Oral Public Comments

IACC Full Committee Meeting

July 15, 2008

List of Oral Public Comments

Kelli Ann Davis

July 15, 2008

Ms. Davis did not submit a statement but read the following letter into the record:

Hon. Michael O. Leavitt
Secretary, Health and Human Services
200 Independence Avenue SW Room 615-F
Washington, DC 2020 I

Re: Strategic Plan for Autism Research

Dear Secretary Leavitt:

The autism community worked with Congress to enact the Combating Autism Act (CAA) of 2006, P.L. 109-416. The CAA authorized $640 million over five years to expand and intensify autism basic and clinical research conducted by NIH to "investigate the cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder." Congress directed the Interagency Autism Coordinating Committee to develop, submit, and annually update a comprehensive Strategic Plan (SP) with a budget for the conduct of this research.

We write to bring to your attention serious process failures in the development of the SP that violate both the letter and spirit of the CAA, and to seek *your* assistance to develop a SP that responds to the tasks set by Congress and meets the needs of the community to harness the power of science and medicine to find the cause of autism, treat and *support* existing cases, and prevent the factors that lead to new cases. Strong community support for the SP is essential for its success.

Briefly, the process to date has been as follows: The IACC, newly reauthorized by CAA, held its first meeting November 30. The NIMH staff presented a tentative plan to gather public and scientific input for the SP with over 500 comments filed by January 5. However, comments and/or summaries have not been made public. Over seventy scientists met in groups January 15-18 and generated 41 general research topics. These meetings were closed to the public and the 41 initiatives have not been made available to the public. An initial workgroup met on February 21. The IACC met again on March 14 and expressed a need for historical funding information and a consensus for a new workgroup to conduct detailed analysis and begin the process of drafting the SP. The newly organized workgroup met on April 21 with public access available via telephone. The workgroup reached a consensus that it needed clarification of its mandate from IACC and several more meetings to complete the task of drafting the SP.

During-their most recent meeting on May 12, the IACC again expressed a strong consensus that the workgroup should reconvene for further analysis and development of the SP as well as expanding the workgroup as an ongoing subcommittee similar to the Services Subcommittee. Despite repeated requests by the IACC for more information and for a continued role for the workgroup in drafting the SP, most of the drafting has been captured by NIMH staff with little practical input from the IACC, or the workgroup. The NIMH has consistently failed to follow the guidance of the IACC and the workgroup

regarding ways to improve the quality and oversight of the SP. The NIMH intends to present its draft SP by July 2, with only a brief opportunity for "review" by the workgroup during a three hour teleconference on July 8. The draft SP will be presented to the IACC on July 15. Significant and valuable work has been accomplished to date, but significant involvement by the IACC and the workgroup in making deliberate and possibly "hard" choices is essential for the SP to fulfill the goals set by Congress and to earn and deserve the support of the community.[1]

The community can enthusiastically support a SP that ensures progress toward Congressional goals with all deliberate speed. Therefore, the SP must be much *more* than an unprioritized listing of interesting research topics relating to autism (as was the "autism roadmap" developed in 2003).

The SP must address at a minimum: (1) a mission statement incorporating the goals set by Congress; (2) specific goals; (3) analysis of past and present research, accomplishments, and gaps (including unfunded projects as a measure of demand); (4) a prioritized plan for present and future research initiatives that specifically includes a focus on environmental causes including vaccines; (5) changes to the funding process to reduce delay, rely on mechanisms such as special emphasis panels with defined budgets and research targets, and increase community participation in funding decisions; (6) transparency, accountability and performance metrics; (7) a justified research budget driven by scientific opportunity and demand; and (8) collaboration and partnerships with non-NIH public and private research funders.

