Written Public Comments

IACC Full Committee Meeting

January 19, 2010

List of Written Public Comments

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

Theresa Meuse

December 20, 2009

Subject: possible cause to exponential rise in ASD diagnosis?

I have some ideas of what might be contributing factors for the geometric increase in diagnosed children with autism spectrum disorders. In case it is helpful to someone in the autism research community, I am passing these ideas on to you should they be of any use to use (no strings attached). I believe that the main contributors to our unexplained autism rise could be: vaccines have enabled more ASD children to survive childhood (than would have typically survived) surviving ASDs are having children we are becoming more aware of the ASD condition

To explain, please excuse my lay persons understanding of your fields.

I believe that the signal-to-noise ratio of childhood survival to childhood deaths has significantly increased over the last century thanks to vaccines; they have "exposed" genetic variations that were otherwise "covered-up" by the previous survival threshold (noise floor), that would otherwise not have survived (ASDs would have been the children who would not have survived childhood (whose lives would have been terminated "by nature").

For example, my mother, from a middleclass family, who grew-up in post-civil war Spain, was the youngest and only survivor of six children (five boys who died before she was born). My grandparents were not destitute, however, those days, early childhood deaths were greatly grieved, but were not uncommon. All five boys died of (unknown to me) childhood diseases; to my knowledge they received no vaccinations. I wonder, had one or all of them survived, might him/they have been ASDs. Families with at least one childhood death were just the way things were. Today in the US, with only 2.1 children per family, having a family suffer a childhood death is really not that common.

I grew-up with the understanding that young boys were more delicate creatures than girls: a young boy's life was cherished and protected more so than that of a girl's life (hence it seems intuitively natural to me that boys were somehow more genetically vulnerable to a genetic ASD condition [thus childhood death] than girls were). I wonder what our current boy-to-girl survivability ratio is. However, not all ASDs/systematic thinkers are males (I might be lucky enough to be one).

I like to think of humans as a colony, like that of ants or bees that have mainly two different populations: 1.) neurotypical, and 2.) ASDs (analogous to worker bees, and non-worker bees). ASDs might have been born in fewer numbers, with an Intelligence Quotient (IQ) skewed to a particular dimension that enhanced the overall colony's IQ (whereas a neurotypical's IQ is more "well rounded", with no particular outstanding dimension).

The collective maximum IQ of the colony would then be the maximum over each dimension over the entire colony's population. This collective max IQ contributes to the survivability of the entire colony. However, occasionally the IQ of an ASD with a particularly outstanding IQ in a certain dimension would survive, which would help leap the collective max IQ by generations, thus increasing the colony's survivability. Hence the maximum collective IQ volume would occasionally have a new local prominence by that ASD's contribution (hence the ASD "multidimensional oval" IQ would make the colony's collective max IQ larger than it would have been without the ASD's contribution).

However, the current increase in survivability of ASDs might be altering our neurotypical-to-ASD colony ratio. Since more ASDs are being born, our collective max IQ may also be accelerating, a good thing to have for this age of information sharing/mining.

I like to think of genetics as a multigenerational memory. What experience has been "memorized" is passed down to the next generation via the genome or epigenome. So what survival experience did humans have to cause autism, still remains a question.

Lastly, in our "brave new world", having more children survive childhood is a good thing! I suspect that as we continue to push our childhood and elderly survival rates, we will see higher incidences of other yet unknown problems emerge that will need to be solved, one at a time.

Theresa Meuse
Mom of [PII redacted]

Ross 'Bubba' Nicholson

December 21, 2009

Subject: Nicholson's new book: cures for crime, drugs, and perversion

Of Love: Kisses Pass Epigenetic Pheromones in the Pathogenesis of Sociopathy, 'Mental Illness' and Disease.

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Dan Eckard

January 4, 2010

Subject: National Institutes of Health (NIH) EMPLOYEE WITH ASD

Gentlemen,

I am the father of an individual who began work in a clerical position at NIH out of high school in a special program with Montgomery County Schools.

My son, named [PII redacted], is 38 and passed the Maryland Functional tests.

He lives alone with some help from us, since his GS-1 (General Schedule) salary is below the poverty level.

He has basically been ignored by NIH and didn't even receive a step increase until after several years when my wife (his mother) contacted Human Resources (HR) and asked about NIH policies.

Now that we understand Spectrum Disorders better, we are attempting get my son into a more self-actualizing position and possibly having him contribute in some way to a better understanding of ASD.

As a start, I am attempting to contact someone at NIH involved with this area who might be interested in working with [PII redacted] in some capacity, possibly as an NIH employee who could transfer to the appropriate group.

[PII redacted] has most ASD characteristics, including missing many social language cues very extroverted in social settings, almost savant-like memory for areas that interest him (he knows everything about football for the past 10 years, including details and scores of each game, players, etc.) and can give calendar information far back.

Any suggestions you might have concerning how [PII redacted] might be better placed would be appreciated.

Dan Eckard, PhD
[PII redacted]

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Donna Young

January 4, 2010

Subject: RE: Input suggestions for Conference - January 19, 2010

Please forward to your Canadian Board Members and the United States of America members for suggestions of topics on your next Conference Meeting. Thank you. I will be making this suggestion a public appeal. Please reply, thank you.

I am concerned that those parents with current problematic children with various forms of the autism(s) seek a cure because it is too late for prevention of their child's disorder. They must ask for government or donated money to help them raise their children. All our property taxes are increased to deal with rising health care costs and special education needs. We cannot abandon these victimized children. But a social conscience must be developed for unity in contributing factors for prevention of the next child being compromised. A universal Questionnaire then must be developed. I hope you agree too, this is one way of knowing contributing situations.

