Oral Public Comments

IACC Full Committee Meeting

October 23, 2009

List of Oral Public Comments

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

Paula C. Durbin-Westby

October 23, 2009

ASAN
The Autistic Self Advocacy Network

Thank you for permitting me to address this meeting of the Interagency Autism Coordinating Committee. I am representing the Autistic Self Advocacy Network.

I appreciate having had the opportunity to represent ASAN at the recent Scientific Workshop. The meeting offered many opportunities to make changes as the Strategic Plan is updated for 2010.

Inclusion of an objective to study ethical issues related to "the assessment and communication of genetic, environmental, and clinical risk for autism" was one of the recommendations from Panel 1, the panel I participated in. This objective does not go far enough in that it only addresses assessment and communication of risk. It does not address other ethical issues which we believe to be important. Therefore we strongly urge an objective that would address ethical, legal, and social issues related to all aspects of research, not just the communication of risk, although that is a critical area, given recent developments in identifying prenatal risk factors.

Another area for concern about ethics is early intervention, as interventions are initiated at earlier and earlier ages. Ideas about what early interventions will work are generally based on assumptions of non-autistic people about what "the reasons for autistic behaviors" might be, with little to no input from autistic adults, who can inform and guide research.

A concerted effort is being made to increase acquisition of biological materials, such as skin fibroblasts, brains, and other tissue types. There is an ethical concern with collecting biologic samples from young children, who are not capable of giving permission. Potentially, children might not want to contribute biological material, if one of the purposes was for developing a prenatal test aimed at selecting people like themselves out of the gene pool. Although there are many reasons for collection of biological materials, this concern must be addressed. People on the autism spectrum who can communicate, and people with other disabilities such as Down Syndrome, and their families, have advocated against, and continue to advocate against, such an aim.

In general, recommendations of many of the panelists to include adults in many sections of the Strategic Plan are a step in the right direction.

Although the IACC does not fund research, presumably it has some influence on research priorities, or it would not bother to come up with budget recommendations. Here are some figures from the 2009

Strategic Plan.

Recommended budget for diagnosis and assessment: $133,600,000

For biology and risk factor research, $179,000,000. For causes and prevention, *$216,400,000.* Treatment and intervention gets $190,100,000.

For "Where Can I Turn For Services?" Where, indeed? Not to the IACC recommended budget, which suggests a grand total of $25,330,000. If research were really funded at the levels *recommended by the IACC*, that question becomes even more anxiety-provoking for autistics and our families. We will certainly need to turn to avenues other than the IACC for answers to questions about needed services and supports. Research into causes, biomarkers, prevention, etc. will not help people who are alive today and need evidence-based information about services and supports.

Recent research and initiatives in the United Kingdom can provide a model for services-oriented research and also research into adult issues. The National Health Service has released a study of autistic adults, indicating that prevalence of autism in adults in the UK is one in a hundred, similar to the recent figure here of 1 in 91 children. Interestingly, the NHS report avoids alarmist rhetoric and talk of "an epidemic of autism." In addition, initiatives such as the "Don't Write Me Off" employment campaign and "Supporting people with autism through adulthood" can make a real difference in the lives of autistics, especially and young people who are transitioning out of school settings. Sadly, the United States is falling behind on crucial issues related to services and lifespan issues and is failing autistic adults, families and communities.

Currently the Strategic Plan does not address communication differences and disabilities at all. This is a surprising omission, since one of the criteria for an autism diagnosis is communication disability. Although panel 4, on treatments and interventions, mentioned communication as an emerging tool, *specific mention of communication research* should be incorporated into the 2010 Strategic Plan.

Paula C. Durbin-Westby Board of Directors
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Theresa Wrangham

October 23, 2009

safeMinds
Sensible Action For Ending Mercury-Induced Neurological Disorders

Good afternoon. I am Theresa Wrangham, President of SafeMinds and mother to a 19 year old daughter recovering from autism. I thank the committee for the opportunity to speak today. I thank the committee for listening to the questions that have been posed by our community and that I have had the privilege to deliver for the last year and a half as I have traveled from Colorado to Washington. I thank the committee for listening to my daughter [PII redacted]'s questions that she asked over a year and a half ago, which in essence were why have off-label treatments improved my cognition, make her feel better physically and when will you fund the necessary research to give her those answers?

We wait for your answer. We do not offer public comment for the sake of hearing our own voices. We comment to give voice where in fact many of people with autism are unable to give voice to their needs – for the vast majority of those with autism cannot tell you what they need, where it hurts or what helps. There have been few answers coming from this committee on vaccine safety research, expansion of objectives federal members voted down which were unanimously supported by public IACC members for treatment, biomarker identification and environmental factor investigation, studying recovered children or the treatments that have recovered them. So we ask where is the scientific curiosity and urgency that should accompany the alarming announcement that autism has now grown to affect 1 in 100 individuals.

