

Written Public Comments

**IACC Full Committee
Meeting**

February 4, 2009

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Eileen Nicole Simon

January 17, 2009

Can I find out if auditory system impairment due to oxygen insufficiency at birth was considered for the plan at the January 14 meeting? I would appreciate some feedback. Thanks.

Eileen Nicole Simon

Attachment #1

1.) Can we get feedback on whether comments from the public are discussed, and reasons why public comments were not considered for inclusion in the strategic plan?

2.) Autism should be investigated in the way that transportation accidents are investigated by the National Transportation Safety Board (NTSB). A link to their Strategic Plan for 2007-2012 is at:

http://www.nts.gov/AbtNTSB/Plans/Strategic-Plan_2007-2012.pdf (IACC Note: URL is not valid.)

Note a few of the key points in this plan:

- Maintaining their congressionally mandated independence and objectivity – page vi (pdf p8)
- Mission – includes assistance to victims of transportation accidents and their families – page vi (pdf p8), page 1 (pdf 11).

“ . . . we have responsibility for coordinating communication with and assistance to the family members of accident victims.” – page 2 (pdf page 12).

- Strategic plans, performance goals, planning process – page vii (pdf page 9) “The cost of transportation accidents to society is unacceptable, and growth in transportation activity in the United States will exacerbate the problem.” – page 4 (pdf page 14)

“Maintain a competent and effective investigative workforce” – page 5 (pdf page 15)

- Performance measures – page 5 (pdf page 15)
- Stewardship of resources – page 9 (pdf page 19)

“Every agency of the United States Government has a duty to ensure that the resources appropriated to it by Congress are expended in an efficient, responsible, and results oriented manner. At the NTSB, the scope of our responsibility is broad and our team of dedicated employees is relatively small.”

- Strategic goals refined, enhanced, and prioritized with performance goals – page 16 (pdf page 26)
- Strategic plan meeting schedule – page 20 (pdf page 30)

3.) Autism is a catastrophe. Autism is not just a fertile field for research. Autism is the negation of everything worth looking forward to. Life-long care for increasing numbers of victims of autism cannot be brushed aside as merely a family concern. Families or siblings cannot be expected to provide life-long care – mental health professionals need to understand that autism is traumatizing. Family members suffer from major depression that professionals want to overlook. Please review the NTSB strategic plan and revamp the one for autism.

4.) Please do not dismiss oxygen insufficiency at birth as an etiologic factor in autism – unless you can cite specific evidence to the contrary.

Following is a letter-to-the-editor that I submitted to the British Journal of Obstetrics and Gynaecology (BJOG). It was rejected for publication in part because my response on November 2, 2006 was to an article that had appeared more than three months earlier:

Baskett et al., in their paper on respiratory depression at birth, reported a delay of up to 3 minutes in initiating and maintaining respiration in 5.2 per 1000 infants after birth [1]. Infants with an Apgar score less than 3 at 5 minutes numbered 1 per 1000, and neonatal seizures occurred in 0.7 per 1000. Infants with at least one of the three measures yielded a composite outcome of 6.2 per 1000.

These statistics closely resemble those for the increasing prevalence of autism. For example, the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/ncbddd/autism/), provides prevalence rates for autism spectrum disorders (ASDs) between 2 and 6 per 1,000 individuals. Putting it another way, they state that between 1 in 500 (2/1000) to 1 in 166 (6/1000) children have an ASD. Lately, the 1 in 166 figure is quoted often.

Autism is associated with several medical conditions such as prenatal exposure to alcohol or other drugs, prenatal infections, tuberous sclerosis, fragile X syndrome, and other genetic metabolic disorders. However, in PubMed, a search using terms such as autism & "obstetric complications" yields several citations. Glasson et al. in 2004 identified infants who later developed autism "were more likely to have taken more than 1 minute before the onset of spontaneous respiration" [2, pages 621-622].

An important goal for autism research will be to investigate the final common pathway in the brain, susceptible to damage from all etiologic factors. A lapse in respiration at birth has been shown to have variable and unpredictable effects. However, Myers (1972) demonstrated, in newborn monkeys, that catastrophic total interruption of respiration resulted in ischemic damage of the brainstem auditory pathway. He also demonstrated that a period of chronic partial oxygen insufficiency leads to the more widespread pattern of neuropathology usually associated with cerebral palsy.

Involvement of brainstem auditory nuclei is an important piece of evidence. Human children learn to speak "by ear," which requires intact transmission of acoustic information. Analysis of acoustic signals also takes place within the brainstem nuclei, and normal development of the language areas of the cortex depends upon trophic neurotransmitters produced in nuclei of the brainstem auditory pathway. Papers on these subjects can be found in PubMed using keyword "inferior colliculus," the auditory nucleus most susceptible to damage.

Baskett et al. noted that after 1996, umbilical artery pH was measured for depressed infants, which would imply that the modern protocol for clamping the umbilical cord within seconds following birth was followed. Most infants breathe immediately at birth. The importance of Baskett et al.'s research is that it provides evidence that a substantial number may need continuing circulation from the placenta for several minutes after birth.

Evidence-based medicine must include appropriate care for patients outside statistical norms. Until the mid-1980s, textbooks of obstetrics taught that the umbilical cord should not be tied or clamped until the newborn infant was breathing on its own. A return to this tradition seems warranted.