Prevention may be the only means. I ask, which of these children if they had a choice, or which of the parents with the current care of a compromised child, if they had a choice, would not have sought prevention of the disorder in the first place. Prevention is worth an ounce of cure. We will always have an increase in the various autism(s) if we do not take an accounting of contributing factors, which I believe must be dealt with, since vaccination has not proven the common cause of many of the impaired children. There may have been contributing factors other than injection of live pathogens, or those injections with known Mercury, or multiple injections at one time. Or when the child was yet anemic when injected with any kind of substance. Injections must be included for mothers who had conceived at the time they accepted an vaccination or even a drug or X-ray.

What is missing is a Cooperative and volunteer Questionnaire of common links.

<u>The links in common are the following:</u>

1. Personal life choices involving the family's own connection of two or three or current generations of relaxation drugs which are fat soluble. The top of the list would be experimental use of both male and female users of pot. The risk is that the street drugs have unknown strength and elements added. The youth think they are taking in a safe drug relaxer, but they are not educated that it is a fat soluble element seeking to be stored in the reproduction fat cells of the users, male or female. The fat soluble products could then make mutations in the sperm and the eggs. The mutations may be carried forward to the future generations. So the question on personal life habits and choices would be the volunteer but confidential sharing of how far back one or both sides of the family experimented with pot. Then list other known street drugs including over-the-counter or prescribed drugs the volunteer chooses to acknowledge.

2. Area pollution: This the common folk cannot stop, but they can include the area's common pollution area of an agricultural area and is use of sprays, and fertilizers and the risk of contamination in the air and drinking water supplies. The soil may be tested too, for radiation of the area if they area was close to the radiation exposure going back to the mid 1950's above ground testing. These elements in the air are yet radioactive.

3. Exposures to X-rays, like radiation, the male can be exposed to the risk of even X-rays in the Dentist office. They are likely not protected of the sperm area like females may be but only if they are known to be pregnant. X-ray and chemical exposures are known to cause the Down syndrome.

4. Birthing issues: Most common factor will be the trend to cause an anemic condition by instant and early umbilical cord clamping. The whole blood of the infant that was not extra or surplus blood is trapped in the placenta and the cord. It is then drained off or syringed off to be sold for profits to the private and public cord blood banks. The whole blood is separated at these tissue banking services into stem cells, sold for $30,000.00 USA dollars a collected unit. Also sold for a broad range of profits are the elements of the whole blood of growth hormones, per the sex of the child, enzyme proteins per the sex of the child, including blood types of various colors and/or races. Selling involves platelets, plasma, and white cells. The child is testable anemic. The amount of blood taken from their property is measurable, drained or syringed from the placenta and the umbilical cord. Sometimes the child is seen so weakened; it is a visual evidence of causing bodily harm.

4A. Other birthing issues are harmful flat on the back birth positions, when the correct teaching is supported gravity births, squatting or lying forward leaning position on one's side.

4B. Other birthing issues is injection of any kind of antibiotic drug or vaccination soon after the child's birth, while the child is yet testable anemic after early umbilical cord clamping was imposed, no true informed consent of no clamping ever. ONLY if the medical person dropped the baby and tore away the umbilical cord need the cord be tied. Or, the persons put a knife into the cord or the placenta while dealing with a C-section or a condition of what may be called, placenta previa. The fear factors of problems with the child's blood and other reasons are guessing of a condition without substance of fact to support the early cord clamping.

<u>False reasons for any early umbilical cord clamping:</u>

The fear factors are supported in known facts of science when the cord was being stopped of its inflow of the placenta blood into the infant's expanding lungs. Doctors properly educated on this issue never weaken their own offspring. They prefer to have the stronger infant who get all their placenta blood infusion. The doctors then determine whose children will be sacrificed to donate that child's then sought blood for the purpose of research, or other science community's needs. The baby receives no benefit being caused a medical anemic condition which is only testable by a blood test. The appearance of the child reveals a normal looking child, but one who is weaker of the blood deprived them.

5. Reportable offences to the person: Reportable weakening of the newborn citizen comes under reportable offenses to the person as a duty of nurses, midwives, doctors or any person with knowledge an institution allowed the seeking of the placenta blood to any child born on their premises. The reportable policies are to the society of mis-information of a trend to teach early umbilical cord clamping. The policy makers are those who published medical research or create policies. Those involved are the expert group that must be held accountable for false teachings or bulletins directing immediate or early umbilical cord clamping. The issue must go before a Private Prosecution for a fine to be the judgment of the Court. This will be to the College involved in the false bulletin, such as The American College of Obstetricians and Gynecologists (ACOG). One bulletin was #216, November 1995. ACOG, in 2000, never went public to inform the threat of 60 percent total blood volume deprived the child for their policy of instant umbilical cord clamping. Reference: The Lippincott Manual of Nursing Practice, 2001, 7th edition, page 1161.

The various teaching hospitals or universities were not contacted to not impose by the choice of the medical person, their own discretion of clamping off, hand-squeezing off the umbilical cord before full infusion of the placenta blood was inside the baby's body. The placenta blood purpose is to go into the expanding lungs while maintaining proper pressure and volume to all brain cells, to the heart to prevent its shrinking (Reference T. Peltonen 1981); and then the lungs are not damaged nor any other organ, muscle or tissue in the newborn body. The babies who are cosmetically being clamped and cut off their umbilical cords become the next victim of the various forms of autism. The autism may be subtle to severe. All or most all children do look normal but they may never mature to deal with the problems of the world, today, or to live independently. The children may then remain a liability to the community they live in. The goal of having a child is to raise them so they can be whole and mature adults who have had the equal security of person to reach their fullest potential. We cannot have that if we are harvesting the babies at their time of birth to use their blood for another's cause and for profits, as well.

The references are:
www.medicalveritas.com
www.cordclamp.com
The Petition site: Protect Babies and Mothers, Too, if you search on line for this Petition.

