Oral Public Comments

IACC Full Committee Meeting

November 10, 2009

List of Oral Public Comments

Jim Moody

November 10, 2009

Subject: The Strategic Plan – Useful Tool or Unfulfilled Opportunity

The heart of the Combating Autism Act was the strategic plan, research budget, and annual updates. This mechanism was designed to bring rigor and discipline to the process of expanding and focusing research to achieve the goals of preventing and treating autism.

Epidemic Denial Cripples the Urgent Response Demanded By This Crisis.

The plan must include a call upon President Obama to declare a national health emergency for autism. Autism prevalence has jumped from 1:10,000 to 1:91 during the past three decades, yet CDC's "official" count" is still a decade late. Concerns over adult prevalence and the precise boundaries of "autisms" must not interfere with the urgent need for identification of environmental triggers so that new cases can be prevented and treatments for existing cases. The families deserve a response on the scale of SARS, lead-painted toys, tainted peanuts and spinach, and swine flu, and a re-engineered process akin to NASA or the Manhattan Project. IACC is still operating on a schedule of years and decades while families need answers now. High-ranking public officials have bragged recently that they meet on swine flu daily, yet IACC struggles with more than four meetings a year. Why not weekly, if necessary. And, which high-ranking officials can claim that they focus daily on preventing and treating autism? The plan talks about research on "x" environmental factors and "y" treatments but these remain unidentified. How long must the families wait? The CAA called for increased public participation in decisions relating to autism, yet the small DOD CDMRP remains far ahead. The Senate Report called for an Autism Advisory Board but this remains unimplemented. A rigorous cost-of-disease study must be done and compared with the demand for competent science to determine how much and how rapidly the autism research budget must be increased.

Take the Politics Out of Vaccine Research

Vaccine Court began quietly compensating autism cases - many of which are secret - in 1991. Merck identified the risks from vaccine mercury – and safer alternatives - in 1991. Sir Michael Rutter first published on vaccine caused autism in a 1994 paper. Wakefield's 1998 case series and Bernard's 1999 review of the similarities between autism and mercury poisoning came relatively late to the debate, yet they get all the "blame" (credit). Do vaccines cause autism. As a matter of science, clinical medicine, and law, the answer is a definite "yes." What remains is the body count, how to prevent new cases of vaccine-caused autism, and how to treat - and compensate - the unintended victims of our one-size-fits all national vaccine experiment. A comprehensive program of vaccine research was unlawfully deleted from the plan last January, supposedly to await the "expert" input from NVAC. The claim that a conflict of interest prevented HHS from funding vaccine-research – because it might help families obtain just compensation for their injured "child soldiers" in Vaccine Court – is perhaps the best proof that fear and politics are being used to defeat sound and necessary science. The only way to end this controversy – not whether but how many and how can future injuries be prevented – is with a comprehensive program of IACC funded vaccine research, beginning with an immediate and ongoing comparison of vaccinated and unvaccinated children.

In conclusion, STOP THE TALK - START THE CURE!

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

Paula Durbin-Westby

November 10, 2009

ASAN
The Autistic Self Advocacy Network

Thank you for this opportunity to comment on updating the IACC Strategic Plan. I am representing the Autistic Self Advocacy Network.

My comments on October 23 focused on ethical issues, concerns about the appropriateness of early intervention and associated research, permissions for acquisition of biological materials, and the IACC's recommended budget being skewed severely in favor of research into "causes and prevention" rather than practical and appropriate interventions, such as improvements in educational interventions, services and supports.

I have had an opportunity, through the IACC Scientific Workshop Panel process, to make some language changes and suggestions that should apply throughout the Strategic Plan. Since I was on Panel 1, "When Should I Be Concerned?" I will use that section of the 2009 Strategic Plan as an example of changes ASAN would like to see incorporated throughout the entire 2010 Plan:

Many of these changes reflect either more accurate and useful terminology or more respectful language that does not introduce an undertone of disrespect, fatalism, or excess pathologizing of autism.