References

- 1.) Baskett TF, Allen VM, O'Connell CM, Allen AC. Predictors of respiratory depression at birth in the term infant. *British Journal of Obstetrics and Gynaecology*. July 2006;113(7):769-74.
- 2.) Glasson EJ, Bower C, Petterson B, de Klerk N, Chaney G, Hallmayer JF. Perinatal factors and the development of autism: a population study. *Archives of General Psychiatry*. June 2004;61(6):618-27.
- 3.) Myers RE Two patterns of perinatal brain damage and their conditions of occurrence. *American Journal of Obstetrics and Gynecology*. January 15, 1972;112(2):246-76.

5.) If statistics for plane crashes were the same as for “respiratory depression” at birth, not many people would want to risk flying as a means of transportation. Look at the abstract for the paper by Baskett et al. in PubMed, where they state as their conclusion:

“Overall, the rate of respiratory depression at birth in the term infant was low and the serious manifestation of seizures was less than 1 in 1000. There was a significant relationship between operative delivery in labour and respiratory depression at birth.”

Baskett et al. did not follow the development of infants who suffered respiratory depression at birth. They are not in a position to state that serious manifestations were low – they did not look for long-term evidence that respiratory depression at birth is not a serious problem.

6.) The NTSB is sponsoring a meeting Feb 3-6 in Washington on the safety of helicopter emergency medical services, also to be telecast on www.nts.gov. It would be interesting to watch some of this and compare their meeting to those held by the IACC. I will try to do this. See: <http://www.nts.gov/Events/Hearing-HEMS/Hearing-HEMS-announcement.htm> (IACC Note: URL is not valid.)

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

Sarah White

January 20, 2009

Subject: Scientific safety studies on Vaccines/ IACC Strategic report

I learned recently through an autism organization, that the IACC decided to drop vaccines safety studies from the IACC's final strategic plan report and that this was approved at the final hour. As a parent of an autistic child, I feel that this action is a betrayal to every parent who witnessed there once healthy child regress after having them vaccinated.

I learned that the main proponent of this change was Dr. Edwin Trevathan. Dr. Trevathan cited concerns about possible conflicts of interest even though Dr. Trevathan himself is both a Centers for Disease Control and Prevention (CDC) Department head and a paid consultant to GlaxoSmithKlein.

As a federal health entity, it is not the job of the IACC to protect corporate interests. It is the job of the IACC to work for and protect autistic children and assist families affected by autism. Parents like myself put our trust in members of your committee to see that our concerns are represented and that decisions are made with fairness.

I strongly urge the committee to reject the last vote and put the scientific studies on vaccine safety back on the table where they belong.

Thank you,

Sarah White
[PII redacted]

Eileen Nicole Simon

January 22, 2009

I see a lot of anger on the internet about vaccine research not being funded. What about inquiries into obstetric protocols, which I have been trying to bring to the attention of the IACC? Please let me know if my comments are being included or discussed, or just dismissed. Thanks.

Eileen Nicole Simon

Ken Brzezinski

January 26, 2009

Subject: Vaccine Study

Three things have happened the last twenty years. The number of Vaccines required for children has increased. The air has gotten significantly cleaner. The number of children diagnosed with autism has increased from one child in 10,000 to 1 child in 150. This is not a number due to previous poor diagnosis. It is a number due an increase in the number children diagnosed with AUTISM. The Centers for Disease Control and Prevention (CDC) Pharmaceutical Companies and doctors say that there is no correlation between the increase in autism and the increase in the number cases of autism. They have their [offensive language redacted] because they have a vested interest in keeping children vaccinated. They are making money vaccinating children at a rapid pace. They do not want a study that says that they are responsible for this outbreak.

Ken Brzezinski

Ginger Shamblin

January 27, 2009

Subject: autism studies

Having met hundreds of parents of vaccine-injured children, I have no doubt whatsoever that autism IS mercury/aluminum poisoning from vaccines (either to the pregnant mother or the child). To refuse to even consider this possibility in your studies strains credulity!

Ginger in Knoxville, Tennessee TN4SaferVaccines

Eileen Nicole Simon

January 29, 2009

Subject: Vaccine Research Strategy

[Vaccine Research Strategy: Comment for the IACC meeting on Feb 04, 2009.](#)

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

Jean Public

January 29, 2009

I want big pharma to stop dictating what happens to American citizens. I think we are all intelligent enough to make our own decisions. The attitude that this agency should force Americans to [derogatory language redacted]. We don't want our kids given 60 mandated doses of any vaccines. Particularly [derogatory language redacted], where there is no quality control at all and to have mercury, formaldehyde, soy, aluminum injected? You all have got to be [derogatory language redacted].

[PII redacted]

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

Barb Sachau

January 29, 2009

I want big pharma to stop dictating what happens to American citizens. I think we are all intelligent enough to make our own decisions. The attitude that this agency should force Americans to "submit" is [offensive language redacted]. We don't want our kids given 60 mandated doses of any vaccines. Particularly when [derogatory language redacted], where there is no quality control at all and to have mercury, formaldehyde, soy, aluminum injected. You all have got to be [derogatory language redacted].

B. Sachau [PII redacted]

Matthew Carey

January 30, 2009

I have written in the past to provide my input as a stakeholder in the autism community. Even though my son is quite young, I believe that adult issues are an area that is underserved and, yet, vitally important. I am pleased to see the IACC Strategic Plan address this area as well as many other important areas of autism research.

At present, I am very concerned that some autism organizations and individuals are attempting to hijack the Strategic Plan process.

Much is being made by some parent-led groups of the “intent” of Congress in formulating the Combating Autism Act (CAA). Many groups and individuals quote from the Colloquy in support of this notion. It is important to separate the intent of a subset individual senators and that of the legislature as a whole when considering this question.

