee on Oversight & Government Reform
Subcommittee on Government Operations

May 20, 2014

Chairman Mica, Ranking Member Connolly, and members of the committee, thank you for allowing Autism Speaks to provide testimony.

Autism Speaks began as an idea to give a voice to millions of struggling families around the nation and has materialized into the world's leading autism science and advocacy organization. We are dedicated to funding research into the causes, prevention, treatments, and a cure for autism; increasing awareness of autism spectrum disorders (ASD); and advocating for the needs of individuals with ASD and their families.

Autism Speaks has committed more than \$200 million in private funding to research and has supported innovative scientific and clinical programs such as the Autism Speaks Autism Treatment Network, a network of hospitals, doctors, and researchers across the United States and Canada dedicated to improving the care of children with autism. This research has led to improved screening tools that can be used by pediatricians and more effective behavioral and medical treatments for people with autism throughout the lifespan. Autism Speaks provides resources and support for families in the autism community, handing out thousands of free tool kits and awarding hundreds of thousands of dollars in grants for community programs, camp scholarships, and families in crisis each year. In 2013 alone, our Autism Response Team and Autism Treatment Network responded to nearly 30,000 phone calls and emails from families looking for assistance.

In November 2012, Bob Wright, who along with his wife Suzanne founded Autism Speaks, testified before the full committee. Since Mr. Wright spoke, the Centers for Disease Control and Prevention has released new findings on the prevalence of ASD. The numbers are sobering: 1 in 68 children has an ASD (1 in 42 boys). This marks a 30% increase from the prior prevalence estimate in 2012. This year tens of thousands of children will be diagnosed with an ASD, more than the numbers of children who will be diagnosed with pediatric AIDS, juvenile diabetes, and childhood cancer combined.

The challenge lies in coming to a consensus on what to do going forward. **We believe that the best course is to build on what we have learned and what we have accomplished through the Children's Health Act of 2000, the Combating Autism Act of 2006, and the Combating Autism Reauthorization Act of 2011, to work for greater accountability and better coordination, making sure that every dollar is well spent.** Our community has urgent issues that must be addressed, including the needs of the 50,000 young people with ASD who transition into adulthood each year. This year portions of the Combating Autism Act will sunset unless Congress acts. We cannot allow that to happen. **The Combating Autism Act must be reauthorized.**

Beyond reauthorization, much more needs to be done. Mr. Wright's prior testimony laid out a vision that bears repeating. As you examine the federal response to ASD, we ask that you consider again the 2012 testimony, which we have attached. Mr. Wright concluded by saying, "One in 88 can't wait." The rise in prevalence to 1 in 68 makes a coordinated and strong federal response even more urgent. We need a national strategy that will channel all of the public and private resources toward the most effective means of addressing this crisis.



AUTISM SPEAKS™
it's time to listen.

Written Testimony Provided for the
House Committee on Oversight & Government Reform

Bob Wright
Co-founder, Autism Speaks

November 29, 2012

Good afternoon, Chairman Issa, Ranking Member Cummings, and members of the committee. I am Bob Wright, co-founder of Autism Speaks. Thank you for inviting me to testify.

More than seven years have passed since my wife, Suzanne, and I founded Autism Speaks. During that time, we have seen the prevalence of autism in America nearly double – from 1 in 166 children in 2005 to 1 in 88 today, including 1 of every 54 boys. The prevalence of autism has increased by 1,000 percent over the last 40 years. This year alone, approximately 46,000 children will be diagnosed with an autism spectrum disorder – that’s more than pediatric AIDS, juvenile diabetes, and childhood cancer combined. Yet even these alarming statistics may understate the true picture – the most comprehensive study to date, completed last year in South Korea, found a prevalence rate of 1 in every 38 children, including 1 of every 27 boys. The methodology used in this study is now being replicated in South Carolina, with funding from Autism Speaks, and may well yield similar findings. There is no getting around the facts: autism has become an epidemic.