Anywhere the term "high risk" is used to characterize the likelihood of siblings also being on the autism spectrum, the language should be changed to just that: "high likelihood" rather than "high risk."

"Abnormal" should be changed to "atypical," as we have done for the Panel 1 final document.

Anywhere interventions are mentioned, the use of the qualifier "appropriate" should be inserted, addressing our community's concerns about "intervention for the sake of intervention," and especially in the light of the obvious disregard of and dismissal of autistic input into the research process to date.

Rather than "early warning signs," we strongly suggest "early indicators," which is more scientifically accurate and does not introduce negative value judgments into identifying indicators of autism or atypical development.

Instead of "symptoms," "characteristics" and "conditions" are more appropriate, since autism is not a disease process but a neurobiological difference. The use of the term, and concept of "severity," is questionable for several reasons. First, "severity" is often contextual, over both time and other things like situation and location. What is being looked at when using the "severity" criterion is how "observable" the autistic characteristic is. Whether or not a characteristic is observable and to what degree does not necessarily correlate with other aspects of the person. For this reason we prefer the

term “variability,” which indicates that both abilities and disabilities can be present in the same person, and that abilities and disabilities can change over time, whether permanently, or temporarily, in the presence of other factors, such as external environment.

I have made another language change, from “pathology” to “differences in neurobiology and cognition,” which is more specific and avoids the concept that all autistic differences are pathological. Many of them are not.

I have rewritten the first section of the Strategic Plan, with its three sub-questions, to read:

“When Should I Be Concerned?”
-“What are the Early Indicators of ASD?” (rather than “What are the early warning signs?”)
-“Are there typical characteristics that are part of an ASD diagnosis?” (I left that the same, since you already used “characteristics”, which is the preferred term.)
-How much variation is there in characteristics and pattern of abilities and disabilities (over time and depending on context)?”

In addition, undue focus should not be placed on “losing symptoms” of autism, without qualifying language indicating that the “loss” could be due to *learning of skills,* and certainly should not indicate, at this early stage in research, that these research subjects have become non-autistic. Especially in the light of reports that many of the subjects still retained co-occurring symptoms often found in autistics, such as OCD, anxiety, ADHD, etc., the public should not be encouraged to think that “loss of autistic symptoms” is “loss of autism.” I have changed the sentence in Panel 1’s draft to: *“Finally, evidence is emerging that some children ‘lose’ explicit characteristics of ASD although it is not clear whether that loss of autistic characteristics is permanent throughout the lifespan, or whether it reflects “learning skills” rather than “losing characteristics.”*

I have reformulated one of the Research Opportunities to: “Inclusion of bioethical and other ethical considerations into the diagnosis and screening process, including but not limited to consideration of the implications of genetic testing and detection of maternal antibodies. Maternal antibodies is an emerging area of concern for us which is reflected nowhere in the current Plan or suggested revisions.

NIMH and other grant-making institutions should not fund research that uses or promotes the use of restraints, aversives, and seclusion. There is a growing movement in society away from the use of these draconian measures, reflected in current legislative efforts to ban their use. Restraints, aversives and seclusion are used disproportionately against people with disabilities, including autism and other developmental, intellectual, and behavioral disabilities. In no case should researchers applying for grants to study restraints and aversives, either to further their use or to legitimize that use, be allowed access to federal funds, including funds from private/federal partnerships. Research that promotes restraint reduction and elimination should be funded as a high priority in order to keep autistic and people with other disabilities safe.