Answers we have been given are: CDC statements on uncertainty if the rise is real. Mr. Trevathan, the CDC appears to have no problem counting 131 cases of measles and locating farms responsible for contaminated food. Data on the environmental reality continues to mount from studies like those recently published by the MIND Institute and Vanderbilt. Surely 1 in 100 represents an easier counting target and the public can reasonably expect more current data, since the 1 in 100 estimate is already over 10 years old. How many have autism today? What steps CDC is taking to improve their reporting on autism in determining what is real?

We are told regression after vaccination is coincidental, parent's stories of recovery and response to treatment are anecdotal, parents are desperate and imagine improvement, its unethical to recruit unvaccinated children, if we investigate vaccines could send the wrong message, there are optics and conflicts involved, a vax/unvax study is too hard to design or unethical. Ms Singer recently stated, “a single ear infection is a greater immunological challenge to a child than all childhood vaccines combined." and the list goes on.

The word anecdotal is treated as a four letter word by this committee. However, as demonstrated by CDC surveillance study, had doctors listened to parents concerns early on delays in development, the

median age of diagnosis would not be as substantially outside the age of early intervention as it is now. Parents are your best resource, we live the dailiness of autism with our children and science begins with observation of the anecdotal. Parents are not so desperate as to imagine improvement where none exists. The only desperation I see is that parents are desperate for answers and giving this committee valuable information to be acted upon in getting those answers. Given the rich clinical data available on successful treatments used by physicians treating and recovering our children, the number of clinical trials, biomarker identification and objectives on environmental factors must be expanded in the manner supported by public members of this committee who unanimously supported their expansion and were ultimately out voted by the majority of federal members of this committee.

Additionally, it would appear that few IACC's committee members have actually read the NVAC report which found many of the same vaccine research gaps that our community has long requested be remedied. This report made autism specific recommendations. Any yet, Dr. Insel, you are worried about optics and messaging. In offering testimony to Senator Harkin you didn't refer to the NVAC report as it applies to autism when clearly you had knowledge that the Senator was interested in hearing about vaccines research gaps. Offloading research to NVAC which has no budget to conduct research is dishonest. NIH and more specifically the IACC have research monies to allocate. Optics can be overcome in the manner suggested by Dr. Mark Noble earlier this year – yet no response on overcoming the "optics" has been issued.

With the rise in unvaccinated populations noted in the NVAC report, what is the impediment in counting those individuals for a vaccinated/unvaccinated study – a study that former CDC Director Dr. Julie Gerberding stated "could and should be done."? I am from Boulder County – another highly unvaccinated county with the distinction of also being one of the most highly educated. Parents there make a conscience choice. Gathering information on the unvaccinated is not difficult or unethical and is likely to already be available via HMO general consent waivers already in place for various lines of scientific inquiry and/or could be easily obtained by permission.

From a prospective perspective, Dr. Landis, who is no longer with us, worried about the cost of adding protocols to existing studies to gather vaccine records. People with autism impact our economy at between $30-$90 billion dollars a year. Over the course of their life, care for an individual with autism costs about $3.2 million according to Harvard. $40 million to add these protocols is equal to just over the cost of care for 12 people with autism. It is a small price to pay to understand whether or not vaccines have a role in total health outcomes beyond their beneficial impact to infectious disease. It is money well spent to in gathering verified medical records and active recruitment of families who by choice do not vaccinate. My eldest daughter was fully vaccinated. My youngest has only received one vaccine and as a family we chose to stop. My children eat the same food and breathe the same air, etc. Gathering this information presents no real difficulty in terms of bias selection concerns.

This committee is a research committee not a public policy committee. Former NIH Direct Dr. Healy has stated "The public values vaccines. But more importantly, I don't think you should ever turn your back on any scientific hypothesis because you're afraid of what it might show." Dr. Louis Cooper, a former AAP President and Dr. Samuel Katz, a former ACIP chair, also recognized the vaccine safety research deficits and wrote in Newsweek "...there's been grossly insufficient investment in research on the safety of immunization. We need visible leadership from the incoming secretary of HHS, supported by President Obama."

Vaccine court has quietly awarded compensation for vaccine injuries resulting in autism since 1991; over 1,300 awards for vaccine injury have been made. Yet this committee is more worried about policy than science. What kind of message are you sending by refusing to conduct vaccine science to those with whom your duty lies – people with autism? The message we hear and heard by others outside the autism community is that the vaccine injured are acceptable collateral damage; that from a scientific perspective you are uninterested in understanding the mechanisms of injury and working to reduce injury where possible and as mandated by the 1986 Congressional Mandate for Safer Childhood Vaccines and Combating Autism Act. I seriously doubt that the the injured would share Ms. Singer's point of view and the views held by many on this committee.

My daughter [PII redacted], and the sons and daughters of the many parents who watched as their children disappeared into autism, have funded research through organizations like SafeMinds, ARI, NAA and many others, published papers and stand before you waiting for answers. Because of the dearth in answers and lack of will to investigate an obvious starting point, the National Vaccine Information Center in on day two weeks ago raised $110,000 for vaccine research. Thus, I leave you with a quote from Dr. Albert Einstein: "*The world is a dangerous place, not because of those who do evil, but because of those who look on and do nothing."*

Sharril Hemry

October 23, 2009

My name is Sharrill Hemry. I am the mother of three children, aged 12-16, all of whom have the blanket diagnosis of autism.