The incremental lifetime cost of caring for a single person with autism is staggering – as much as \$2.3 million. The annual cost of autism in the United States is now estimated at \$137 billion – a figure that exceeds the gross domestic product of 139 countries. These spiraling costs are borne not just by families but by taxpayers at the federal and state level, as well as by localities. Consider as well the cost to our economy – when one of every 54 boys is diagnosed with autism, 2 percent of the productivity of our nation’s male workforce is diminished. The toll on our families, however, is unimaginable. A diagnosis of autism too often leads to divorce, personal bankruptcy or shattered careers. A spouse in Michigan has to give up working in order to care fulltime for a child with autism at home. A family from Alabama is uprooted as they search for jobs in states where treatment for their child with autism will be covered by insurance. Parents in Utah are forced to surrender custody of their children to the state because they cannot care for their needs. And most shamefully, we see the U.S. Marine back home in Texas after being wounded in combat in Iraq having autism treatment denied to his son.

These burdens on families can be addressed, the costs can be reduced, and the quality of life for individuals with autism improved. But it will require new thinking, engaged leadership, and a concerted effort bridging all sectors of our society.

Autism Speaks began as an idea to give a voice to millions of struggling families around the nation and has materialized into the world’s leading autism science and advocacy organization. We are dedicated to funding research into the causes, prevention, treatments, and for those who desire a cure for autism; increasing awareness of autism spectrum disorders; and advocating for the needs of individuals with autism and their families.

Since our founding seven years ago, Autism Speaks has committed more than \$180 million in private funding to research and has supported innovative scientific and clinical programs such as the Autism Speaks Autism Treatment Network, a network of hospitals, doctors, and researchers across the United States and Canada dedicated to improving the care of children with autism. Our research efforts also have led to improved screening tools that can be used by pediatricians and more effective behavioral and medical treatments for people with autism throughout the lifespan. Our awareness activities include the worldwide “Light It Up Blue” project on World

Autism Awareness Day (April 2nd) and the “Learn the Signs” campaign with the CDC and Ad Council which has generated over \$316 million in donated media.

Autism Speaks provides resources and support for families in the autism community, handing out thousands of free tool kits and awarding hundreds of thousands of dollars in grants for community programs, camp scholarships, and families in crisis each year. In 2012 alone, our Autism Response Team and Autism Treatment Network have responded to over 25,000 phone calls and emails from families looking for assistance. Recently, our AutismCares program allocated \$120,000 in private funding to help families impacted by Hurricane Sandy.

Through the work of our government relations team in state capitals and on Capitol Hill, individuals with autism have better access to applied behavior analysis (ABA), the most widely used behavioral intervention for treating autism, and other critical health care services. Thirty-two states, representing 75% of the US population, now have comprehensive autism insurance coverage, and beginning in 2013 many federal civilian employees will gain access to behavioral health treatments through the Federal Employees Health Benefits Program.

We are incredibly proud of what Autism Speaks has accomplished. We cannot, however, go it alone. We need a strong federal partner.

Our families are not asking for a blank check from the federal government. We are asking for real help that delivers meaningful results more quickly to our community and with a transparency that provides accountability to taxpayers. We are asking our elected leaders to recognize that there is a public health crisis racing across this nation and we are not keeping pace. We need a plan and we need it now.

Autism Must Be a National Priority

I want to say this again: the rate of autism in America is now 1 in 88 children, including 1 in 54 boys. It has become alarmingly apparent that we are no longer dealing with just a public health crisis, but a public services crisis as well. As this population continues to grow, our ability as a society to care for people with autism falls further behind.

Real families struggle every day with autism and those struggles do not end when a child with autism becomes an adult. A recent study found that more than one-third of young adults with autism have no paid job experience or post-secondary education in the first six years after high school. In other words, they most likely live at home with nothing meaningful to do during the day. That is a sobering statistic when you consider that more than half a million children with autism will reach adulthood within the next decade.

But with this sobering reality comes a meaningful opportunity for this country. We know that there are effective therapies that will improve the life-trajectory of people with autism. This means that with more effective translational research and better access to supports and services for the individuals I described, we can help them lead more independent lives and in some cases join the workforce. The trend that contributes to the \$137 billion in annual costs can be reversed dramatically for the country as a whole and for the people affected. In the current fiscal crisis,

this potential reduction in current and future costs should be appealing to both sides of the aisle and across the ideological spectrum.