Research into communication differences must be given higher priority than it was given in the 2009 Strategic Plan. A mere mention of Picture Exchange Communication Systems is not enough, given that PECS does not work for everyone on the spectrum, nor does it address the needs of people who need communications technology and/or systems part-time, as a supplement to speech and/or writing, or the need for systems that are flexible enough to accommodate a wide variety of changing communication needs. It also does not address the needs of people who use non-language-based communication

systems. Every person communicates in some form, but that communication is often not well-understood, and to this date, has been under researched. To separate autistics into “verbal” and “non-verbal” categories and leave it at that is to miss a critically important area for research, far surpassing in practical importance the finding of yet another “autism gene” or maternal antibody. The need for *all* autistics to communicate in ways that others can understand is crucial for our empowerment, life chances, access to basic needs, and for the chance to engage in reciprocal communication with people who do not easily access our various ways of communicating. What do autistics want? Ways of communicating that work for us and that allow us to communicate effectively with a wide range of others. What do parents of autistics want? Ways of communicating with us. A glance at comments online and in news media indicate that more parents are interested in being able to communicate with their autistic children (including adult offspring, who are by no means to be written off) than are interested in what gene/s are responsible for autism.

Finally, in order to accomplish the goal of achieving the best possible outcome for all people on the autism spectrum, autistic adults should be consulted and should participate in all levels and tasks of research on autism. Autistic adults with a perspective that focuses away from questionable cures and “elimination” of autism should be given a seat on the Interagency Autism Coordinating Committee. Nothing About Us Without Us.

Paula C. Durbin-Westby
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Katherine Walker

November 10, 2009

Good morning. I am Katherine Walker, mother to 7-year-old [PII redacted] who is recovering from PDD-NOS, and a Government Affairs Committee Member representing SafeMinds. [PII redacted] has responded tremendously well to toxic metal detoxification and biochemical correction. In other words, we have been cleaning out the toxic heavy metals in his body and brining his body's biochemical make-up into balance in order attempt recovery from regression into PDD-NOS. My husband and I thank God for the progress [PII redacted] has made, and are thankful to all those who have helped us along this long and arduous journey. I thank the committee for the opportunity to speak today on behalf of my family and the many families SafeMinds represents.

We offer public comment in hopes that the committee will respond to the many requests SafeMinds and the autism community have sent the IACC with regard to vaccine safety research and lack of federal member support of public members who were outvoted last year on the expansion of investigations of toxins, biomarker and treatment objectives.

Government statements regarding the uncertainty of autism's rise to 1 in 100 ignore the growing body of research indicating that not only is the rise real, it is likely that environmental factors are driving the increase in prevalence. The strategic plan must incorporate this data and respond with greater urgency in addressing the needs of those with autism. The word "anecdotal" must be a positive mile marker for the funding of treatment research in discovering which individuals are more likely to respond to one treatment versus another. Expanding the number of toxins and other environmental factors to be investigated is reasonable to enable much needed understanding of causation, treatment and prevention. Increasing biomarker and treatment objectives will bring us much closer to these goals. We request these expansions, as they reflect the corresponding urgency required of this committee by the community.

Additionally, we remind the committee that expertise requested by IACC of the National Vaccine Advisory Committee (NVAC) was delivered in July to assist in determining the validity of vaccine objectives removed from the strategic plan and which were inserted in the draft plan document provided by Lee Grossman to the IACC on October 23rd. As is well known, the NVAC report made autism specific recommendations that must now be integrated into the strategic plan in accordance with the intent of the Combating Autism Act and the 1986 Congressional Mandate for Safer Childhood Vaccines, which requires research to reduce vaccine adverse effects.

Former NIH Director Dr. Healy has stated "The public values vaccines. But more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show." Dr. Louis Cooper, a former AAP President and Dr. Samuel Katz, a former ACIP chair, also recognized the vaccine safety research deficits and wrote in Newsweek "...there's been grossly insufficient investment in research on the safety of immunization." Vaccine court has quietly awarded compensation for vaccine

injuries resulting in autism since 1991; over 1,300 awards for vaccine injury have been made. Messaging from this committee should not be that the vaccine injured are an acceptable collateral damage not worthy of investigation.