Some individuals who made the Colloquy statement included comments about vaccines. The statement itself is not as strong a call for vaccine research as many have characterized it. However, the legislature as a whole did not include vaccine-specific language in the CAA. Ironically, the comments by these individual senators making the Colloquy make it is obvious that the absence of language specific to vaccine-related research in the CAA is not an oversight by the legislature.

I feel this is worth repeating for emphasis: it was no oversight that a mandate to conduct vaccine-related research was not included in the actual language of the CAA. Instead, it seems clear to this stakeholder that the CAA would not have passed were vaccine- specific language forced into it.

Similarly, it seems clear that there are likely not enough votes to approve the Strategic Plan if the vaccine language is reinserted.

I do not wish to see the entire IACC Strategic Plan process held hostage over a single issue. This is doubly true given the scientific consensus that vaccines are not implicated as causal in autism. Also, these provisions were added outside of the normal procedure for the Strategic Plan, having bypassed the scientific committees and been added at the 11th hour.

It is the opinion of this stakeholder that the vaccine question has already caused considerable delay in finalizing the Strategic Plan. Now, individuals and organizations threaten to hijack the entire planning process over this single issue.

Matthew J. Carey, Ph.D. San Jose, California

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

Phil Gluyas

February 1, 2009

In case you are not aware, there has been a campaign launched by the Safe Minds website to try and force a reversal of a decision to stop supporting the funding of vaccine-autism research at your January meeting. Certain allegations have been made against Tom Insel in relation to this, and these allegations may form a case of slander - as follows;

In a highly unusual departure from procedure, government representatives to the IACC voted on January 14th against conducting studies on vaccine-autism research despite approval of the same studies at their prior meeting on December 12, 2008. The research was supported by numerous autism organizations and requested by IACC's scientific work groups and Congress. The maneuver to re-vote was initiated by the IACC's representative from the Centers for Disease Control and Prevention (CDC) and pushed through by the IACC Chair, Dr. Tom Insel, Director of the National Institute of Mental Health of National Institutes of Health (NIH). Review of the studies was not listed on the committee's official agenda, in violation of normal committee practice.

Unlike most Federal advisory committees, the IACC is dominated by government representatives occupying 12 of the 18 seats. Dr. Insel admitted at the meeting that Department of Health and Human Services (HHS) agencies (which include NIH and CDC) have a conflict of interest in conducting vaccine-autism research due to "Vaccine Court" litigation in which HHS is the defendant. Of the 6 non-government (public) members, 5 voted to retain the vaccine research at the January meeting. The lone dissenting public member resigned from her organization, Autism Speaks, the night before the meeting. Autism Speaks has issued a statement denouncing her vote.

The Federal members of the IACC must know that the autism community objects to their manipulation of committee procedures to block unbiased research on the possible link between vaccines and autism.

This leads to a letter campaign that I urge the IACC to ignore. The IACC needs to make it clear to the public that there is no verifiable link between vaccines and Autism, and further I ask that the IACC denounce calls to the contrary as "panic based mischief to cover for the lack of understanding of the Autistic Spectrum" - or words to that effect.

The Internet has a worldwide effect, and this nonsense is affecting other countries including my home in Australia. I find this frightening to say the least and I ask that the IACC take a strong and resolute stand against this campaign of conspiracy theory and misinformation. I also ask that support structures be the priority of the IACC so that this panic can be tied down as effectively as possible to allow education and finally the fact that Autism can be a good thing can come out instead of allowing this 100 percent bad rubbish.

Yours faithfully,
PHILIP GLUYAS [PII redacted]

Irva Hertz-Picciotto

February 2, 2009

Statement to the IACC on Autism Research: Funding for the Study of Vaccines and Autism

Irva Hertz-Picciotto
Professor and Chief, Division of Environmental Epidemiology
Department of Public Health Sciences
School of Medicine
Deputy Director, Center for Children's Environmental Health
Director, Northern California Collaborative Center for the National Children's Study
University of California, Davis

February 2, 2009

The problem of what myriad factors contribute to autism in any one child is undeniably complex, yet pales in comparison to the issue of causation population-wide. As we all know, considerable attention has been drawn to vaccines. Unfortunately, the ratio of the amount of heat compared to the amount of light on this discussion is far too large. The observations offered here are aimed at advancing the evidence base and generating a firmer foundation for addressing etiology of autism, including the interactions of genetic susceptibility with environmental exposures. They are also motivated by recognition that the ability of medicine & public health to deliver the good life depends on trust, which we must earn through the practice of transparency and the pursuit of high quality science.

To begin, it is crucial to note that there are several different concerns falling under the rubric of 'vaccines and autism.' The three major ones are: (1) the MMR vaccine and a possible leaky gut syndrome; (2) thimerosal-containing vaccines and the potential effect of the ethyl mercury; (3) the growth in the number of vaccines being administered within a short time period, which is suggested to overwhelm some infants. Each concern generates its own methodologic problems; moreover, the literature is quite distinct, and the evidence needs to be evaluated separately, as the biologic/pathophysiologic questions are somewhat dissimilar. To lump them together not only is illogical and lacks any scientific basis, but could lead to overlooking some data that might enrich our understanding of mechanisms of the neuropathology of autism. The peer-reviewed publications on the MMR vaccine appear to include strong designs with little support for the GI link. The human data on thimerosal-containing vaccines will be discussed below. Scant research into the number of vaccines and the young ages at significant antigenic challenge appears to have been conducted. Thus, the story is not singular: there are several stories, each with a different set of relevant threads.