Clearly, we have a long way to go in meeting the needs of people with autism and their families. The status quo isn't working. We have to do better, and we have to act now. It is time we commit to a **comprehensive national strategy** for autism.

A Comprehensive National Strategy is Essential

First, we must continue to fund a robust research effort but should do so more smartly.

We are only beginning to grasp the complex connections between genes and environment in autism. There is now growing evidence that certain environmental factors, including chemicals, toxins, infections during pregnancy, maternal nutrition and parental age, can affect brain development in combination with an underlying genetic predisposition. Recent studies are pointing the way to the development of medicines that could reduce the core symptoms of autism and help improve communication and social skills. Novel behavioral health interventions are being tested that can be started with young infants, as well as implemented later in life to help adolescents and adults develop the skills they need to be successful, productive adults. These new treatments have the potential to significantly impact lives and reduce the burden of autism to families and society. The federal commitment to autism research through the Combating Autism Act (CAA) has been an important first step in better understanding the causes and underlying pathology of autism. Autism has historically received a fraction of the research funding of many less prevalent disorders, and even under the CAA, autism research comprises about one-half of one percent of total NIH research funding. The research into environmental factors I have noted is an example of an area of research that was mostly neglected prior to the CAA. Further, the Interagency Autism Coordinating Committee (IACC) established by the CAA has served as a convening function for scientists and autism advocates to have a dialogue with the National Vaccine Advisory Committee on the important vaccine safety issue.¹ These steps have been important, but much more can and needs to be done. What continues to be lacking is a policy that directs funding according to a strategic plan, measures meaningful progress, operates with a sense of urgency, and assures accountability. We need a national commitment – much the way the country has committed to address the AIDS crisis or Alzheimer's disease – to invest the resources needed to solve this growing public health crisis. We must demand results that improve the lives of people with autism today, not just in the future. Through a smarter investment in research we can unlock the door not only to autism, but a variety of brain disorders.

Second, we must commit to diagnosing children with autism, regardless of background, no later than 18 months of age, and increasing access to early intervention.

Five years ago, the American Academy of Pediatrics recommended that all children be screened for autism at 18 and 24 months, and that appropriate referrals be made if autism is suspected. This is crucial because we know that early intervention can alter the life trajectory of children with autism. Today the average age of diagnosis remains close to five years. Geography, ethnicity, and race may place a child at a particular disadvantage in getting a timely diagnosis.

¹ Louis Z. Cooper, Heidi J. Larson, and Samuel L. Katz, *Protecting Public Trust in Immunization*, Pediatrics 2008:122; 149

Research shows that children from ethnic minority backgrounds must go to the doctor many more times before receiving a diagnosis and thus, they begin receiving services at a much older age. Autism is not something that a child outgrows. We must develop new and better ways to increase access to early diagnosis for all children no matter what their background is.

Third, we have to develop and make available effective medicines and treatments for the debilitating aspects of autism.

Too often, scientific discoveries gather dust on laboratory shelves or are entombed in the pages of academic journals. We need to speed to market products that improve the lives of people with autism. For our part, Autism Speaks recently established a not-for-profit affiliate, **Delivering Scientific Innovation to Autism (DELSIA)**, to help do this work. From Washington, we are looking for the National Center for Advancing Translational Sciences (NCATS), NIH's newest center, to take a key role in fostering collaboration between public and private efforts at real world solutions. This committee can be instrumental in providing oversight for this opportunity.

As we develop the technologies of tomorrow, we must fully utilize the treatments and interventions of today. Right now, autism is considered a treatable disorder. But ten years ago, many experts didn't believe it was. Today, we can change the course of a child's development and outcome. Research has shown that early intensive behavioral intervention significantly increases IQ, language abilities, and daily living skills, while reducing the disabling effects of autism and the demands on taxpayers for avoidable costs, such as special education. Autism is not a static disorder; we can treat it and help those affected lead better, more fulfilling lives.

Fourth, we must recognize and address the disparities in access to proven behavioral health treatments.

We have long known the benefits of behavioral interventions in autism, including the use of ABA. In 1999, the Surgeon General of the United States reported that "[t]hirty years of research demonstrated the efficacy of applied behavioral methods in reducing inappropriate behavior and in increasing communication, learning, and appropriate social behavior." Yet today families across the country continue to fight for behavioral health benefits, negotiating a complex maze of state and federal laws and insurance company practices.