The SP must strategically justify necessary resources, prioritize research questions, is accountable and transparent. The community must have an effective plan to take back to Congress to obtain the necessary appropriations. Accordingly, in addition to the above, the SP must address the following major issues:

1. The SP Must Propose a Research Budget: CAA tasked IACC to "develop and annually update a strategic plan for the conduct of, and support for, autism spectrum disorder research, including proposed budgetary requirements, and submit to the Congress such strategic plan and any updates to such plan." 42 U.S.C. 280i-2(b)(5), (6). The Senate HELP Committee report (S. Rep. No. 109-318," emphasis added) was quite specific in the reason for and expected contents of this autism research budget: "To increase the accountability and focus on autism spectrum disorder at the National Institutes of Health (NIH), the committee specifically authorizes a strategic plan related to autism spectrum disorder. In requiring the Director of the NIH to develop a strategic plan for autism spectrum disorder, the committee wants to ensure that this plan provides not only an outline of key research activities and questions but also ties those activities to specific budgetary outlays to improve the transparency of the planning process… In reporting on the expected spending and providing an analysis of what was previously expended, the committee strongly encourages the director to provide such dollar amounts using clear and consistent methods for determining the monetary allocation." Despite this clear requirement,[2] the NIMH has repeatedly claimed "there is no new money" and forbidden both the science panels and workgroups from addressing budget requirements. A rigorous cost-of-disease analysis must be included to justify the social return on the research expenditures. A rigorous analysis of past research must be included in order to assess both failures and accomplishments from spending thus far and the need for new directions and priorities in the allocation of funding. An analysis of unfunded autism projects must be conducted to assess in general the demand from the research

community for autism-related funding. Since CAA was only "authorizing" legislation, the community needs a research plan with a price tag and an ROI to obtain the necessary funding from Congress.

2. The SP Must Specifically Research Vaccines as a Potential Cause of Autism: The CAA specifically listed 13 scientific fields that should be included in the research plan: pathology, developmental neurobiology, genetics, epigenetics, pharmacology, nutrition, immunology, neuroimmunology, neurobehavioral development, endocrinology, gastroenterology, and toxicology. Both House[3] and Senate[4] legislative history singled out a single research opportunity, vaccines, transcending many of these fields. Considerable public input (from the January request for written comments, following the IACC March 14 request to fill any "gaps," and the May 3 town hall meeting in Sacramento) insisted that the research agenda must include vaccines. However, none of the 41 broad initiatives under consideration even mentions this topic.

The SP must not be ruled by implicit censorship or fear, [5] but by a sincere commitment to use science to uncover the truth about vaccines and autism. The need for vaccine-autism research is particularly urgent, especially a comprehensive retrospective and prospective comparison of the health outcomes of vaccinated versus unvaccinated children. The present vaccine schedule must be regarded as experimental because its safety with respect to chronic disease has never been validated by a customary double-blinded randomized clinical trial in either an animal or human population.

Mounting evidence from animal models, especially results presented at the preeminent autism scientific conference IMFAR in May, suggests the expanded schedule is unsafe. That pilot study showed significant neurological impairments and bowel disease in vaccinated macaques versus unvaccinated controls. Even the Institute of Medicine has left open the possibility that vaccines could cause autism in a genetically susceptible population.[6] The lead author of the only US epidemiological study relied upon by IOM published a retraction [7] of any "no causation" inference, and called for further research.

3. The SP Must Clearly Embrace Prevention As Part of Its Mission and Goals: The CAA required NIH to "expand, intensify, and coordinate" basic and clinical research to investigate "cause (including possible environmental causes), diagnosis or rule out, early detection, prevention, services, supports, intervention, and treatment of autism spectrum disorder." 42 U.S.C. 284g. Prevention is an attractive goal in terms of the direct and indirect cost of autism and the burden it imposes on individuals, families and society as a whole. The sharp rise in autism rates can only be fully explained by environmental factor causality (interacting with genetic susceptibility), these environmental triggers can be identified and eliminated, thereby preventing disease spread and potentially ameliorating the condition in existing cases.