With regard to the thimerosal-containing vaccines, the NIEHS, at the request of the House Appropriations Committee and with assistance from the CDC, convened an expert panel in May 2006 to address "Thimerosal in Pediatric Vaccines: Feasibility of Studies Using the Vaccine Safety Datalink." The charge to the panel was to: determine whether the Vaccine Safety Datalink of the CDC could be usefully mined to conduct further studies of vaccines and autism, including identification of strengths and weaknesses of the database; develop recommendations for design, conduct, analysis, and oversight of any proposed studies; and discuss the impact such studies might have. The workshop participants were

drawn from a number of academic institutions and represented expertise in epidemiology, neurotoxicology, mercury toxicity, autism and related neurodevelopmental disorders, biostatistics, risk assessment, and clinical pediatric research. In its consensus report, the panel made a number of specific recommendations for study designs that were judged to be feasible, and for methods to improve the quality and reliability of the exposure and outcome data. The panel further delineated a series of questions that would need to be addressed and validation work that would need to be performed prior to the launching of any epidemiologic study. Dr. Julie Gerberding, Director of CDC, concurred with the vast majority of the findings of this report.

A further subtlety, requiring a more nuanced approach, is that more than one hypothesis has surfaced relative to thimerosal. For instance, a number of studies attempted to examine whether the upward trend of autism incidence in the 1990s was due to the single risk factor of thimerosal-containing vaccines. Although none of the studies was conducted in such a manner as to meet the fundamental assumption of a correlational time trend analysis – i.e., in no instance could all other factors be said to be held constant – the continued rise well beyond the removal of thimerosal from vaccines has provided strong evidence that the hypothesis of this single cause has low probability of being true. A multitude of other scientific questions, however, remains to be addressed: Are some children more vulnerable to the doses of thimerosal administered in early life because of a genetic predisposition to concentrate mercury in target tissue of the CNS? Is the combination of vaccine antigens plus mercury too potent in a subset of children with an immune system that may have been partially weakened by earlier, perhaps prenatal exposures to other toxins? Are there specific developmental stages of heightened susceptibility? Within a family having sib-pairs, one affected and one unaffected, how similar are the vaccination histories? Of import to the IACC: Have we designed studies to rigorously answer these types of questions? Why should such studies be taken off the table?

Currently, no robust scientific study has demonstrated an association between risk of autism and exposures to thimerosal-containing vaccines. Numerous reports are cited as exonerating thimerosal-containing vaccines, but how strong have these studies been? If the rationale to not study vaccines and autism any further is based on the belief that the extant literature is conclusively negative/null in its findings, then I would urge the IACC to take a closer look at the evidence.

Several investigations have been ecologic studies, widely known to be the weakest possible epidemiologic design (Madsen et al 2003, Schechter & Grether 2008). Even restricting discussion to the individual-level designs, published studies conducted in Denmark, the UK, and the US are characterized by serious, even fatal, flaws. The individual-level study by Hviid and colleagues (2003), though otherwise well designed and executed, used non-comparable sources of autism diagnoses: the thimerosal-exposure period was prior to 1995 and included only inpatients whereas the the post-thimerosal-exposure period beginning in 1995 broadened to include inpatients and outpatients. (The non-comparability still holds even though the definition of inpatient includes those not hospitalized but receiving daily treatment as an outpatient.) The appropriateness of exclusions that amounted to nearly 25% of the birth cohort in the investigation by Verstraeten et al (2003) was questioned in the NIEHS expert panel report, and Dr. Julie Gerberding concurred that further work should be done using the VSD to address this weakness. Andrews et al (2004) examined a specific hypothesis, namely, that autism risk would be increased from early administration of thimerosal-containing vaccines, based on the number of vaccines received prior to 3 months, prior to 4 months, and the timing and number of vaccines prior to 6 months of age. The unexplained oddity that three of the nine categories of developmental disorders (general developmental disorders, attention deficit disorders, and unspecified developmental delay) were significantly reduced in those with early vaccines would suggest the possibility that confounding

(acknowledged by the authors as a problem) could have resulted in a 'healthy vaccinee' effect. In other words, the healthiest babies would be those who were vaccinated at the earliest times, while vaccines may have been withheld for later administration to those not thriving or with indications of problems predictive of developmental deficits. Another explanation might be that the critical time window occurs later, perhaps after 6 months of age. Regardless, this downward bias casts doubt on the validity of any null finding, in particular, the hazard ratios of 0.89, 0.94, and 0.99 for autism, based on the three exposure metrics. That another study in the UK (Heron et al 2004) relying on the same categorization of exposures observed a similar reduction in risk for several developmental outcomes would appear to confirm the problem of non-random uptake of vaccines in relation to child's age, even after adjustment for numerous confounders. This latter study also had inadequate sample size to examine an association with autism. In any event, the possible phenomenon of 'healthy early vaccinees' indicates a need for a deeper investigation into age-related patterns of vaccinations in the population.

In summary, on the one hand, there are no credible epidemiologic studies implicating thimerosal-containing vaccines in the etiology of autism. On the other, several large studies finding no association are far from robust, as they suffer from numerous biases that seriously limit their definitiveness. These include: non-comparable sources for ascertainment of cases, uncontrolled confounding, unrepresentative sample due to selective exclusions, and an as-yet unexplained pattern whereby children with earliest vaccines are the least likely to have developmental deficits. Thus, the body of evidence at this point is inadequate to draw conclusions.