Consider this – civilian employees of the federal government who for the first time in 2013 will gain coverage for ABA through the Federal Employees Health Benefits Program because administrators finally came to acknowledge the therapy as a valid medical intervention. But over in the military, the administrators of the TRICARE program view ABA differently and offer only benefits limited to active duty personnel. Even wounded warriors who retire because of combat-related injuries cannot get ABA treatment for their children.

Here is a classic example of two agencies within the same government heading in opposite directions on the same issue. It is appalling that our military families end up with the short end of the stick. Getting help for any child, let alone the child of a parent who has honorably served our country, should not be so difficult. We can do something right now to help these families – we can enact a National Defense Authorization Act (NDAA) that clarifies the coverage of behavioral health treatment for autism. The House passed a version of the NDAA that assures all Department of

Defense members of the military, regardless of their duty status, will receive autism insurance benefits for their dependents. Now it is time for the Senate to pass a bill with the same provision.

This same incongruity can be found all across America. Repeatedly, we find families overjoyed to gain coverage for ABA when their state enacts autism insurance reform. They are happy because they have the good fortune to work for an employer with a state-regulated health plan. Their neighbors, however, may not be so fortunate. Because many employers self-fund their health plans, they are exempted from following state insurance laws. Their plans are regulated by the federal government under ERISA. Two families, same problem, but different outcomes. This is fundamentally unfair, illogical and, with autism prevalence on the rise, unsustainable.

Fifth and finally, we need to address the needs of adults with autism for continuing education, employment, housing, and community integration.

With early identification and intensive intervention, some children with autism can lose their diagnosis, but most children with autism become adults with autism. To be frank, we do not know very much about the life experiences of adults with autism; only 2% of total autism research funding is spent on lifespan issues. Young adults with autism face real challenges. The majority of adults with autism are unemployed or underemployed, a tragic waste of potential. Hiring people with autism is smart business – just ask Walgreens, TIAA CREF, AMC Theatres or any of the other national employers who have made the investment in our community.

Executive Order 13548, which has increased the percentage of disabled workers in the federal workforce, has been an important step in the right direction, as has been a proposed rule calling on federal contractors to set a goal of hiring people with disabilities for at least 7 percent of their workforces. People with autism generally follow rules and pay close attention to details. They want to work. Give them the support they need and they will succeed. It's time for corporate America to recognize the potential of employing people with autism. They will find a partner at the National Governors Association, whose chairman, Delaware Governor Jack Markell, has made his top initiative increased employment opportunities for people with disabilities.

Like all Americans, adults with autism should be able to choose where they live, with whom they live, and how they live. But the great demand for housing among people with developmental disabilities and the lack of appropriate support services often force families to decide whether to make their own housing arrangements or wait indefinitely for an adult child with autism to move out of the family home. A broad range of housing and support options must be available to meet the needs of people with autism. These options must not be limited by government-imposed restrictions. Where people choose to live should drive where the government directs our money.

People with autism and their families should have the ability to save and plan for the future. The Achieving a Better Life Experience (ABLE) Act would allow tax-advantaged savings accounts for employment support, housing, and other life needs of people with disabilities. These accounts would be subject to much the same rules as 529 college savings accounts and would not jeopardize eligibility for Medicaid and other means-tested federal programs. A bipartisan majority of House members and 40 Senators have signed on to co-sponsor ABLE. This is readily achievable in the current Congress and would bring relief to parents who face their own financial cliff – what happens to their child with disabilities when they are no longer around to support them? I ask the members of this committee to help pass ABLE in this Congress. In this time of

fiscal cliffs, this is a common sense solution that will help disabled individuals and their families achieve even greater independence.

If the list of what must be accomplished seems long, it is because the stakes are very high. On a personal scale, there is this harsh reality: ten years ago, even five years ago, many people in this committee room would have known autism only from what they read in the newspaper or saw on television. Today, they are the parents, grandparents or relatives of affected children. Autism has become ubiquitous. Autism has changed our lives, and it continues to change the lives of millions of Americans. We must face up to the crisis. We are ready to join you as a partner. One in 88 can't wait.