These two objectives are budgeted at $16 million, representing a fraction of the IACC's budget. We acknowledge Dr. Lawler's recent statement regarding animal and cell models being the “bread and butter” for NIEHS in discovering pathways and mechanisms, we note NVAC has agreed on this point with regard to vaccine research. We appreciate Dr. Insel's recognition during the committee's last meeting that panel recommendations were not meant to be the sole source used for improving the strategic plan, as NVAC's expertise was recognized by the full committee months ago. Indeed, it is unlikely that panel three's expertise exceeds that of NVAC, since the panel was purposely made to be diverse enough to address more than vaccines. We also acknowledge that panel three members themselves have noted a lack of toxicological expertise, and the panel’s inability to fully address other aspects of causation and prevention. We recommend the correction of this oversight in future planning.

With the rise in voluntarily unvaccinated populations, as noted by NVAC, CDC and the Institute for Vaccine Safety, perceived impediments and ethics are without foundation in terms of conducting a comparative population study for critically needed baseline information on vaccines and their effects. This is a study Former CDC Director Dr. Julie Gerberding believed could be done. Vaccine research as acknowledged by NVAC, will require an array of ongoing studies. Incorporating active recruitment protocols in current studies such as NCS with commiserate monies to obtain medically verified vaccine records must also be implemented. Dr. Duane Alexander estimated the cost for NCS to gather these records at $28 million. Additionally, protocols are easily added to assure statistical power and are a wise investment in closing existing vaccine safety research gaps.

In closing, our community expects scientific curiosity to supercede policy concerns, as this committee is first and foremost a research committee. In this committee's acknowledgment of HRSA's conflicts of interest, vaccine research objectives must be independent from vested interests and have independent oversight. We have loudly and repeatedly made clear the need for this research, as has the NVAC and numerous Members of Congress and public health officials. Thus, I leave you with a quote from Dr. Albert Einstein: “*The world is a dangerous place, not because of those who do evil, but because of those who look on and do nothing.”* It is now up this committee to do something.

Dr. Kerry Lane

November 10, 2009

PUBLIC SUBMISSION

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Docket: FDA-2009-N-0138
Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting.
Comment On: FDA-2009-N-0138-0001
Joint Meeting of the Drug Safety and Risk Management Advisory Committee, Nonprescription Drugs Advisory Committee, and the Anesthetic and Life Support Drugs Advisory Committee; Notice of Meeting - Notice of Meeting
Document: FDA-2009-N-0138-0005
Kerry Scott Lane MD - Comment

Submitter Information
Organization: St. Mary's Medical Center, W. Palm Beach, FL

General Comment
Acetaminophen, Glutathione Depletion, and Regressive Autism

Acetaminophen toxicity in the liver is well established. One of the known toxic effects of this commonly used drug is depletion of the most important antioxidant, glutathione. Disease states linked to depletion of glutathione and excessive amounts of oxidized glutathione, versus reduced glutathione, include Diabetes, Atherosclerosis, AIDS, Alzheimer's, Pregnancy Induced Hypertension (PIH), and others.

Regressive Autism is a condition that has defied a definitive pathobiology to date. The attachments enclosed reveal that acetaminophen, by exacerbating an already depleted glutathione antioxidant system due to a preexisting condition, triggers autism in the peri-vaccination period by reducing glutathione levels to below a critical level. Adequate glutathione levels are crucial to the effective functioning of the Metallothionein (MT) System. The MT system is involved in metabolism of metals, as is glutathione. However, the MT system is especially critical to the metabolism of Zinc in the brain. In states of depleted glutathione and excess oxidized glutathione, free Zinc is released in brain cells. This free zinc is toxic to the mitochondria, causing cellular hypoxia and a generalized neurological malfunctioning that we now recognize as Autism.