Although NIMH Director Insel stated to Congress[8] that prevention is a goal of NIH autism research, a glaring absence from both the draft mission[9] and vision[10] statements presented by Dr. Insel at IMFAR is an express commitment to "prevention." This absence reflects the irremediable failure of NIMH to develop an acceptable SP and demonstrates a fundamental need to overhaul the SP exercise. Any acceptable SP must come to grips with the fundamental nature of this disorder. As you clearly articulated during the first IACC meeting on November 30, autism is both preventable and treatable. The SP must incorporate this vision.

4. Funding Process Re-Engineering to Ensure Transparency and Accountability: The CAA specifically directed IACC to "make recommendations to the Secretary regarding public participation in decisions relating to autism spectrum disorder." 42 U.S.C. 280i-2(b)(4). Funding must be reprioritized to place greater emphasis on environmental factors as potential causes and modifiers and on treatments. IACC's review of progress in achieving the goals of the autism roadmap concluded that these areas in particular had been underfunded. Greater reliance must be placed on RFA's (with specific monetary allocations)[11] with review by special emphasis panels (as opposed to the more generalized study section review of ROl grants)[12] to ensure that crucial scientific questions of greatest urgency and impact are matched with the funding and talent to get answers as quickly as possible.

Additionally, there must be community involvement in decisions relating to both scientific merit and programmatic relevance, a model used very successfully for the newly-funded Congressionally Directed Medical Research Program for Autism.[13]

Adherence to the six "values'' adopted by IACC (Sense of Urgency, Spirit of ·Collaboration, Consumer-focused, Scientific Excellence, Partnerships in Action, and Accountability) requires significant-community participation at each stage of funding decisions as well as structural reform to ensure that the "scientific excellence" will actually achieve measurable benefits in finding the cause, prevention, treatment, services, and supports for autism.

We ask your help to achieve two process improvements essential to an effective SP. First, we ask you to establish an Autism Advisory Board composed of scientists, clinicians, and advocates. This would not in any way duplicate the work of the IACC, which is broadly concerned with coordinating all federal activities relating to autism, including critical activities related to services. Rather the AAB would be concerned with the narrower scientific research agenda and the ongoing CAA mandate to annually measure performance of and update the SP.

Both the House[14] and the Senate[15] recognized the usefulness of an AAB in the legislative history for the IACC. The experience of convening scientific workshops and two different workgroups this spring highlights the need-for an ongoing body that brings together these three crucial sources of advice.

Second, several governance issues at the IACC require resolution. Although FACA requires transparency for the IACC, none of the materials relating to the SP process have been made public, e.g. on IACC's website. These include: meeting minutes, transcripts, or summaries; public comment in response to the two RFI's due last January; summaries of the public comment prepared for the workgroup and scientific workshops; slides presented during the IACC and workgroup meetings; the "gap" initiatives filed with the NIMH after the 3/14 IACC meeting; rosters of the four scientific workshops and two workgroups; and the prioritization votes taken by the workgroups.

Of additional concern, votes are not being taken at IACC meetings with apparent consensuses subject to reinterpretation by the NIMH (recent examples include the recommendation for a Strategic Planning Subcommittee and reconvening of the second workgroup for further analytical and drafting work for the Plan). Any attempt to place items on the agenda and collaborate prior to IACC meetings have also been stifled by the NIMH, with IACC members accused of "insulting" behavior and threatened with dismissal for these attempts.

Formal votes should be taken on motions to document the decisions of the IACC. Such actions by NIH staffers violate the values set forth by the IACC and clear guidance should be publicly given that IACC members may communicate directly with each other (e.g. by email) concerning IACC business and may, as specifically authorized by law, [16] collaborate prior to meetings.

Sincerely,

/James A. Moody/
James A. Moody
Director, SafeMinds

1. Rather than simply a listing of interesting studies, Congress required rigorous analysis of past achievements and future priorities in the SP: "Further, in crafting the specific strategic plan, the committee encourages the director to:

    A. Determine and establish priorities among critical scientific questions related to autism spectrum disorder;

    B. Specify the short and long-range objectives to be achieved, and estimate the resources needed to achieve these objectives;

    C. Evaluate the sufficiency of existing research programs on autism spectrum disorder to meet the specified objectives and establish objectives, timelines, and criteria for evaluating future research programs; and

    D. Make recommendations for changes to existing research programs on autism spectrum disorder, including potential consolidation of research activities if such consolidation would improve program efficiencies and outcomes."