Yours truly,

Birth Researcher since 1998
Ms. Donna Young
[PII redacted]

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John Best & Andrew Hall Cutler

January 5, 2010

The IACC is ignoring the fact that we have been curing autism since 2001 with chelation. Please note Dr Andrew Cutler's protocol and give it out to the world so parents can learn how many of us have helped our autistic children safely.

While the IACC has been wasting time by allowing people to serve on your committee who advise people that we should not even try to cure this nightmare, many of us have helped our children by following Dr Cutler's advice.

My son spent the first eight years of his life spinning in circles and screaming in pain for hours at a time because no doctor would even try to help him. His time in school was a total waste because his autism was so severe that no teacher could reach him on any level. He would bite himself for hours at a time, smeared feces all over the house hundreds of times and banged holes in every wall in the house with his head.

Within two months of starting chelation, the head banging stopped, the feces smearing diminished and the constipation that he had suffered from for years vanished. He began to make eye contact, something he had not done since he was ten months old and he began to learn at school.

It took some time to end the self-biting that went on for years but it's now gone. The feces smearing are gone. The pain that he was experiencing from some unknown source is gone. He no longer needs Seroquel or painkillers that he used to take every day. He is a happy child and he is making progress.

After five years, we are still using chelation and my son continues to improve. We took two years off due to the biting. Without Dr Cutler's help in removing mercury from my son's brain, he would still be a "zombie" and he would probably be stuck in an institution.

The IACC has an obligation to learn from parents who have cured their children completely with chelation and report this success to the world. You need to throw those people off the committee who refuse to accept the fact that mercury caused this "horror show" and go about the business of helping these horribly impaired and suffering kids.

Dr Cutler's protocol and contact information is pasted below my signature. Thank you.

John Best
[PII redacted]

Andrew Hall Cutler, PhD, PE (Professional Engineer) [PII redacted]

January 22nd, 2001

alpha lipoic acid (ALA)/ Dimercaptosuccinic acid (DMSA) Mercury Detoxification Protocol

The unique advantage of this protocol is that literature pharmacology and pharmacokinetics were put into standard textbook formulae to design an appropriate detox approach in the manner major drug companies often do when seeking Food and Drug Administration (FDA) approval for a new drug to treat a specific condition.

Protocol

This detoxification protocol uses alpha lipoic acid (ALA), an over the counter nutritional supplement, and may optionally also use DMSA or DMPS (2,3-Dimercapto-1-propanesulfonic acid). All are administered orally with adequate frequency to maintain reasonably steady blood levels.

ALA detoxification is effective for the removal of mercury and arsenic from the brain. DMSA is effective for the removal of lead, and assists in the removal of mercury. DMPS assists in the removal of mercury and arsenic.

Due to its pharmacokinetics, ALA must be administered no less frequently than every 4 hours. If it is administered less often, e. g. every 8 hours, it preferentially concentrates mercury into the highest affinity tissues. Most patients on infrequent ALA suffer an increase in symptoms rather than a reduction. By administering it at least every 4 hours the toxins are preferentially removed rather than redistributed. It is essential to continue to administer ALA at night. If the nighttime doses are skipped the chelation cycle must be ended and several days must elapse before chelation is started again.

Chelation is done by giving ALA round the clock for several days, then skipping at least as many days and repeating. It is necessary to have skip periods to avoid increasing body levels of copper and zinc too much as ALA inhibits their excretion. Chelating for 3 days and the 2 intervening nights then skipping at least the rest of the week is practical in terms of patient (and caretaker) tolerance for lost sleep and side effects. Giving the ALA every 3 hours during the waking period and every 4 during sleep seems to work well.

DMSA changes the side effect profile of ALA and also accelerates detox by 30-40 percent. DMSA must be given no less often than every 4 hours and it is best to give it with the ALA for convenience. DMPS may also be used orally in combination with ALA. Subjectively this leads to a much lower side effect profile. DMPS must be administered no less often than every 8 hours. Administration with every other ALA dose is suggested for simplicity. Reasonable dosages are 1/8 to 1/2 milligrams per pound for each of ALA, DMSA and DMPS. There is no need for any specific ratio between them, most people adjust their ALA dosage up and down to find a level where side effects aren't bothersome and then stay at that dosage. Since toxin removal goes as the square root of chelator dose there is no reason to tolerate substantial side effects in order to hurry things along.

Side effects are an increase in symptoms or appearance of new symptoms during the chelation cycle and for up to one day afterwards.

It is necessary to administer antioxidants due to the increased oxidative stress toxin mobilization causes. B complex, C and magnesium should be given four times a day, and zinc, E, carotenes, etc. at least daily. The B and C are not effective if not given four times a day due to their pharmacokinetics.

Diagnosis

Since this detox protocol is only effective for specific metals a good diagnosis is required. This may be done according to the checklist method in Amalgam Illness: Diagnosis and Treatment. Hair element analysis is especially helpful. For mercury, use the procedure at http://hometown.aol.com/noamalgam/countingrules to interpret the results.

Since autism appears to be the final common pathway of several different underlying conditions differential diagnosis against all other causes must be performed. A high index of suspicion for some other cause should arise if the patient does not show marked improvement within 3 cycles if under 8 years, or 10 cycles if over age 8.

Tracking and management

While hair elements, fractionated urine porphyrins, and any other laboratory abnormals can be used to verify that therapy is working as they will normalize, there is no appropriate 'tracking test.' The determination of when chelation is finally done is subjective and is performed clinically when there are no further improvements and there are no longer side effects. Test results normalize well before therapy is complete.