As a scientist, I have no stake in this controversy. As an environmental epidemiologist, vaccines are not at the top of my list of suspects. I am an avid supporter of vaccines, insofar as they might have changed my family history for the last century had they been developed sooner: my maternal grandmother died in the influenza pandemic of 1919 when my own mother was only 1 year of age. Several decades later, my mother herself spent more than a year of my impressionable childhood in the hospital with TB. Thankfully, the sulfa drugs arrived in time and she survived. The difference between those two generations permanently altered the course of my life. Public health is what I think about every day. That and scientific integrity.

My final thoughts: *The polarization between the lay public and the medical/public health/scientific community is unnecessary and it erodes the trust that is fundamental to a strong health infrastructure.* We are all interested in finding out the answers to the question: what are the causes of autism? I thoroughly understand the fear that vaccination rates will plummet and sympathize with the urge to want to provide reassurance. The actual impact, however, may be contrary to that intended. Denial that there are any unanswered questions is difficult to defend and as a consequence may, in the long run, only add fuel to the critics' firepower. I firmly believe that evidence-based public health is the only effective way we can truly reassure the public. To regain the confidence that we in the medical/public health/scientific community need in order to fulfill our mandate to protect health, we cannot avoid facing these tough scientific questions head-on, grappling with them at the molecular, cellular, systems, and population level. Concretely, this means funding solid scientific research into vaccines, thimerosal, and the related issues of susceptibility.

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

Kathryn Craig

February 2, 2009

Subject: autism and mercury

I was thrilled when the funding was announced for research into the causes of autism. I was very disappointed when I learned that the IACC had made a decision not to pursue the autism-vaccine connection.

My 25 year old son [PII redacted] has autism. His older cousin in [PII redacted] had some allergy tests last year that showed he was allergic to thimerosal. My husband has had an allergic reaction to swordfish, the most heavily mercury-contaminated fish in the sea.

I hope you will consider our family's experiences with mercury and those of other families, and overturn your decision to reject the vaccine-autism. In our family's case, we believe the idea has merit.

Kathryn Craig, [PII redacted]

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Jan Turner

February 2, 2009

Subject: Forward: Autism Action Alert/Urgent!

When your committee quietly took a revote in January '09 and **reversed its December '08 affirmed vote** to proceed with Autism/Vaccine research, it strongly gives the appearance of true fear among many of the committee members, and government related health organizations, **to actually proceed with an unbiased autism/vaccine study**. One step forward has turned into two steps backwards. We, the families experiencing autism first hand, need to have our voices heard. Is anyone ever going to listen to the parents?

It seems that **those involved in government have forgotten why they are serving** in their positions. We need our government agencies, committees and legislators to act in supportive, proactive ways in order to find a cause or the contributing factors of this devastating neurological disorder, as well as to advocate for its youngest, most vulnerable citizens. "Children are the heart of our nation and the hope of mankind." What will it take? We do not live in a third world country. How can you put this off, turn a blind eye and ignore American citizens who continue to plead for action?

Along with keeping costs manageable, we understand the goal of the Centers for Disease Control and Prevention (CDC) is to immunize the masses with as many vaccines (multiples) as possible when the patient is available. Where are the studies that show that multiple vaccines are safe? With even a possibility that there is a relationship between vaccines, autism and other developmental disabilities, why is the CDC forging ahead with so many mandatory vaccinations at such **an early age?** Not moving forward with these studies and responding to the concerns of all **parents and the pleas from the autism community, screams of a huge conflict of interest on the part of the Department of Health and Human Services (HHS) and the federal members of the IACC**. We don't hear anyone advocating to get rid of vaccines, but "We the People" want to see these research studies take place, and for the CDC to take positive action to relieve concerns about multiple vaccines and the current recommended schedule. Both of these dilemmas have very simple solutions.

Most of the diagnosed children have families that make every effort to take good care of them and seek proper treatment, while incurring huge expenses and receiving little or no help from insurance--but that's a discussion for another day. What happens when those family members have exhausted all of their resources or pass on leaving the affected children behind? How many of those children will have the luxury of having lifetime care provisions set up for them? Currently, with **1 in 150** children and **1 in 94** boys receiving this diagnosis, our citizens will feel this burden in the near future. For those already affected and those who will receive this overwhelming diagnosis in the future, **NOW is the time to put every effort into leaving no stone unturned**. It is critical so that this devastating epidemic can be stopped. Please move forward. **INDEPENDENT vaccine studies are crucial**.

Sincerely,

Jan Turner, [PII redacted],

(The following people have asked to have their names added to this letter)

Ray Turner / Atlanta, Georgia / [PII redacted]
Erin Harvin / Marietta, Georgia / [PII redacted]
Billy Harvin / Marietta, Georgia / [PII redacted]
Iris Turner / Smyrna, Georgia / [PII redacted]
Jason Turner / Smyrna, Georgia / [PII redacted]
Susan Harvin / Braselton, Georgia / [PII redacted]
Bill Harvin / Braselton, Georgia / [PII redacted]
Patty King / Atlanta, Georgia / [PII redacted]
Pam Spears / Atlanta, Georgia / [PII redacted]
Diana Abernathy / Knoxville, Tennessee / [PII redacted]
Harvey Abernathy / Knoxville, Tennessee / [PII redacted]
Mary Gaites/Flowery Branch, Georgia / [PII redacted]
Julia and Mike Balson

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Mary Gaites

February 2, 2009

Subject: Forward: Autism Action Alert/Urgent!

Hope this helps. I believe that multiple vaccines are most likely the cause of increased Autism in our nation's children. I hope this helps to keep the research going. Our children deserve at least that! I added my name to the letter.

