Oral Public Comments

IACC Full Committee Meeting

November 21, 2008

List of Oral Public Comments

Eileen Nicole Simon

November 21, 2008

Please see this presenter’s slide presentation: http://www.conradsimon.org/IACCfor21nov2008.pdf

Note: Personally Identifiable Information (PII) has been redacted in this document

Maribel McIntyre

November 21, 2008

Your child has Autism. After hearing these words, and going through the stages of grief, we ask ourselves…what options do we have? How can we help our children? How is science looking at this condition? Possible causes? Potential treatments? On 2007, the IACC invested about $15 million dollars (12% of the ASD Research budget of $126 million dollar) on Characterization of ASD and Associated Genetics and another $20 million dollars (16% of total budget) on Genetics/Genomics. Although I understand that gene or phenotype/genotype identification is very important, I also think that treatment development, specifically biomedical, and risk factors identification are very urgent questions that need to be addressed and properly funded.

As a mother of a child with ASD, I am positive that my experience with autism might be different from some of yours: I live with autism 24/7! When I think about autism, I don't think about it in abstract concepts such as autism symptoms or autism behaviors, I think about my son. I think about his developmental challenges and also about his health, especially his gastrointestinal issues (G.I.). But, what do GI issues and diarrhea has to do with autism, you might ask. Well, it has to do a lot with it. I may suggest you to look this site [PII redacted] to see what the majority of us have to deal with on a daily basis. Due to these children's G.I. issues, many of them develop yeast, parasite, bacterial and viral infections throughout the gut. This is a website in which parents submit pictures of their children' BMs. Let me warn you, it is very graphic!

As we all know, there's more to autism than just gut issues. There is the behavioral aspect; a lot of these kids are highly sensitive and get easily overwhelmed by their environment, so normal activities such as going to the movies, the pool, or the zoo are very stressful, or just simply out of the question. Due to their texture sensitivities, getting them to try new food looks very much like a high-protocol negotiation or a wrestling match, it is just plain hard; which brings us to the nutritional aspect of kids with ASD. Can a child consume and absorb enough calories and vital nutrients from a self-restrictive diet while experiencing constant diarrhea? Wouldn't this deficit in calories and nutrients be an aggravating factor in autism symptoms? I asked these questions to my child's pediatrician but I didn't get a satisfactory answer. I also asked for some tests to be perform to see if my child was allergic and/or sensitive to some foods, but she said that this was just a phase…a phase that lasted 2 ½ years!

Now, let me to take you back in time to the Spring and Summer of 2007. [PII redacted] was about 2 ½ years old, and this was the height of his self-restricting diet phase. He basically ate cheese, yogurt, milk, bread, pasta and fruits. I painfully remember that [PII redacted]'s eye contact had diminished to almost nothing and he wouldn't even respond to his own name. He had lost most of his social interaction skills as well as his vocabulary. He always looked like he was in a fog and seemed more interested in spinning toys and looking at lights than in interacting with us. We were all worried and thought that his behavior was odd, but the word Autism hadn't entered our minds yet.

At the time, my mother-in-law, who was helping us with the arrival of our newborn, pointed out that [PII redacted] was a bit old to be drinking milk from a bottle. She took it upon herself to teach him how to drink milk from a "sippy cup." He refused to drink milk from a cup, so, he stopped drinking milk altogether. The most interesting thing happened within 3 days of his “milk-strike”, he started speaking again… he started using his old words: “mamma”, “dadda”, etc. He also learned how to use the spoon to feed himself, his eye contact improved, and he appeared more interested in interacting with us. It was fascinating and refreshing to see these changes in him. Throughout the weeks and months to follow, he kept on surprising us with his progress. Although he was still engaging in self-stimming behaviors and was still suffering from GI issues, he showed a lot progress in many areas. He was learning, he was imitating, and he was connecting with us. Within months, our child had gone from being almost non-responsive to wanting to learn and repeat everything that he saw or heard. We were thrilled by his progress, but puzzled. What had initially caused [PII redacted]’s development to slow down and eventually regress? What had triggered his development to initiate after a regression? Most importantly, what does milk have to do with it?