Common conditions that should be checked for and treated to reduce symptoms and side effects are: elevated plasma cysteine (test at Great Smokies Labs) which is treated with dietary and supplement sulfur exclusion (thus no NAC (N-acetylcysteine) or glutathione for this 50 percent of your patient population); low red blood cell (RBC) magnesium which is treated with oral supplementation to just short of laxative effect, and intramuscular injections if needed; impaired cortisol response which is treated with stress avoidance and medications if unavoidable; impulsivity etc. (or abnormal) which can be treated with carbamazepine or valproate; 2fast liver phase 1 metabolism (causing chemical sensitivity with anxiety or agitation due to hydrocarbon fumes) treated with niacinamide qid (quarter in die, or four times a day) or grapefruit juice qid.

If the case is requiring a large amount of management, go back to differential diagnosis, and make sure that the supplements (e. g. NAC, glutathione) aren't harmful to that specific individual by appropriate testing.

For more information

Amalgam Illness: Diagnosis and Treatment - http://hometown.aol.com/noamalgam.
Continuing education - http://hometown.aol.com/noamalgam/courseflier.
I can be reached electronically at [PII redacted]. Parent reports are on http://www.egroups.com/community/Autism-Mercury (IACC Note: URL is not valid.).

Eileen Nicole Simon

January 5, 2010

Subject: Regarding: Save the Date - Upcoming IACC Full Committee Meeting - January 19, 2010

The ever increasing prevalence of autism demands a change in strategy. Rather than looking for new research opportunities, an urgent search for prevention strategies should be made the new focus of activities for the IACC. Enough evidence can be found in the medical literature to warrant changes in perinatal care: (1) No drugs should be used during pregnancy, (2) Labor should not be induced, (3) The umbilical cord should not be clamped until pulmonary respiration has clearly been established, (4) Vaccinations should not be given in the neonatal nursery. The IACC should be in a position to mandate that the obstetric and neonatal care professionals change their increasingly invasive practices.

Eileen Nicole Simon

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Sallie Bernard

January 13, 2010

SM IACC January 10 Statement

Good morning. I am Sallie Bernard, mother to my son, [PII redacted] – a young adult recovering from autism. I am a co-founder and director representing SafeMinds today and thank you for the opportunity to offer public comment.

We acknowledge that the committee is addressing questions made during public comment by voting on a procedure for response and would add that a procedure is also needed for responding to correspondence directed to the committee outside of the public comment venue.

With the recent release of prevalence numbers of 1 in 110 from the Centers for Disease Control and Prevention (CDC) on the Friday before Christmas we continue to have grave concerns regarding the lack of standardization in surveillance data gathered by the CDC. More specifically, the data represents a lack of urgency in that the gathering of educational records is not required or funded, which results in the undercounting of individuals affected by autism; in not funding the 1996 birth cohort there is additional lack of time trend data available; states were allowed to drop and new states added to surveillance efforts and potentially skew prevalence data; and finally the lack of state to state standardization and funding of surveillance measures does not allow for true comparative time trend data. In states like Colorado the 2007 prevalence report was based on two reporting counties, in the most recent report only one county reported, effectively changing the demographics measured. Finally, the lack of urgency on the part of the CDC in announcing the increased rate of autism is shamefully on display by the announcement being made on the Friday before Christmas when the story would be buried.

These actions speak clearly to the lack of urgency in addressing the autism epidemic and must change. Though the most recent prevalence data contains many deficits, by their own admission, the CDC cannot rule out that the increased rates are a true increase in prevalence and that environmental factors are responsible for the increase. Certainly recent studies from Vanderbilt and University of California, Davis MIND (Medical Investigation of Neurodevelopmental Disorders) Institute indicate that environmental factor research must be more vigorously funded in determining environmental exposures driving the increase in autism rates. A higher degree of surveillance funding and standardization of measurements to include educational records is required from the CDC.

Additionally, the strategic plan must also reflect greater urgency in its recommendations for environmental research in response to the increase in rates. Expansion in the number of toxins and other environmental factors to be investigated is needed to enable an understanding of causation, treatment and prevention. Increased 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.

SafeMinds has also formally requested that this committee respond to our request to integrate the recommendations made by the National Vaccine Advisory Committee (NVAC) that are autism specific.

The current vaccine objective adopted by this committee also requires independent oversight, as there are acknowledged conflicts of interest that prevent its objective oversight. We also request that the CDC report to this committee how it will integrate the NVAC recommendations into the Immunization Safety Office's (ISO's) research agenda.

Finally, we have also requested an evaluation of ongoing studies that have been stated as being candidates for gathering prospective vax/unvax data and where protocols are deficient in obtaining vaccine records, that recommendations to expand and fund those protocols be included within the strategic plan. To date we have no response.

We are hopeful that the committee will provide the public with these much needed answers.

Thank you.

James Moody

January 13, 2010

Statement by the National Autism Association

The IACC Strategic Plan For Autism Research Fails to Fulfill Its Promise

The Combating Autism Act of 2006 set forth a bold new approach to quickly identify the cause of and treatments for autism, the strategic plan (and budget) for autism research. Yet this promise remains largely unfulfilled as the Plan, although it has some good general and aspirational goals, is simply too general, lacking in detail, and especially devoid of infrastructure reform to adequately respond to the urgency of the autism epidemic. The Plan remains too much a political rather than a scientific document, and has not brought the advanced tools of science and medicine to bear squarely on autism as an environmentally triggered disorder that can be prevented and treated with biomedical and aggressive, early behavioral interventions.

The Plan continues to underfund environmental causes and both biomedical and behavioral treatments. The recently published supplement in Pediatrics on autism and bowel disease was a very welcome yet long overdue contribution to the paradigm shift that children diagnosed with autism are sick, not crazy, and therefore they must have a full medical workup and treatments for their biomedical illness (rather than just psychiatric drugs). But it was also a stunning admission that treatments, including home-spun diets, in long and continuing use by parents and complementary and alternative medicine (CAM) practitioners, are not being adequately funded by National Institutes of Health (NIH) through this strategic plan. A tiny fraction of autism has a purely genetic cause yet gene research and diagnostic screening continue to be over-funded at the expense of research on environmental and epigenetic factors. Indeed, the Plan fails to identify even a single environmental trigger – or a process to identify them – for scrutiny.