2. In doubling the President's budget proposal for FY09 autism spending, Senator Dodd explained: "It continues to be a challenge to determine how much Federal funding is actually going to study the causes of and treatment for autism. In fact, some estimates are that actual NIH funding for research specific to autism is less than half of what is being reported. That is why this amendment is so critical. It will redouble our Federal commitment to funding autism, the fastest-growing developmental disability in the U.S. At a time when the number of children and families living with autism has grown exponentially, the President's budget proposes to freeze Federal spending on autism at levels that are insufficient to make the kind of discoveries in autism that are needed… There are so many unanswered questions about autism. And it will require a major scale-up in funding to bring us closer to answering them. We should close no doors on promising avenues of research into the causes of autism and my amendment allows all biomedical research opportunities on autism to be pursued. The amendment I am offering would enable us to redouble our efforts on autism research and treatment services by increasing funding for research, treatments, education and interventions by $197 million in fiscal year 2009 and I urge my colleagues to support the amendment. Again, I emphasize it is the fastest growing developmental disability in our country. The number of children who will be born with autism is increasing every day in this country." 154 Cong. Rec. S1971 (March 12, 2008).

3. House Chairman Barton added: "With respect to possible environmental or external causes of autism, some have suggested a link exists between autism and childhood vaccines.... I recognize that there is much that we do not know about the biological pathways and origins of this disorder, and that further investigation into all possible causes of autism is needed. This legislation is not designed to predetermine the outcome of scientific research. Rather, the legislation rightfully calls for renewed efforts to study all possible causes of autism- including vaccines and other environmental causes. Simply put, we should leave no stone unturned in our efforts to find a *clue,* whether it means exploring possible environmental factors, paternal age, genetic factors, or any other factors that may hold answers." 152 Cong. Rec. H8787 (December 6, 2006).

4. Senate HELP Committee Chairman Enzi explained that the CAA research mandate as: "the bill reported by the HELP Committee contemplates key research activities, including environmental research, that focus on a broad range of potential contributing factors, with meaningful public involvement and advice in setting the research agenda. However, I want to be clear that, for the purposes of biomedical research, no research avenue should be eliminated, including biomedical research examining potential links between vaccines, vaccine components, and autism spectrum disorder.... No stone should remain unturned in trying to learn more about this baffling disorder, especially given how little we know." 152 Cong. Rec. S8772 (Aug. 6, 2006).

5. Former NIH Director Bernadine Healy explained in a May 12 CBS News interview: "I think that the public health officials have been too quick to dismiss the hypothesis as irrational… There is a completely expressed concern that they don't want to pursue a hypothesis because that hypothesis could be damaging to the public health community at large by, scaring people. First of all, I think the public's smarter than that. The public values vaccines. But more importantly, I don't think you should ever tum your back on any scientific hypothesis because you're afraid of what it might show... What we're seeing in the bulk of the population: vaccines are safe.. But there may be this susceptible group. The fact that there is concern that you don't want to know that susceptible group is a real disappointment to me. If you know that susceptible group, you can save those children. If you tum your back on the notion that there is a susceptible group... what can I say?"

6. "Determining causality with population-based methods such as epidemiological analyses requires either a well-defined at-risk population or a large effect in the general population. Absent biomarkers, well-defined risk factors, or large effect sizes, the committee cannot rule out, based on the epidemiological evidence, the possibility that vaccines contribute to autism in some small subset or very unusual circumstances. However, there is currently no evidence to support this hypothesis either." IOM, Vaccines and Autism at 11 (2004).