It was not until 6 months after [PII redacted]’s “milk-strike” that we learned about the GFCF diet and other biomedical interventions. It was kind of surreal to read about the benefits of removing gluten and casein from the diets of kids with ASD. These benefits were eerily similar to [PII redacted]’s changes following his milk withdrawal. Excited by his improvement, we researched more and found a doctor that follows the DAN! Protocol. Finally a doctor who was open to testing for food sensitivities and who understood the severity of [PII redacted]’s GI issues…so different from his regular pediatrician! Promptly, she ordered two specialized laboratory test: the Urine Peptide Test for Casein and Gluten and the Organic Acid Test (OAT). [PII redacted]’s peptide labs showed high levels of casein (he was still eating yogurt and cheese) and moderate levels of gluten. It appears that these unbroken protein chains have an opiate effect when they reach the brain; which could explain that “zone-out” look he used to have. The OAT test showed high levels of bacterial overgrowth, yeast, and Krebs cycles among other markers.

Under our new doctor’s care, [PII redacted] started taking digestive enzymes, probiotics, nutritional supplements (such as Calcium, Magnesium and Glutathione), and anti-fungal medication. I’m happy to say that in combination with ABA therapy and physical, occupational and speech therapy he has improved tremendously in the last year, besides, his BM’s are more solid and don’t have the toxic smell they used to have. So, “potty training” is looking much more attainable these days. It is amazing to see all the progress that we have attained using information provided from these two tests. Imagine the possibilities, the therapies and treatments that could be crafted if more resources were poured into this area!

I know that [PII redacted]’s story is not unique, and that many kids have experienced progress in varying degrees with diet manipulation and biomedical interventions. I encourage you to look at websites such as “Age of Autism”, “Safe Minds” and “T.A.C.A.,” or join yahoo groups such as GFCFkids@yahoogroups.com to learn more about the struggles and triumphs of families that have been touched by Autism. We are seeing progress in our children, but we need more studies that would validate, expand and deepen our current pool of knowledge on biomedical interventions, dietary manipulation and other therapies. We also need to get pediatricians and other health care providers to be aware and become active participants of the current alternative ways of treating autism. On 2007 only about 1% of the total ASD Research budget, of $126 million dollars, was allocated to biomedical treatments…only 1%. I guess that my question is why is the IACC not investing more resources in finding biomedical answers for treating Autism?

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Katherine J. Walker

November 21, 2008

Gluten Free Casein Free Diet is Integral Component of Treatment of ASD – A Call for Continued and Thorough Study

Two summers ago, I took my son [PII redacted], who has PDD-NOS, to a popular water park. My son is pretty high functioning, and loves the water. The park had a gentle, wide slope into a large pool; so younger children could run and play in shallow water. While at the park, I kept watch over [PII redacted], my twin daughters who are a year older than [PII redacted], and my teenage nephew and niece. [PII redacted] was loving the pool and getting more adventurous with the encouragement of his male cousin.

As the two boys ventured further into the water, things went bad quickly. The cousin went a little too far. [PII redacted] followed, but couldn't reach the bottom anymore and panicked. Thank God, [PII redacted] was close to the side of the pool, and a young lifeguard was right there next to [PII redacted]. The lifeguard kept looking at [PII redacted], but did nothing to assist him, even though [PII redacted] was crying. Being non-verbal, [PII redacted] couldn't say "HELP" but it was obvious he needed help. [PII redacted] was up to his ears, and barely keeping his head above the water. I ran into the pool, frantically yelling "He needs help, help him!" [PII redacted]'s cousin starting yelling too, and tried to get the lifeguard's attention and get back to [PII redacted].

When I reached [PII redacted], I was nearly chest deep in water, [PII redacted] was terrified. I looked up at the young lifeguard who was supposed to be watching for swimmers in distress. "Can't you see him? Didn't you see him?" I yelled. The young lifeguard said nothing. I carried [PII redacted] out of the pool and calmed him down. It wasn't long before he was running back in for more. So, all in all, not a real traumatic experience for [PII redacted]. But it was a horror for me, and a harsh awakening to reality.

Many if not most of our ASD children can't tell us when they are in distress. They can't tell us their tummy or their bottom hurts even when they have continual gastrointestinal distress and diarrhea. They may not tell us when they are hungry, tired or need to use the restroom. The degree to which I tune in so closely to [PII redacted]'s body and verbal signals is so high, that my twins often feel left out and ignored. Having a special needs kid in the family is a continual balancing act. Perhaps some of you here understand that. I would hope that at least some members of the IACC and the groups that decide where research funding goes do experience this daily battle.