The Plan's biggest failure remains the unanimous refusal of the federal members to fund research on vaccines as an environmental trigger of autism. This was the only specific environmental factor singled out in legislative history. Yet to date IACC has not spent one dollar on vaccine-specific research. This refusal is political, not scientific. There was general agreement at the science sessions that more work on vaccines was justified – especially getting baseline data on unvaccinated children so the rates of chronic vaccine-caused illness, including autism, could be quickly and fairly assessed – and eliminated. The "expert" committee to which this question was referred last year, National Vaccine Advisory Committee (NVAC), unanimously recommended this research, along with several other vaccine-autism topics, yet IACC remains "politically" steadfast in its refusal to address this key gap in our science. Vaccine Court has been compensating autism cases since 1991, yet again, IACC remains crippled in its inability to even fund research on the specific biomarkers that could distinguish vaccine-caused autism so that these children can receive the justice morally and as mandated by Congress. Even IOM (Institute of Medicine) has conceded that epi studies could not rule out the possibility that vaccines cause autism in vulnerable children, called for vaccine research in its 2007 conference on Autism and the Environment, and has committed again to consider recommending including "secondary autism" as an adverse event on the Vaccine Injury Table. Such decisions must be based on sound science and not on the political discomfort associated with making vaccines safer. Non-NIH funded science continues to

point to vaccines. A recent study on infant primates by Hewitson found functional and structural brain damage impairing the acquisition of survival reflexes from just the birth dose of the mercury-containing Hepatitis B vaccine. And a recent epi studies by Goodman, again focusing just on the Hepatitis B vaccine, revealed that those who received the series were 7 times more likely to need special education services and three times more likely to have autism.

IACC has an as yet unfulfilled opportunity to aggressively research the cause of and treatments for autism, and respond with genuine urgency to the staggering consequences of the ever-increasing epidemic. Even CDC (Centers for Disease Control and Prevention) has finally conceded that the epidemic is "real," although continues to hide behind the "denialism" of better awareness and diagnosis. How many children must be stricken with autism before CDC will actually take its "Prevention" mandate seriously? The Plan should include a cost-of-disease versus research opportunities analysis to justify a substantial increase in research funding appropriate to the urgency of this crisis. Although the Plan cites "urgency" as part of its core values, it must implement that "value." The Plan must devote substantial resources to vaccine research and to other specific environmental triggers so that these can be identified and eliminated. The Plan must devote substantial resources to treatments currently in use so that they can be validated (or modified) and biomedical/behavioral interventions yet to be developed. A generation of sick children cannot wait 20 years or more for these answers and for IACC's "glacier" to finally make significant forward progress. The Plan must implement better coordination, infrastructure reform, and re-engineer the funding process to that money can quickly reach the army of scientists and doctors eager and able to solve these puzzles. Please take the politics out of science!

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Cecilia Feeley

January 14, 2010

These remarks are in response to planning for the future of adults and seniors with autism.

I make this plea to the Interagency Autism Coordinating Committee as both transportation professional and as a parent of a 10-year old diagnosed with classical autistic disorder. I fear that even we begin to address the transportation component now when my son turns 21 there will still be problems. Reshaping the transportation infrastructure and supporting organizational framework will take many years to implement.

In addressing the components that make up a fulfilling, independent life including work and community participation as well as non-work daily living, a key component must be included: Transportation. If adults with autism are to remain members in their communities they must be supported in all aspects of life. This may require the development a new paradigm on public transportation and para-transit services, such as developing new procedures, protocols and technologies that service the developmentally disabled.

In 2002, the National Council on Disabilities noted ""Accessible Transportation represents one of the chief barriers to participation in economic and community life." This will remain true for the developmentally disabled if the problems are not addressed in correlation with employment and community. As per the IACC aspiration goal:

Advances in Intervention, Education, and Services will Support and Enable People on the Autism Spectrum to Lead Fulfilling and Productive Lives in the Community

To reach this goal we will need a holistic approach that includes housing, employment, an accepting community as well as a transportation system that provides all individuals with Autistic Spectrum Disorder safe, effective, accessible and reliable services. This may be a complex goal since the varying skills levels and various service demands. However with early planning and implementation it is possible.

While these are much larger and scope and more narrowly focused than what the IACC is currently proposing, the can be incorporated with the current short term and long term objectives. For instance, the following objectives can include transportation components:

Conduct at least two clinical trials to test the efficacy and cost-effectiveness of interventions, services and supports to optimize daily functioning (e.g., educational, vocational, recreational, and social experiences) for adolescents, adults, or seniors living with ASD by 2012. *IACC Recommended Budget:*
$8,000,000 over 5 years

Conduct a cost/benefit analysis on provision of services and interventions over the lifespan with regard to long-term benefits including employment, productivity, and the need for federal/state assistance. *IACC Recommended Budget: $2,300,000 over 3 years*.

To achieve successful results transportation professionals need to be brought in early in the process to develop and field test best practice standards that can be implemented nationally. While the initial investment in the transportation aspects may be small, its inclusion is essential to the success of independent living. It is essential that the need is recognized now. These practices may include developing the following:

Understanding transportation and land-use patterns for individuals with autism developing travel training modules for the transition process and the adults population Training transit operators, drivers, other service providers and support personnel evaluating street crossing and intersection design to facilitate the needs of our community (as has been done for the visually impaired) Educating the para-transit and fixed route operators on the increasing demographics and the potential needs. Outreach to and dialogue with national, state, regional and local transportation engineers and operators integrating the autism community with the United We Ride and Council on Access and Mobility Participation in Transportation conferences exploring and supporting Intelligent Transportation Systems and technologies that can assist individuals with autism, such as a proposed project at the University of Iowa that provides a simulated driver training course for individuals with Asperger's.