7. The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended, which is the conclusion to which a neutral study must come.... A neutral study carries a very distinct message: the investigators could neither confirm nor exclude an association, and therefore more study is required. . . . The bottom line is and has always been the same: an association between thimerosal and neurological outcomes could neither be confirmed nor refuted, and therefore, more study is required." Pediatrics, 2004;113;932.
8. Statement of Thomas B. Insel, M.D., Autism Research at the National Institutes of Health, Before the Appropriations Subcommittee on Labor, Health, and Human Services, Education, and Related Agencies, United States Senate at 7 (April 17, 2007) ("Ultimately, our goal is prevention, based on

early detection of risk, understanding environmental factors that increase or decrease symptoms, and development of effective interventions before behavioral and cognitive deficits appear.")

9. Draft Mission Statement: "The purpose of the Strategic Plan is to focus, coordinate, and accelerate high quality research and scientific discovery in partnership with stakeholders to answer the urgent questions and needs of individuals on the autism spectrum and their families."

10. Draft Vision Statement: "The Strategic Plan will accelerate and inspire research that will profoundly improve the health and well-being of every individual on the autism spectrum across the lifespan. The plan will set the standard for public-private coordination and community engagement."

11. Recent examples relating to autism include Identifying Autism Susceptibility Genes, RFA-MH-05-007, Autism Centers of Excellence, RFA-HD-06c004, and Development of lnnovative Treatment Approaches to Autism, RFA-MH-01-101.

12. Most recently used by CDC on June 12 to award 2008-R-VAC01, Associations of Vaccine Adverse Events and Human Genetic Variations, 2008-R-VACOI.

13. http://cdmrp.army.mil/arp/default.htm. (IACC Note: URL is not valid.) The CDMRP includes consumer input at the beginning of the annual planning cycle and during both levels of proposal review, scientific merit and program relevance, explaining: "Consumer advocates participate in setting CDMRP priorities and making funding decisions. Consumer advocates' firsthand and personal experiences with a disease provide a unique perspective that complements scientific expertise during proposal review. The Consumer perspective increases awareness of the human side of research and how it impacts survivors. Funding decisions incorporate the concerns and needs of patients, treating clinicians, and survivors, their families, and communities. Conversely, scientists impart a new understanding of the research community to the Consumers on the review panels. The mutually beneficial partnership between Consumers and scientists is a valuable aspect of the peer and programmatic review process at the CDMRP. Through 2007, Consumers have participated in more than 1,700 peer review opportunities." Strong consumer participation was "recommended by the Institute of Medicine and reviewed with approval. See I0M, Strategies for Managing the Breast Cancer Research Program: A Report to the U.S. Army Medical Research and Development Command, National Academy Press, 1993; IOM, A Review of the Department of· Defense's Program for Breast Cancer Research, National Academy Press, 1997, McCaughan, S., The DOD Congressionally Directed Medical Research Program: Innovation in the Federal Funding of Biomedical Research, Clinical Cancer Research, 8:957- 62 (April, 2001).

14. Chairman Barton explained: "The IACC has been tasked with making recommendations to the Secretary regarding the public participation in decisions relating to autism. For instance, the committee notes that the IACC may recommend providing other formal mechanisms, such as an Autism Advisory Board, to provide public feedback and interaction. Further, the Secretary may opt to provide such a mechanism under existing statutory authority, without the recommendation of the IACC. Public participation, especially among the parents and families of those affected by autism, is necessary to emphasize the human side of autism research and to ensure that Federal resources are used wisely. 152 Cong. Rec. H8787 (December 6, 2006)."

15. "The committee further re-examined the Interagency Autism Coordinating Committee (IACC). In particular, the committee wanted to increase the amount of public participation {from two

individuals) to at least six. In addition, the IACC has been tasked to make recommendations to the Secretary regarding the public participation in decisions relating to autism spectrum disorder. For instance, the committee notes that the IACC may recommend providing other, additional, formal mechanisms, such as an Autism Advisory Board, to provide additional public feedback and interaction. Further, the Secretary may opt to provide such a mechanism without the recommendation of the IACC." S. Rep. 109-318 at·17.

16. 41 C.F.R. § 102-3.160: What activities of an advisory committee are not subject to the notice and open meeting requirements of the Act?