It is impossible for you to understand unless you live it, unless you have a child with ASD, and deal with it all the time. We are in the trenches everyday waging war against ASD. We are the ones who understand and see the ins and outs of ASD. We see what works for our children, and we see what doesn't work. This is why I find it inconceivable that the reports from parents of what works as treatment for their children is labeled as "anecdotal". The last time I checked the process for scientific method, it was form a hypothesis, conduct research and experiments, and then come to a conclusion based on the results.

How can the medical establishment tell us that our everyday “experiment” with ASD is not adequate enough to merit and trigger formal, clinical unbiased studies? I have [PII redacted] on a gluten free casein free (GFCF) diet and by no means am I the first to say the gluten free casein free diet has a positive impact on children with ASD. My son [PII redacted] has responded well to the diet and I have seen great improvement in real terms of attention, verbal communication, temperament and interaction with his family and peers. He is generally a calmer, happier little boy.

I can tell you that when he has a transgression of the diet, like the pizza he ate at Chuck E. Cheese’s during the recent holiday, his symptoms flair, especially behavioral symptoms, screaming, agitation, sleeplessness. It is unreal how gluten and casein affect my son.

Indeed, parents of ASD children are not the first or only group arguing the importance of diet in treatment of a chronic illness. There is support of diet being an integral part of easing symptoms and treating chronic illnesses such as:

- Strict Carbohydrate Diet and Elemental Diet for Crohn’s Disease.
- Ketogenic Diet as early treatment for pediatric epilepsy.
- Gluten and glucose management for type 1diabetes.
- Diet and Nutrient management for type 2 diabetes.
- Vegetarian/Vegan Diet for treatment of fibromyalgia (a disease of unknown etiology).
- Plant based diet for recurrent prostate cancer.
- Gluten free diet for celiac disease.

(Articles to support the above list are submitted with my written comments and were obtained from various peer-reviewed medical journals.)

Even common medical conditions are treated with dietary changes, such as high cholesterol. With this in mind, how can the National Institutes of Health, CDC and the IACC not support more thorough and intense study of the use of the GFCF diet for ASD? You can’t tell us diet is important for one disease, and not important for another one. The American Academy of Pediatrics can’t have it both ways.

We started GFCF after learning [PII redacted] had intestinal yeast (Candida). We discovered this problem through testing, ordered and supervised by a doctor. We have realized, like thousands of others, that there is a direct relationship between the gut and the brain. This can no longer be ignored by organizations such as AAP, NIH, CDC or large autism groups. What we put into our children’s gut, especially when the gut is being attacked by fungus, bacteria or even viruses, has a most serious impact on how their brains function.

I strongly encourage the continued support and expansion of studies such as that being conducted at The University of Texas Health Science Center at Houston. However, it must be ensured that the study is of adequate duration to yield valid results. The effects of gluten can take much longer than four weeks to subside. Most parents that support the GFCF diet tell those just starting the diet to wait a few months to see the real impact of removing gluten.

I also encourage the continued support of the studies being conducted by Ann Reynolds at the University of Colorado and by Sherie Novotny at R. W. Johnson Medical School/University of Med/Dent NJ.

That summer day at the pool, a young lifeguard was not paying enough attention to my son. He did not look close enough into the water to see [PII redacted]'s source of struggle – even though the outward signs of distress were evident. As parents, we must realize that no safety system is foolproof. It is imperative for us to realize we are the ones that must advocate for our children when the safety system is failing or does not have a broad enough scope.

I am the one who will reach out for help for [PII redacted] even when conventional medicine may not approve. When the typical safety system does not work efficiently or effectively, when the lifeguard is not paying attention for whatever reason – I must act. The NIH, CDC and the American Academy of Pediatrics all have roles as "life guards" in protecting our children, in helping discovery all possible ways to help those dealing with ASD. I speak for myself, and thousands of other families using the GFCF diet as an integral part of their treatment for ASD – there must be continued and broadened studies on the effect of the GFCF diet.

As our government entities, the NIH, CDC and IACC must listen to parents and stop belittling our experience as anecdotal. The AAP and large autism groups are not the only groups who hold authority on the world of ASD. In fact, I would argue they are too often too far removed from life with ASD to truly offer raw, valid firsthand knowledge.