At the January 2010 Transportation Research Board's Annual meeting I was able to address the issues concerning the autism communities growing numbers. While this was a first, initial step a more comprehensive approach will be needed to facilitate any changes on a large scale.

Thank you for your time and consideration on this matter,
Contact information:
Cecilia Feeley
[PII redacted]

Cecilia Feeley is the founder of Feeley Consulting – A Transportation Research and Planning Firm Specifically for the Autism Community

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Sallie Bernard

January 14, 2010

Attachment #1

Comment on Addressing Public Comment: The IACC agenda for its meeting of January 19, 2010 includes consideration of procedures addressing public comments made to the IACC. As the primary deliberative body of the Federal Government on autism issues, the IACC should be fully informed by and responsive to the views of the interested public. SafeMinds asks that all public input be made easily accessible to IACC members and to the public, both iPagen an unfiltered format and in a summary format, and that the summary format be compiled in a fair, balanced and timely manner. Public input should consist not only of what is submitted by the public during written and oral comments for the specific meetings or in response to IACC Requests for Information (RFIs), but other communications sent in by individuals and organizations at any time for the IACC's consideration. The IACC should make a good faith effort to respond to comments and provide reasons for adopting or rejecting them.

Comment on CDC Prevalence Report: Dr. Cathy Rice of the Centers for Disease Control and Prevention (CDC) is on the agenda to present the latest CDC autism prevalence estimates of 1 in 110 children born in 1998. SafeMinds requests that the IACC take the opportunity of Dr. Rice's presence to ask her to respond to the following concerns related to the prevalence report.

a) ***Lack of urgency:*** The study results were released on the Friday before Christmas and with little public awareness efforts, even though the report was four years in the making and could have been released on another date. Accompanying the CDC statements had only vague recommendations and no new initiatives about how to address the relentless increase in numbers, in terms of finding the causes and providing services and treatments. CDC is capable of mounting a large response to a public health need, as seen by the millions of dollars spent on the swine flu pandemic.

b) ***Inadequate epidemiological practices***: The CDC surveillance approach lacks rigor in several important ways and reflects the low prior which CDC has assigned to autism. The IACC should request better methods and higher funding in the next Request for Proposals (RFPs) for the Autism and Developmental Disabilities Monitoring (ADDM) project.

    i. Although CDC has known for years that a significant percent of cases are only identified through educational records, the gathering of educational records is not required or fully funded by CDC, which results in the undercounting of cases. Access to all records should be a site requirement, and funding should be provided to enable

such access.

ii. Although fair comparisons of prevalence trend over time requires that sampling sites be held constant, CDC has allowed the study sites to change significantly with each reporting period. Sites have been eliminated during RFP process and new ones added. Even repeat sites have been allowed to change their sample collection area. (For example, the Colorado sample dropped from two counties to part of one county, but was still reported as "Colorado".). Only sites used in previous years should be considered in future surveys.

iii. Even though CDC knows that autism rates have been increasing for over a decade, they decided not to fund surveillance for the 1996 birth cohort, skipping four years of data from the 1994 births to the latest 1998 births. Autism surveillance must be conducted at least every two years and preferably on a continuous basis, given that the rate is not stable but rising.

iv. Although the needs of families and individuals differ by their type of autism spectrum disorder, the CDC methodology does not allow discernment of key subtypes like Asperger's, classic autism and pervasive developmental disorder not otherwise specified (PDD-NOS). In person assessment of a subsample of cases should be instituted so that prevalence by subtype can be reported.

c) ***Environmental contribution minimized:*** Despite the deficits in the most recent prevalence report, the CDC by its own admission cannot rule out a true increase in prevalence and the role of environmental factors in the increase. Certainly recent studies from Vanderbilt and University of California Davis MIND (Medical Investigation of Neurodevelopmental Disorders) Institute indicate that environmental factor research must be more vigorously funded in determining environmental exposures driving the increase in autism rates. Dr. Rice should state what increased activities, over the existing Study to Explore Early Development (SEED) studies, the CDC is recommending to investigate the environmental factors that are driving autism rates.

Comment on Environmental Factors Research: Dr. Birnbaum is also representing to the committee. Given the increase in autism prevalence, NIEHS (National Institute of Environmental Health Sciences) needs to take a more prominent role in directing autism research activities to identify and understand the role of the environment in autism. Expansion in the number of toxins and other environmental factors to be investigated per the autism research strategic plan is needed to enable an understanding of causation, treatment and prevention. Increased biomarkers and treatment objectives, informed by environmental factors research, will bring us much closer to these goals.

Comment on Vaccine-Autism Research: Safeminds has also formally asked the IACC to respond to our request to integrate the recommendations made by the National Vaccine Advisory Committee (NVAC) that are autism specific. The current vaccine objective in the strategic plan adopted by this committee requires independent oversight, as there are acknowledged conflicts of interest that prevent its objective oversight. We also request that the CDC report to the IACC how it will integrate the NVAC recommendations into the Immunization Safety Office's (ISO's) research agenda.

SafeMinds further requests an evaluation of ongoing studies that have been proposed for gathering prospective data on vaccinated and unvaccinated groups, and, where protocols are deficient in obtaining vaccine records or lack active recruitment of by-choice unvaccinated or alternatively vaccinated samples, that recommendations to expand and fund those protocols be included within the strategic plan to assure statistical power of the data. We have no response to prior requests to the IACC for such actions and formally request a response.