    The following activities of an advisory committee are excluded from the procedural requirements contained in this subpart:

    A. Preparatory work. Meetings of two or more advisory committee or subcommittee members converted solely to gather information, conduct research, or analyze relevant issues and facts in preparation for a meeting of the advisory committee, or to draft position papers for deliberation by the advisory committee; and

    B. Administrative work. Meetings of two or more advisory committee or subcommittee members convened solely to discuss administrative matters of the advisory committee or to receive administrative information from a Federal officer or agency.

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

Margaret Dunkle

July 15, 2008

My name is Margaret Dunkle. Some of you know me through my current position as Senior Fellow with the Center for Health Services Research and Policy at George Washington University, and some from my prior work running policy seminars on Capitol Hill. Some of you know me as recipient of the American Academy of Pediatrics' Dale Richmond Award for outstanding achievement in the field of child development, or for the collaborative efforts I direct in Los Angeles County to ensure all children receive good developmental screenings and effective follow-up.

More recently, some of you have come to know me because my nephew's daughter, [PII redacted], is the little 9-year-old girl from Athens, Georgia who was the subject of a case the government conceded in vaccine court. The nine vaccines [PII redacted] received on one day in July of 2000 significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism and manifested as a regressive encephalopathy with features of autism spectrum disorder. Indeed, [PII redacted] has autism, with a clear DSM-IV diagnosis based on the Diagnostic and Statistical Manual of Mental Disorders.

I believe in a strong and safe immunization program. Yet, every day more parents and some pediatricians reject the current vaccine schedule. I am concerned that many people are missing [PII redacted]'s clearly scribbled handwriting on the wall. She has provided a critical clue (mitochondrial dysfunction) and a historic opportunity for our public health leaders and policymakers to act responsibly and decisively – undertaking serious science to address the very real concerns so many parents and families are raising.

[PII redacted]'s condition is not rare. The best evidence available strongly suggests that at least 7%, and perhaps as many as 20% or 30%, of children with autism have mitochondrial dysfunction similar to [PII redacted]'s. With one in every 150 children on the autism spectrum, these issues are both urgent and important.

> Now that we know this, it is time to follow the prestigious Institute of Medicine's 2004 report that said: "Determining a specific cause [for autism] in the individual is impossible unless the etiology is known and there is a biological marker. Determining causality with population-based methods requires either a well-defined at-risk population or a large effect in the general population."
>
> Mitochondrial dysfunction defining an autistic subpopulation and the role of neuro-inflammation in autism are not esoteric theories. They are real leads that need to be quickly followed.

I urge you to support the following recommendations that reflect your Committee's mission to coordinate, monitor and recommend changes concerning federal autism efforts.

#1: First and most importantly… With Marshall Plan speed and focus, I recommend a new, intense basic science research program to get to the bottom of what is going on with the many [PII redacted]s out there – specifically focusing on the role of mitochondrial dysfunction and neuro-inflammation in autism and other disorders.

> How many [PII redacted]s with mitochondrial dysfunction are there? 4%? 7%? 10%? 20%? Where do these dysfunctions come from? How do they work? Can the negative effects be undone or limited?
>
> This research must be bold, going wherever the science takes it, with nothing off the table.
>
> I estimate $200 million will be needed to jump-start this research. This money must be a new or redirected appropriation, not borrowed or taken from the Vaccine Injury Compensation Program (VICP).

#2: Quickly find ways to screen for and identify the subset of children like [PII redacted] for whom vaccines can cause or exacerbate mitochondrial damage and lead to symptoms of autism.

> For example, start screening the siblings of children with autism to identify biomedical markers that could lead to screening tests and treatment.

#3: Piggyback new research onto existing studies to answer important questions about autism, vaccines, mitochondrial dysfunction and neuro-inflammation.

> For example: Test alternate vaccine schedules and frequencies through the National Children's Study and use this data set of 100,000 children to get longitudinal data on these issues; and Build new analyses into existing studies and cohorts of patients with known mitochondrial dysfunction – such as research already underway at Hopkins, the Cleveland Clinic Foundation and Columbia.