Thanks,

Mary

Mary Gaites/Flowery Branch, Georgia [PII redacted]

Janet Norman-Bain

February 3, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

As you are well aware, some initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. As you yourself noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

I approve of the move to submit those initiatives to a re-vote in the January IACC meeting, and agree with the majority of the IACC members that it is inappropriate to keep these initiatives in the Plan at this time.

In addition, I would like to express my concern that the IACC Strategic Plan process has been significantly delayed already by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Janet Norman-Bain
Prince Edward Island, Canada

Michelle Neely

February 3, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

I fully support the IACC's decision to remove language in the IACC Strategic Plan that would mandate studies of links between autism and vaccine. There are millions of affected families who are tired of autism research being held hostage by groups with a strong political agenda and no scientific acumen.

No amount of time or money devoted to studying a connection between vaccines and autism will ever convince the anti-vaccine groups like SafeMinds and Generation Rescue that there is no connection. I am very dismayed that Autism Speaks has aligned itself with these fringe groups, and have withdrawn my financial support from the organization. I can only hope that other science-minded representatives from Autism Speaks will resign as Ms. Singer did.

The Strategic Plan process has been delayed long enough by the anti-vaccine groups and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Michelle Neely
Des Peres, Missouri

Charles Bakk

February 3, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

Initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. These initiatives should stand as is or every initiative approved by the IACC should stand for a re-vote I would like to express my concern that the Strategic Plan process has been significantly delayed already and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress as currently stated.

Respectfully submitted,

Chuck
Fairfax, Virginia

Judy Badner

February 3, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines (forward)

As you are well aware, some initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. As you yourself noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

I approve of the move to submit those initiatives to a re-vote in the January IACC meeting, and agree with the majority of the IACC members that it is inappropriate to keep these initiatives in the Plan at this time.

In addition, I would like to express my concern that the Strategic Plan process has been significantly delayed already by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Judy Badner

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

Brian Scott

February 3, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

I am writing to you in hopes of convincing you that there is much to be learned by evaluating the possible relationship between a more aggressive vaccination schedule and the apparent increase in autism diagnosis.

In the last few years, there have been a series of articles published in widely respected journals that unquestionably point towards the presence of an ongoing inflammatory process in children with autism; and in some cases, specifically, in the brains of people with autism. Considering these findings, I believe it is prudent that we find a way to determine if the artificial stimulations of our infants' immune systems at an early age may be related to what has been observed at a diagnostic level.

Specific examples of an ongoing inflammatory process in the brain and central nervous systems (CNS) of people with autism have been observed in at least three studies in the past four years:

In January of 2009 researchers in New York published "Elevated immune response in the brain of autistic patients." When compared with control samples, the brains of people with autism were found to have highly increased levels of several inflammatory cytokines, including tumor necrosis factor (TNF)-alpha, Interleukin (IL)-6, and Interferon (IFN)-gamma. The authors concluded that localized brain inflammation may be related to the pathogenesis of autism.

In 2007, researchers in Chicago measured levels of cytokines in the cerebro-spinal fluid (CSF) of children with autism. What they observed was very highly increased levels of tnf-alpha in children with autism when compared to children without this diagnosis. This paper is entitled: "Elevation of tumor necrosis factor-alpha in cerebrospinal fluid of autistic children"

In 2005, researchers at Johns Hopkins found that people with autism showed signs of immune activation at greatly increased levels compared to people without this diagnosis, in their paper, "Neuroglial activation and neuro-inflammation in the brain of patients with autism". Once again, there was a marked increase in pro-inflammatory cytokines in subjects with autism.

On a more indirect measurement level, but corresponding well to observe increased head size in autism, in 2006, researchers at Washington University observed increased water retention in the brains of children with autism as opposed to children without a diagnosis. The authors believe that this could be the result of an ongoing inflammatory process, and that this inflammation could actually be what drives increased brain size, as opposed to a 'lack of pruning'. This study is entitled: "Gray matter abnormalities in autism spectrum disorder revealed by T2 relaxation".

There are, of course, many other studies identifying an inflammatory cytokine profile in autism, but I have only included those that speak directly to the CNS for purposes of brevity. There should be no

doubt, however, that the immune system in autism is deregulated, and is skewed to a pro-inflammatory state.

If we look for mechanisms by which a dysregulated inflammatory immune response might be generated in children with autism, we also have many recent studies wherein key upstream immune messengers responsible for controlling immune responses have been shown to be abnormal in autism.

In August 2008, researchers from Yale published "Macrophage Migration Inhibitory Factor and Autism Spectrum Disorders". This study found that children with autism had greatly increased levels of macrophage migration inhibitory factor (MIF) when compared to children without that diagnosis; and as levels of MIF increased, so did measures of autism severity. Increased levels of MIF have been well documented to be associated with autoimmune and inflammatory diseases such as asthma, arthritis, some cancers, and type 1 diabetes. This particular study also utilized genomic mapping, and children with autism were found to be much more likely to harbor known MIF promoter alleles than their non-diagnosed peers.

In this paper, the authors state:

"Thus, the central hypothesis underlying this research was that a genetic predisposition to a particular level of MIF production may lead to a proinflammatory profile of cell activation that, if present during a neurodevelopmentally sensitive period, might contribute to the etiopathogenesis of autism."

In 2008, researchers at the University of California found that children with autism were much more likely to have decreased levels of transforming growth factor beta 1 (TGF-B1) when compared with children without a diagnosis. TGF-B1 is a critical immune component that participates in the control of immune responses. When circulating levels were measured, children with less TGF-B1, exhibited more severe autistic behaviors. This study is entitled "Decreased transforming growth factor beta1 in autism: a potential link between immune dysregulation and impairment in clinical behavioral outcomes."