Comments on the Strategic Plan: There are areas of the strategic plan which require additional action that were flagged during the initial development in 2008 as requiring attention and which remain unaddressed by this year's strategic planning process. Areas of concern were listed in our letter to Dr. Insel of December 7, 2009, submitted here as an attachment to our public comments and summarized as follows:

> **Lack of Environmental Expertise**: We are concerned by the lack of expertise during the updating of the strategic plan as it relates to toxins and environmental factors. Please clarify why this expertise continues to be absent, given that it is considered a promising area of research and was noted as lacking in 2008's strategic planning process. What measures will be taken overall to prevent these expertise deficits in the future?
>
> **Include vaccine research** (see comments above).
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> **Process:** We share the concerns expressed by IACC public members Ms. Redwood and Ms. Singer that not enough time is given for the updating process, particularly the committee's time in reviewing and discussing the draft product.
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> **Urgency**: ASD "is" a national health emergency, not an "emerging" emergency and the plan does not currently reflect the necessary urgency commiserate with the continued growth of ASD. Time must be set aside to update the mission, vision and cross-cutting themes section of the plan to reflect the health crisis in autism.

We are hopeful that the committee will provide the public with these much needed answers to the issues we have raised. Thank you for your consideration of our input.

Attachment #2

December 7, 2009 *****VIA EMAIL*****

Thomas Insel, MD
Chair, Interagency Autism Coordinating Committee
National Institute of Mental
Health 6001 Executive Boulevard
Bethesda, MD 20892-9669

Re: Update of Strategic Plan for Autism Research

Dear Dr. Insel,

SafeMinds is taking this opportunity to additionally comment on the strategic planning process to date. While there are areas of improvement that we appreciate, such as including of a fuller understanding of the Institute of Medicine (IOM) 2004 report as it applies to the limitations of epidemiological studies to detect susceptible subpopulations, there are areas that require additional action that were noted during the initial strategic planning in 2008 as requiring attention and which remain unaddressed by this year's strategic planning process.

Lack of Environmental Expertise: Specifically, we are concerned by the lack of expertise during the updating of the strategic plan as it relates to toxins and environmental factors. SafeMinds has attended and/or participated in the scientific workshops as well as strategic planning process since the IACC's inception. We note that during the 2008 scientific workshops that IACC member and NIEHS representative Dr. Lawler was the only environmental representative to participate and there was no toxicological expertise present. This year there was no environmental/toxicological expertise present for discussions on causation and prevention (Question 3). The lack of environmental and toxicological expertise present during strategic planning was noted last year and again this year by SafeMinds to the committee and was also noted this year by the science community participating on panel three.

We are appreciative of the committee's recognition for the need of environmental citations and other environmental and epigenetic wordsmithing that Dr. Lawler will be adding to the plan. However, while very needed, these additions should not have fallen to a single IACC member to accomplish so late in the game. It is an area of the plan that SafeMinds and other autism organizations over the course of strategic planning have expressed as needing attention and improvement. Dr. Lawler cannot be reasonably expected to do justice to this section with the little time allotted to her and this section should have been given proper deliberation and consideration during science panels and throughout the course of the updating process that every section of the plan has been given. We feel this is another example of how the absence of environmental risk factor and toxicological expertise contributes to the underdevelopment of this portion of the plan. Now the committee will be asked to evaluate, and approve of, the new

wording during its next meeting. This is simply not enough time.

There were also other comments made by IACC members during the committee meeting of October 23rd regarding additional areas that lacked the expertise necessary during the science panels to adequately address all aspects of the plan. This continued absence of expertise negatively impacts the strategic plan and creates a bias on the importance of genetics vs. environmental risk factor research.

REQUEST: Please clarify why this expertise continues to be absent, given that it is considered a promising area of research and was noted as lacking in 2008's strategic planning process. What measures will be taken overall to prevent these expertise deficits in the future? SafeMinds also requests that the committee consider the following objectives, which were submitted via the RFI process and which, due to the lack of expertise and review/integration of responses, were not considered by the committee. These items would assist in the much needed development of environmental risk factor research absent in the plan.

- Include environmental factor/toxic load screening in early detection.

- Use existing data from National Center for Environmental Health (NCEH) National Health and Nutrition Examination Survey (NHANES) to facilitate the establishment of reference ranges for unusually high exposure levels to a toxicant within individuals/groups, identify the proportion of the population with toxicity levels above those with known adverse health outcomes, tracking time trends in exposures to determine what changed in the environment and set priorities for research on the health effects of exposure to environmental chemicals.

- Conducting body burden studies on our children to investigate the toxic load of toxins like mercury and aluminum, their combined and isolated toxic synergistic effects in the presence of other toxins, as well as when present with viruses and bacterial infections.

Vaccine Safety Research: Following IACC statements in January regarding HRSA and HHS inherent conflicts of interest, there are process issues that remain unaddressed. Additionally, the IACC requested the expertise of the NVAC as it relates to autism vaccine objectives, yet autism specific findings from the NVAC's report are not adequately reflected in the strategic plan. These objectives must necessarily be adopted to comply with the charge as provided by the Combating Autism Act (CAA) and 1986 Mandate for Safer Childhood Vaccines, which requires research to reduce vaccine adverse events. Specifically vaccine related issues are:

- Integration and support of NVAC recommendations specific to autism. Previously removed vaccine objectives specifying animal and cell line models were also acknowledged by Dr. Lawler during the October 23rd meeting of the IACC as being the "bread and butter" of NIEHS and greatly valued. However, this objective was again removed from the strategic plan this year.

- Dr. Lawler acknowledged during the November 10th IACC meeting that using on-going studies prospectively would probably not yield the statistical power necessary to ascertain

much needed baseline comparative information on vaccines.

- Ethics for retrospective comparative population study – Washington, Minnesota and Colorado are but a few states with high by-choice exemptors (5.7%, 6.8% and 4.7% respectively) that could be used for vax/alt-lite-unvax study with no ethical issues. Washington State has noted no differences within their philosophical exemptors that would prevent such a study. Homeschoolers, Amish and other populations are additional opportunities. This retrospective comparison would provide valuable baseline information on vaccines and total health outcomes. To date, we are unaware of any of the suggestions made at the joint IACC/NVAC meeting in this respect being pursued by the IACC to obtain this information as it applies to autism.