It appears acetaminophen alone is not enough to cause Autism. The co-morbid pathobiology is due to the creation of a state of abnormal gastrointestinal biology due to antibiotic administration to the infant. This allows the replacement of the normal GI flora with yeast overgrowth by Candida species and others. Many yeasts and fungi produce mycotoxins which have been shown to be pathological to man and animal alike.

Recently interest has focused on a mycotoxin known as Gliotoxin which has been shown to be immunosuppressive, by killing CD4 cells, along with a multitude of other deleterious effects. Gliotoxin has been shown to form adducts with glutathione, essentially removing it from the pool of bioavailable antioxidants. Over fifty per cent of Candida species have been shown to produce Gliotoxin.

If we envision a sequence of events that results in an undesirable yeast in the GI tract, causing a depletion of glutathione and generalized oxidative stress, followed by a vaccination that includes a metal adjuvant (mercury or aluminum), followed by the administration of acetaminophen (antipyretic) to an infant- at a critical period of neurodevelopment- we can envision the pathobiology of Autism.

The enclosed attachments from peer-reviewed articles are a roadmap to the above described pathobiology. I suggest the FDA act with all due haste to make this material public so the autism epidemic can be properly managed. Additional focus should be directed to the AIDS syndrome, which also involves depletion of glutathione. It would seem acetaminophen is inappropriate in this setting, and possibly in most settings.

Kerry Scott Lane MD
St. Mary's Medical Center
June 6, 2009

Dr. Anita Miller Sostek

November 10, 2009

STATEMENT OF AUTISM SPEAKS ON VACCINE SAFETY RESEARCH AND THE IACC STRATEGIC PLAN FOR AUTISM SPECTRUM DISORDER RESEARCH

Autism Speaks is the nation's largest autism science and advocacy organization. We are dedicated to funding global biomedical research into the causes, prevention, treatments, and cure for autism; to raising public awareness about autism and its effects on individuals, families, and society; and to bringing hope to all who deal with the hardships of this disorder. Consistent with these purposes, we make the following statement.

IACC Statement

In enacting the Combating Autism Act (CAA), Congress intended that the federal government examine potential links between vaccines and autism. During the Senate debate over the CAA, Mike Enzi, Chairman of the Senate Health, Education, Labor & Pensions Committee, instructed that "no research avenue should be eliminated, including biomedical research examining potential links between vaccines, vaccine components, and autism spectrum disorder." 152 Cong. Rec. S8772 (Aug. 3, 2006). In the House, Joe Barton, Chairman of the House Energy and Commerce Committee, was equally clear: "[T]he legislation rightfully calls for renewed efforts to study all possible causes of autism -- including vaccines and other environmental causes. . . . The important thing to understand is that there are no preconceived notions contained in this bill; the bill language is clear that we should follow every avenue that science opens to us in searching for a cure." 152 Cong. Rec. H8787 (Dec. 6, 2006).

Beyond this clear directive of the CAA, Autism Speaks supports rigorous, evidence-based scientific research into all aspects of autism from potential causes, including both genetic and environmental factors, to diagnosis and treatments. As such, we strongly urge that further vaccine safety research be included in the Strategic Plan for Autism Spectrum Disorder Research. Comprehensive "good" science should be the standard in all areas studied and there are aspects of vaccine safety research that have not yet been, and should be, considered.

It is also essential that all scientific research recommended by IACC and funded by the NIH be rigorous and evidence-based to engender the trust of the scientific, medical and entire autism community. Without a solid foundation that supports confidence in scientific conclusions, the entire portfolio of scientific research is at risk of losing community trust. Further, vaccine safety research will increase both the level of confidence in the safety of our nation's vaccine program

and the rate of participation, which is absolutely crucial for the prevention of serious infectious diseases.

Autism Speaks calls on the IACC to consider the importance of evidence-based science, trust, and to remain true to the critical legislative purpose of the Combating Autism Act and asks the IACC to include vaccine safety research in the strategic plan.