I spoke to this group back in March 2008 and have attended every quarterly meeting of the Interagency Autism Coordinating Committee since. I have watched as you developed your current strategy and tried to ensure within that document that both scientific and parental observations were given a voice.

As a result of my observations over the last 18 months, I am confident that this Committee has the potential to make a real difference and so I am here today to ensure that you are aware of new Chronic Fatigue Syndrome research which I strongly believe will have resonance to addressing the illness we know as autism.

In my last message, I stated that my own children have blood markers indicating that a neuro-immune disease process underlies their illness. The mainstream medical community still does not yet acknowledge that many of those with autism have a medical illness and, thus, truly effective treatments remain a figment.

Like autism, Chronic Fatigue Syndrome has sharply risen in the past two decades and has been plagued by the mainstream medical community's slow pace at understanding the underlying cause. But new Chronic Fatigue Syndrome research suggests a possible cause.

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On October 9th, "Science" published a study of Chronic Fatigue Syndrome conducted by research scientists from the Whittemore Peterson Institute, The Cleveland Clinic and several components of the National Cancer Institute, including the Laboratory of Experimental Immunology, Laboratory of Cancer Prevention, and Advanced Technology Program.

The article, entitled, "Detection of an Infectious Retrovirus, XMRV, in Blood Cells of Patients with Chronic Fatigue Syndrome," identified DNA from a human gammaretrovirus xenotropic MLV (murine leukemia virus-related virus) or "XMRV" in the peripheral blood mononuclear cells of 67% Chronic Fatigue Syndrome patients studied (68 of 101) compared to 3.7% of healthy controls (8 of 218).

In still-unpublished work, it is reported that the blood of an additional 500 Chronic Fatigue Syndrome patients in London is being tested and, so far, the same percentage is being found in that population.

The study published in "Science" questioned whether XMRV infection is a causal factor in the pathogenesis of Chronic Fatigue Syndrome or merely a passenger virus in the immunosuppressed Chronic Fatigue patient population.

The study also postulated whether there is relationship between XMRV infection status and the presence or absence of other viruses often associated with Chronic Fatigue Syndrome (e.g., herpesviruses), and conceived that these viruses could be cofactors in pathogenesis, such as occurs with in HIV.

In the study's cell culture experiments, the virus was infectious in both cell- associated and free-cell transmission, while secondary viral infections were established in uninfected primary lymphocytes and indicator cell lines following exposure to activated peripheral blood mononuclear cells (PBMC), B cells, T cells or plasma derived from Chronic Fatigue Syndrome patients. The authors further noted that patients with Chronic Fatigue Syndrome have an elevated incidence of cancer and questioned whether XMRV infection might alter the risk of cancer development in Chronic Fatigue Syndrome patients.

When scientists from Tufts University and the National Institute for Medical Research in London provided written comments on the study, they echoed questions as to whether XMRV alters the risk of cancer development in Chronic Fatigue Syndrome patients and they correlated the "Science" study to another new study, one published in the September "Proceedings of the National Academy of Sciences," in which University of Utah and the Columbia University Medical Center scientists examined prostate cancer biopsies and found XMRV in about one quarter of the samples - with higher grade tumors even more likely to contain the virus.

An October 9th article in the Wall Street Journal reported that 27% of these prostate cancer biopsies contained XMRV as compared to 6% of benign samples. That same article reported that 20 of the 101 Chronic Fatigue Syndrome patients whose samples were used in the "Science" study had lymphoma – the link between XMRV and lymphoma is not yet established - and that using additional testing, more than 95% of the Chronic Fatigue Syndrome samples either contained an active XMRV infection or indication of past exposure.

The Wall Street Journal article further noted that Robert Silverman, the Cleveland Clinic scientist who is one of the discoverers of XMRV, estimates that the virus could have migrated from mice to humans and that, after seeing the initial findings from both the prostate cancer and Chronic Fatigue Syndrome studies, the National Cancer Institute convened a closed-door workshop in July to discuss the public health implications of XMRV infection.

A virus that appears to have migrated from animals to humans, is rarely found in healthy human populations (unlike many of the other viruses associated with Chronic Fatigue Syndrome), has demonstrated infectious tendencies. is linked to at least one form of cancer, and may cause long-term havoc to the immune systems of a subpopulation of people…

Now let me mention that the Wall Street Journal article also reports that Whittemore Peterson Clinic has isolated this virus in the blood of patients with fibromyalgia, atypical multiple sclerosis, and AUTISM.

We have no time to lose.

References

Coffin, John M. and Stoye Jonathan P. "One Virus-How many Old Diseases?" Unpublished Manuscript.
Lombardi, Vincent, et al. Detection of an infectious retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome." Science Express, October 8, 2009, pp.1-4.
Marcus, Amy D. "Cancer causing virus linked to chronic fatigue." Wall Street Journal. October 9, 2009, p. A4.