Decreased levels of TGF-B1 were previously identified by researchers in Japan, in a study titled: "Decreased serum levels of transforming growth factor-beta1 in patients with autism."

Thus, in a very real sense, at a clinical level, we have observed that children with autism have impaired ability to appropriately control immune responses by a variety of identified physiological measures; and indeed, as that impairment grows, so do measures of autism severity. Taken together, observed inflammatory processes and abnormal messenger components constitute the observation of a susceptible subgroup; a population of children who have problems regulating immune responses.

Finally, in an animal model of autism, researchers from John Hopkins were able to create animals with distinctive behavioral and physiological characteristics of autism by administering an agent after birth; but only if that agent was given shortly after birth. The agent in question, terbutaline, has been shown to increase concordance of autism diagnosis in twins. Animals given terbutaline between two and five days after birth went on to display different behavioral profiles, as well as distinctive microglial activation previously observed in people with autism. Animals given the agent between eleven and fourteen days after birth showed no such changes. These physiological changes were persistent until at least thirty days. This study is, "Neuroinflammation and behavioral abnormalities after neonatal terbutaline

treatment in rats: implications for autism."

This bears repeating: by adjusting the timing of a dose of chemical after birth, researchers were able to create physiological hallmarks of autism.

Taking all of this information together, we have learned many things. People with autism have been shown to have a distinctly pro-inflammatory immune profile in their brains and central nervous systems when compared to people without autism. From a mechanism of action standpoint, we have increasing evidence of how children with autism are predisposed to have problems regulating an immune response; with results expected to be skewed towards increased inflammation. These two avenues of observations would appear to be completely consistent with one another. In animal models, physiological features known to be compatible with what is found in autism can be created by adjusting the timing of an agent after the animal is born.

Now, consider vaccines.

The underlying mechanism of creating an immunological memory is the initiation of an immune response by providing a small concentration of bacterial or viral proteins alongside aluminum salts. In the past two decades, there has been a gradual but steady increase in the number of vaccinations given, and a corresponding decrease in the age at which those vaccinations are administered. Concurrently, there has been an increase in combination vaccinations, which are well established to produce more pronounced immune responses (i.e., fevers) than the individual vaccinations which those particular diseases. Simply, more immune challenges, at earlier ages, and those that are more likely to generate a robust immune response.

Unfortunately, our existing suite of research regarding autism and vaccination was constructed before almost all of the above observations were made, and as a result, these studies were not designed to attempt to capture information regarding a relationship between deregulated immune responses and autism. Unfortunately, any association between early aged immune response generation and autism are completely invisible to all thimerosal based studies. Likewise, the remaining components of our research, MMR studies, only take into account vaccines that are given after a dozen, or more, earlier vaccinations are administered. As such, our ability to glean useful information is hindered greatly; especially considering the impact of timing in the animal studies referenced above. It is merely a statement of fact that our existing research based is comprised entirely of thimerosal or measles, mumps, rubella (MMR) studies.

As a scientist, you must accept that as additional information becomes available, new theories are required to try to explain what has been observed. For all the rhetoric concerning 'shifting goalposts' regarding vaccines and autism, one thing seems to be forgotten, or unknown; we now have much more information than we used to. I would assert that it is unconscionable not to formulate new working theories based on our emerging understanding of the immune regulatory issues identified in autism; and we have no valid reason for these theories not to include artificially stimulated immune responses.

Considering that we now know that children with autism are particularly predisposed towards having an impaired ability to control inflammatory immune responses; and indeed, that the timing of insults is critical in the developing nervous system, we no longer have the luxury of believing that there is no viable mechanism of action by which a more aggressive vaccine schedule can contribute to the pathology

of autism. Likewise, we have certainty that our existing research does not provide meaningful information as to the impact of initiating immune responses at earlier and earlier ages.

In autism, we have observed abnormalities in the system that is at the absolute heart of vaccination, all vaccinations, and we have no research one way or the other as to if the two are related or not.

Your decision will not be an easy one, but please consider that history will take note of your actions. Unless all of the research I have referenced above is wrong in the exact same way, we have sufficient evidence to take steps to evaluate if artificially generated immune responses are associated with autism. Unless you believe for some reason that all of the information I have included is incorrect, surely additional findings regarding the immunological dysfunction in autism are likely to follow; and eventually more and more people will come to the conclusion that I have:

The foundation of the scientific method is that you only learn about what you actually analyze; in the case of vaccines and autism, as opposed to thimerosal and autism, or the MMR and autism, we simply have not performed any quality evaluations. Without quality evaluations, it is impossible to actually know if there is a relationship between a more aggressive vaccination schedule and autism rates. Considering what we now know about the handling of immune responses in autism, continuing to assert that vaccine research is a waste of resources constitutes either ignorance of our understanding of autism physiology, or outright denial of what has been observed in favor of political expediency.

The evaluation of your decision regarding funding prioritizations will continue for a long time; and I must admit, I do not envy your position. Throwing aside, for the moment, the very legitimate concerns of questioning the policy of vaccination, you should ask yourself, will it stand up to scientific scrutiny in the future?