I thank the IACC for allowing me the opportunity to speak, and I leave you all with two quotes from Thomas Jefferson:

"It behooves our citizens to be on their guard, to be firm in their principles, and full of confidence in themselves. We are able to preserve our self-government if we will but think so." --Thomas Jefferson to Thomas Mann Randolph, Jr., 1800. ME 10:151

"The force of public opinion cannot be resisted when permitted freely to be expressed. The agitation it produces must be submitted to." --Thomas Jefferson to Lafayette, 1823. ME 15:491

Jim Moody

November 21, 2008

Dear Members of the IACC:

The Combating Autism Act required the IACC to prepare a strategic plan for autism research in order to enhance the quality, effectiveness, and overall benefits of autism research spending within HHS agencies. While the 2008 planning activities reflect improvements relative to earlier Autism Matrix efforts, ultimately the draft plan and the planning process have fallen short. Autism advocates have identified a range of deficiencies and each may place priorities on different concerns. Nevertheless, as a community we are united in expressing our disapproval of the draft plan for the reasons outlined here.

A. The plan fails to communicate a sense of urgency reflecting the alarming increase in prevalence and autism as a national health emergency. The beginning pages of the plan should embody urgency and the critical need of the government to apply the resources to address a crisis situation.

B. The plan fails to allocate commensurate resources. The CM authorized $645 million for NIH research over five years. The plan falls short by close to $200 million. Given the urgent situation, we consider the CM allocation to be a minimum requirement for federal agencies and feel that even greater resources are needed.

C. Research on the environment, gene-environment interaction, and treatment are underrepresented in the draft plan. The plan should apply additional resources to these areas.

D. Provisions for accountability and evaluation for the research spending are absent. Adoption of oversight, review and evaluation mechanisms, such as an Autism Advisory Board and a Department of Defense grant review model, should be added to the plan.

E. The planning process diminished the voices of important segments in the autism community. Future activities related to the SP should ensure integral participation of the diverse community representing families and individuals with autism.

We ask that the IACC approve these specific action items: (a) adoption of amendments to the plan responsive to the above 5 concerns; (b) specification that research spending be at least the CM minimum and establishment of a workgroup to be convened in January 2009 to develop recommendations to the IACC for increasing the research spending to at least that minimum and adding objectives which will bolster research on the environment, gene-environment and treatment; (c) inclusion of oversight provisions including an MB and DOD-model review process; and (d) specification that oversight bodies and workgroups have strong and diverse community representation.

Each day, decisions are being made on autism research by NIH and other federal agencies which are outside of the SP. It is imperative that the plan be improved in the areas noted above at the November 21, 2008 IACC meeting.

Sincerely,
Autism New Jersey (formerly COSAC)

Autism Research Institute -
Autism Society of America
Autism Speaks
Generation Rescue
National Autism Association
Organization for Autism Research (OAR)
SafeMinds
Talk About Curing Autism (TACA)
Unlocking Autism

Dr. Vicky Debold

November 21, 2008

Good Afternoon. My name is Dr. Vicky Debold and I represent SafeMinds, a private charitable nonprofit organization founded to investigate and raise awareness of the risk to child health due to exposure to mercury from the environment and medical products, including thimerosal in vaccines. Additionally, SafeMinds supports research on the potential harmful effects of all forms of mercury, including thimerosal.

We appreciate the opportunity to provide recommendations to the Interagency Autism Coordinating Committee's (IACC) strategic plan for autism spectrum disorders research and recognize that the plan's focus is intended to enhance the quality, effectiveness, and overall benefits of autism research spending within HHS agencies.

Many organizations, ours included, have articulated concerns with the August 15th draft plan being considered today. Specifically, we note that the August version: 1) lacks a sense of urgency; 2) over emphasizes genetics-only research; 3) under-emphasizes environment and gene-environment interaction research; 4) omits oversight and accountability mechanisms; and 5) reflects inadequate representation of the autism community throughout the planning process.

Integral to improving the IACC strategic plan is to clearly communicate the urgency needed to address the alarming rise in autism prevalence and the failure to date of realizing the potential of recovery and gains in quality of life through promising treatments. This language is needed to set the tone for the entire plan and to frame the government's response and allocation of resources at levels commensurate to the obvious crisis at hand. We strongly recommend that all language failing to acknowledge increased prevalence be removed from the plan and that language recognizing the potential for recovery from disability be inserted.

Funding for environment and gene-environment interaction research must be considered relative to genetic research. - Although funding levels for environment-oriented research have increased, an inappropriately large proportion of the August 15th budget is allocated to genetic research. IACC funding initiatives were intended to complement non-governmental initiatives thereby creating a balanced national research portfolio free of wasteful duplication. Fiscally responsible recommendations require that funds earmarked for genetics-only research already well funded in the private sector be shifted to environmental research inadequately funded in all sectors.