 # 4: Institute an immediate nationwide initiative to spot children, like [PII redacted], who have adverse vaccine reactions and speed them into intense early intervention (specifically, the federal IDEA Early Intervention program for children ages 0-36 months and the Preschool Special Education program for children ages 3-5).

> **An important corollary is to strengthen the Vaccine Adverse Event Reporting System (VAERS) so that it actually does the job it was set up to do** – collecting information about adverse events, including "side effects," that occur after the administration of vaccines.

#5: Reform and improve the current vaccine schedule and practices to ensure they are as safe as they possibly can be. For example, examine the number and frequency of vaccines, use of combo vaccines, preservatives used, and ages administered to identify changes that would minimize damage to children, especially susceptible children such as [PII redacted].

> It is significant that the federal Advisory Committee on Immunization Practices' recently downgraded its preference for a MMRV vaccine (four-vaccines in one shot: measles, mumps, rubella and varicella) to "no preference" because of increased seizures among children receiving the MMRV.

#6: Update the Vaccine Injury Compensation Program. For example: 3

> Allow parents longer than three years to file, especially given the newly identified "mitochondrial dysfunction" implications of the [PII redacted] decision and because we want parents and families to devote 100% of their energy to early intervention as soon as they learn their child has a problem; and Update the list of "table injuries" to reflect the emerging discoveries about autism, mitochondrial dysfunction and immunological disorders.

#7: Improve the way the federal government approves and monitors vaccines and vaccine safety – perhaps establishing an independent agency (separate from the Centers for Disease Control, which also runs the National Immunization Program) to research, approve, and monitor vaccine safety and effectiveness.

* * * * *

I am proud that my family is providing hope and voice to the many families across our country who have their own [PII redacted]s. I am also proud of their leadership to nudge those of us who care about good public health and good public policy to do the right thing and to do it right.

A little 9-year-old girl has raised incredibly tough and important questions. Your challenge, as leaders concerned about autism, is to tackle these issues in a way that is effective and unflinching – and that responds to her clear scribbling on the wall with equally clear advances in science and improvements in immunization practices.

Margaret Dunkle
Senior Fellow, Center for Health Services Research and Policy, George Washington University
Director, Early Identification and Intervention Collaborative for Los Angeles County
Recipient, American Academy of Pediatrics' Dale Richmond Award for Outstanding Achievement in the Field of Child Development

James Moody

July 15, 2008
Mr. Moody did not submit a statement but read the following letter into the record:

Thomas lnsel, MD
National Institute of Mental Health
National Institutes of Health
6001 Executive Boulevard
Room 8235, MSC 9669
Bethesda, MD 20892-9669

RE: IACC Strategic Plan

Dear Dr. lnsel:

The Strategic Plan Workgroup meeting held on Tuesday provided important information on the IACC strategic planning process and changes that need to be made to the strategic plan document. SafeMinds formally requests that the following charge be given to the IACC at its meeting on July 15:

1. IACC acknowledges the work of the science workshops, the public comment, the two workgroups and the Autism Team in preparing an early draft of the Strategic Plan.

2. The draft plan is referred back to the existing workgroup for further analysis and completion assisted by the Autism Team and outside contractors, as needed. The existing workgroup has developed a deep expertise on the plan and represents a broad spectrum of stakeholders, both scientific, government, and community. It should be utilized for the implementation phase.