Best wishes,

Brian Scott

[PII redacted]
Tallahassee, Florida

Isaac Pessah

February 4, 2009

Isaac N. Pessah, PhD
Professor of Toxicology
Director, UC Davis Center for Children's Environmental Health and Disease Prevention

There is accumulating evidence that indicates immune dysfunction is associated with autism disorders in a significant subset of children. Peer reviewed scientific publications found in the NCBI PubMed database indicate that scientists have begun to specifically address how the immune system of autistic individuals differs from non-autistic individuals. Nearly 60% of 186 publications with the search terms autism and immune have been published within the last 5 years. Unfortunately we have only scratched the surface in our efforts to understand when and how immune dysregulation contributes to autism risk, severity and susceptibility to environmental triggers. I believe the publication record portrays an awakening within the scientific community that autism is not only a genetically wired problem of brain development. Rather, autisms are now viewed as a cadre of disorders that impact multiple organ systems. In many individuals at risk for autism, active participation by abnormal immune system responses likely contributes to core symptoms and co-morbidities. Much more research is needed in this area. Our need to understand the immune system in autism is not solely based on conjecture since many of the genes identified to confer autism risk regulate signaling pathways common and essential to both nervous and immune system functions. We know very little about how the immune system of autistic individuals differs from those of non-autistic individuals. We are at critical juncture in autism research. In addition to the best basic science aimed at understanding molecular and cellular abnormalities of autistic immune systems, we also need well designed and executed studies to determine if subsets of children at risk for autism respond adversely to current vaccination formulations and schedules. These two scientific approaches are inseparable if we are to gain better understand the complex etiologies we have come to define as autisms. It is therefore essential that the IACC reinstate priority in the strategic plan for funding the best population—based science that directly address the question of vaccine safety for individuals at risk of autism and related disorders, as originally proposed by the "Environmental Factors Workgroup". Considering the weaknesses and uncertainties associated with existing ecological studies of vaccine safety and autism risk, for example those based on the Vaccine Safety Datalink, I ask that you reconsider the wisdom in your decision to remove vaccine safety studies from the IACC strategic plan.

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

Stacy Marcassoli

February 4, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

As you are well aware, some initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. As you yourself noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

I approve of the move to submit those initiatives to a re-vote in the January IACC meeting, and agree with the majority of the IACC members that it is inappropriate to keep these initiatives in the Plan at this time.

In addition, I would like to express my concern that the Strategic Plan process has been significantly delayed already by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Stacy Marcassoli
[PII redacted]

Miruna Stratan

February 4, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

Please do not add back vaccine-autism language back into the strategic plan. The plan has been delayed enough.

As you are well aware, some initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. As you yourself noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

I approve of the move to submit those initiatives to a re-vote in the January IACC meeting, and agree with the majority of the IACC members that it is inappropriate to keep these initiatives in the Plan at this time.

In addition, I would like to express my concern that the Strategic Plan process has been significantly delayed already by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Mom of autistic 4 year old New Jersey

Kate Apgar

February 4, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

As you are well aware, some initiatives were inserted into the IACC's Strategic Plan in December which would budget for vaccine related research. As you yourself noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

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In addition, I would like to express my concern that the Strategic Plan process has been significantly delayed already by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Respectfully submitted,

Kate, Mother of a teenager diagnosed with Asperger's Syndrome Arizona

Matt Wiener

February 4, 2009

Subject: feedback regarding: IACC Strategic Plan and vaccines

I support the removal of the (improperly inserted) vaccine-related items in the IACC's strategic plan. An immense amount of research has gone into the search for some - any - connection between vaccines and autism, and there is no scientific reason to be pushing large additional efforts in that direction. This is especially true since it appears that there is no evidence that could persuade the "vaccine sceptics" that there is no link between vaccines and autism.

The attempts to placate vaccine sceptics has already delayed the strategic plan, and therefore has delayed important research. Please put an end to this.

Respectfully,

Matt Wiener Westfield, New Jersey

Lydia Maher

February 4, 2009

Subject: The Strategic Plan should not be delayed further by vaccine initiatives

As you are aware, some initiatives were inserted into the IACC's Strategic Plan in December to budget for vaccine related research. As you noted in the January meeting, those initiatives did not go through the standard procedure and were not cleared by the science subcommittees.

I agree with the majority of the IACC members that it is inappropriate to keep these initiatives in the Plan at this time.

I would also like to express my concern that the Strategic Plan process has been significantly delayed by attempts to incorporate vaccine language, and I would urge you to not allow these delays to continue. Now is the time for the first IACC Strategic Plan to be submitted to congress and for the research called for in the Combating Autism Act to begin.

Yours sincerely,

Lydia Maher

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

Sharon Boyd

February 4, 2009

I am sitting here listening to a doctor (I'm sorry, I'm not sure who, as she didn't identify herself when she spoke). I am quite upset as a mother of a Severely Autistic son, in hearing the speaker say that we don't know what the other diseases that we are immunizing against looks like, so we worry more about Autism. I am a Critical Care Registered Nurse. I am oncology trained as well. I would take my chances with cancer, measles, chickenpox, and so on, over what we will be living for the rest of our lives. As the speaker stated, we are now a society that lives into our 80's. If you want to discuss fear, imagine worrying about your son being a raging two year old for the next 70 years, knowing that you will not be there to care for him!

In answer to the question of how to regain parents' trust, perhaps treating parents as the EXPERTS on our children that we are. I would welcome any opportunity to help in this process!

Sincerely,

Sharon R. Boyd
[PII redacted]

Jonathan Sollinger

February 4, 2009

Subject: Autism initiative

Let's get going on autism research.....

Let us continue to rely on science and compassion to guide as we venture forth to unravel the mysteries of the human brain.

But please, no more wasted time, energy and funding on the pseudo-science blaming the vaccines. With great respect,

Jonathan Sollinger MD, Fellow of the American Academy of Pediatrics (FAAP)
Father of a middle son with autism
Office based pediatrician in Connecticut

Willows Pediatrics Group
1563 Post Road East
Westport CT 06880