Additionally, research related to environmental triggers explicitly detailed in the Combating Autism Act legislative history, namely, vaccines and mercury-based vaccine components is conspicuously missing from the August 15th plan. The need for rigorous research establishing whether causal associations between exposure to vaccines and autism exist cannot be overstated. Town hall meetings conducted throughout the planning process demonstrated the extent to which this topic is important to the public.

Provisions for accountability, management and evaluation of research spending also continue to be absent from the plan. Oversight and evaluation mechanisms similar to the Department of Defense's grant review model should be developed and implemented by an Autism Advisory Board composed of diverse community representatives as required by the CAA. The Board - composed of scientists, clinicians, and advocates - would not duplicate the IACC's broader work coordinating all federal autism activities including those related to provision of services. Rather, the Board would focus the scientific research agenda and CM provisions related to annual performance measures and strategic plan updates.

In closing, we ask the IACC to adopt the suggested revisions to the plan submitted by IACC member Lyn Redwood, to improve the above noted aspects of the plan. We further ask the IACC to establish a workgroup to be convened January 2009 to further develop recommendations and add objectives increasing funding for environment, gene-environment and treatment research; and develop oversight provisions including an Autism Advisory Board and an improved grants review process.

Mike Frandsen

November 21, 2008

Much of the focus on autism is on **research for children** with autism, but very little is done in the way of research on **services for adults** on the spectrum. NIH and other government agencies need to do a better job of ensuring that people with autism and other disabilities can contribute to their missions.

NIH and other federal agencies have virtually ignored the Schedule A hiring authority, a federal program used to "appoint persons who are certified that they are at a severe disadvantage in obtaining employment." The Schedule A program was developed to help reduce the more than 70% unemployment rate of people with disabilities. These are people who want to work and are more than capable of working. Even years after NIH was notified its lack of response to the Schedule A issue, there has been little if any action taken.

It is ironic and disappointing that an organization whose mission is to "work to improve mental health through biomedical research on mind, brain, and behavior," (the National Institute of Mental Health) does not have an equivalent program to ensure that those disadvantaged with disabilities can fairly contribute to advancing that mission.

I submitted Freedom of Information Act requests to federal government agencies asking how many times the Schedule A certification was used to hire people with disabilities in the three categories defined by OPM as: physical disability, mental retardation, and psychiatric disability.

According to my survey, most federal agencies underutilized the Schedule A program or did not use it at all. In almost all cases in which the hiring authority was used, hires of people with physical disabilities outnumbered those with cognitive disabilities and psychiatric disabilities by an extremely wide margin. Noteworthy results from the survey at www.coachmike.net include the following:

- The Department of Health and Human Services reported that it hired 213 people with disabilities through the Schedule A program from 2000 to 2008. Of those, 198 had physical disabilities; 15 had cognitive disabilities, and **not one had a psychiatric disability** (After the survey, one HHS agency hired a person with a psychiatric disability).

- The Department of the Interior, which has approximately 75,000 employees, used the Schedule A program for people with disabilities to hire exactly three of its current employees.

- From 2003 to 2008 the Department of Commerce hired 36 employees with disabilities under Schedule A. All were in the physical category except for one in the psychiatric category (none were hired with cognitive disabilities). The Department of Commerce has approximately 36,000 employees.

The federal government needs to be proactive in hiring people with disabilities, including those with developmental disabilities. In the hundreds of pages of responses I received from government agencies, not once was there a mention of someone hired who had autism.

While there must have been cases in which autistic people have been hired using the Schedule A certification or otherwise, in the descriptions of the types of disabilities listed by federal agencies in their FOIA responses, the term "autism" never came up, though some agencies did not go into detail other than listing the three major categories.

The categorization of disabilities under the Schedule A program seems to exclude most people on the autism spectrum. The Schedule A Program lists people with disabilities in three broad categories. The first category, "severe physical disability," would only sometimes apply to a person with autism.

The second category, "mental retardation," may apply to a percentage of people on the autism spectrum, but it is now believed by many experts that far fewer people with autism than previously believed have mental retardation, a term, which incidentally, is being phased out in favor of "intellectual disability" or "cognitive disability."

Finally, the third category, "psychiatric disability" does not cover those with autism, which should be classified as a "developmental disability," a term that would be much more accurate and inclusive.

The federal government should ensure that people with autism and other disabilities are adequately represented in the workplace so they can contribute to their missions of HHS, NIH, and other agencies.