- Given HRSA/HHS conflicts of interest, vaccine objectives must be independent in oversight and conduct. Dr. Mark Noble from the University of Rochester presented on methods for achieving the necessary independent oversight and to date we are unaware of any response or action by the IACC to resolve these conflicts in an independent manner.

SafeMinds and many autism organizations feel strongly that the $16 million for vaccine safety objectives removed for a second time from the research agenda is but a fraction of the IACC budget. Indeed, this amount would only cover the lifetime care expenses of 12 autistic individuals. This small investment aligns with the intent of the CAA and is not an overemphasis on vaccine research, as is sometimes asserted by members of the IACC. This is particularly true when reviewing the budget recommendations of the IACC for genetic research, which is well funded privately and which received the lion's share of stimulus funds in Question 3 as opposed to funding the already acknowledged and underfunded environmental objectives within the plan.

REQUEST: To better accomplish goals within the strategic plan and integrate the findings of the NVAC as they relate to autism, and in compliance with the 1986 Mandate for Safer Childhood Vaccines and the intent of CAA, we request the following:

- Identification and analysis of studies, such as CHARGE, EARLI, SEED and NCS, regarding their ability to prospectively and reliably yield comparative health outcomes with recognized statistical power with medically verified vaccine records, etc. on vaccines. Where the ability to yield such information is deemed lacking in the previously mentioned studies, the IACC should develop recommendations and budget estimates to enhance protocols appropriately to assure good use of resources and proactive development in gathering this information.

- Clarification on exclusion of autism specific recommendations from NVAC report from the strategic plan, e.g. "What we know", "What we need" "Research Opportunities" and research objectives.

- Integration of the autism specific recommendations made by the NVAC report.

- Clarification of independent oversight mechanism for newly adopted vaccine objectives to overcome acknowledged inherent conflicts of interest held by HRSA/HHS.

- Clarification of impediments to, and ethical considerations (often cited by IACC members) of, a retrospective comparative population study of vaccinated vs. unvaccinated as a means of gathering data on total health outcomes.

Process: We share the concerns expressed by IACC public members Ms. Redwood and Ms. Singer that not enough time is given for the updating process, particularly the committee's time in reviewing and discussing the draft product. Lessons learned from 2008 planning were not applied to 2009 and for a second year additional special meetings had to be called to complete the strategic plan. Below are specific deficits of the process to date:

- This year's strategic planning process is absent of a mechanism for meaningful review and integration of RFI comments into plan, whereas last year many suggestions were incorporated into the draft plan for the committee's consideration.

- There are possible FACA violations due to the absence of draft and meeting materials not made available to the public for use during meetings. Additionally, public comment for those listening on the phone during meetings is restricted.

- The committee doesn't respond to questions and requests submitted to the committee, further marginalizing meaningful public participation.

- Science panels did not have funding cycle information or progress reports for ongoing studies as they apply to the strategic plan. This lack of information negatively impacted the panel's ability to assess progress of the strategic plan and determine a starting point in updating the plan and noted the need for this information to properly and efficiently make recommendations to the IACC.

- Mission/Vision/Introduction: There was no direction during the RFI process on how to submit comments on this portion of the plan. Additionally these strategic planning statements are absent of NIH values on causation, recovery and prevention. Cross-cutting themes are also absent of recovery statements.

- The updating process, in general, lacks sufficient time for going through the edits, reasonable deadlines for committee members and science panelists to submit edits for final review and discussion during full committee meeting – everything is too rushed at the end.

REQUEST: Please clarify why information necessary for updating of the strategic plan was not available to the science panels and what mechanism will be used to prevent this planning deficit in the future. We request that adequate time be given to the entire process, as did IACC members, and would like clarification on the role of the strategic planning subcommittee in this sense and how the overall process will be improved in the next update of the strategic plan. We also request greater meaningful public participation measures be identified by the committee, such as clarification of what prevents public comment from phone participants when other entities such as the IOM allow for oral public comment by those on the phone; draft/meeting materials be made available to the public on the same basis that they are made available to the committee/panels; a mechanism for committee response to consistent requests made by the

public and a review mechanism for public responses to RFI as they apply to strategic planning for integration into the strategic plan.

The latter could be accomplished via an advisory panel or panels similar to those used by the Department of Defense CDMRP model for autism research. These have been requested to be considered by the committee and recommended to the Secretary to enable a higher degree of meaningful public participation, as well as assist in the strategic planning process. Please clarify why these requests have not been identified as agenda items for the committee's consideration. Given the continuation of previously identified strategic planning deficits, what measures are being implemented to achieve more meaningful public participation and efficient strategic planning in the absence of advisory boards and panels previously suggested?

Lastly, ASD "is" a national health emergency, not an "emerging" emergency and the plan does not currently reflect the necessary urgency commiserate with the continued growth of ASD. Please clarify why with the recent reports of increased prevalence autism remains an "emerging" emergency and why no time has been set aside to update the mission, vision and cross-cutting themes section of the plan.

In closing, we are appreciative of the time committee members give to this process; however, the strategic planning subcommittee appears to have been under-utilized and their scope ill-defined during this year's process. Many of the deficits noted here have been noted prior to this year's updating process and have been previously submitted with no response forthcoming from you or the committee. Thus, the courtesy of your response, as well as a response from the committee, specifically addressing the concerns above is formally requested. Responses should be sent directly to me at [PII redacted]. Additionally, please consider this our public comment for the IACC meeting to be held on December 11, 2009.

Sincerely,

/Theresa K. Wrangham/
Theresa K. Wrangham,

President

cc: Francis S. Collins, MD, PhD - NIH Director
Ms. Lina Perez - Office of Autism Research Coordination