3. The workgroup shall ensure that the concerns addressed at the July 8 workgroup meeting are incorporated into the plan, as specified on Attachment A

4. The workgroup shall complete the draft plan by adding the following elements:

    a. A recommendation for an annual autism research with spending necessary to accomplish strategic planning initiatives. In developing the research budget an in depth analysis of the autism research portfolio will be required as well as a "cost of disease" analysis, including the benefits to society of autism prevention and on the ability of the research community to perform sound science and additional analyses of unfunded initiatives, trends and patterns of autism research funding by NIH and other sources.

    b. A framework for establishing priorities among the research projects set forth in the strategic plan and expressing those priorities in terms of resource allocation over time and across research categories.

    c. A specific plan for researching vaccines as a potential cause of autism.

    d. An action agenda for implementing the plan that addresses investment parameters and revisions to the grant review process to ensure that high priority research is initiated

through RFA's with defined budgets and special emphasis panels to ensure that the research elements set forth in the plan are carried out in a timely and coordinated manner reflecting the urgency of treating existing cases and preventing new cases.

e. Incorporation of broad community participation in funding decisions, inclusive of scientific merit and programmatic relevance, as well as an effort to facilitate coordination between public and private funders of autism research.

f. Mechanisms to ensure evaluation, accountability and transparency, including a means of determining whether particular projects should be counted as part of the autism research portfolio, and which include participation by the broad public and scientific communities.

g. The draft portion of the plan shall be published on the IACC website for public comment, along with the public comments, science workshop initiatives, priority rankings, and other submissions relating to the plan.

5. The draft final plan will be published on the IACC website by November 1 making any changes in time for presentation of the final draft plan at the November IACC meeting. SafeMinds requests that you acknowledge this letter and indicate your agreement with the charge above prior to the July 15 IACC meeting.

Sincerely,

Theresa K. Wrangham, President

Endorsing Organizations

A-CHAMP Autism One
Autism Research Institute
Generation Rescue
National Autism Association
Schafer Autism Report
Talk About Curing Autism
US Autism & Asperger Association
Unlocking Autism

Attachment A

Suggestions for Revisions to the Draft IACC Strategic Plan Made by the Strategic Plan Workgroup

The IACC Strategic Plan Workgroup (SPWG) convened via tele- and web conference on July 8, 2008. Dr. Tom Insel led the meeting. A discussion of each section of the draft SP by the SPWG, as well as comments made by Dr. Insel, elicited additions and changes to the draft plan and planning process. The points are summarized below. These points must be incorporated into the draft SP submitted to the IACC on July 15th.

1. A commitment will be made to include budgetary components (with allocations, prioritization, and funding mechanisms) as well as accountability, evaluation, and oversight mechanisms, to the final SP during what has now been identified as an implementation phase. The draft plan that is being submitted to the IACC on July 15th is now being called the diagnostic phase. The implementation phase will extend until the IACC meeting scheduled for November. The final SP will be submitted to the IACC at that meeting.

2. In developing the final SP during the implementation phase, the Autism Team will enhance public participation, collaboration, and dissemination of relevant documents, and will minimize the filtering of input from the various SP stakeholders.

3. The final draft should include an analysis of the cost of disease, recognize the serious increase in prevalence, and calculate the social ROI for the SP initiatives.

4. The Mission and Vision should include the need for prevention in addition to helping those who currently have an autism diagnosis.

5. The SP should give more emphasis on cutting edge science with the idea that a dramatic difference can be made in addressing the disorder.

6. When environmental science is mentioned, the wording should be revised to recognize the innovation and novel approaches currently in place or being developed by the field. The current wording suggests that cutting edge developments are only occurring in the area of genetics.

7. The current document overstates the robustness of the genetics findings in autism, which have not been replicated and account for a lower percentage of cases than is commonly reported.

8. The draft should balance heterogeneity and homogeneity in autism. Focusing on heterogeneity, while important, assumes that success is met when a finding pertains to only 1% of cases and that efforts to intervene in a dramatic way by finding common pathways are unrealistic. Both hetero- and homogeneity should be recognized.

9. The draft is biased toward prenatal onset. The document should recognize the likelihood of multiple trajectories in autism, including postnatal onset (including but not limited to regression) and postnatal influences. Detection should extend to a continuum of time points, and trajectory research should include an understanding of the biology underlying disease/symptom onset.

10. The final SP should allocate more spending to treatment research than the current level. Obstacles to conducting treatment research, such as the review process, need to be addressed. More and better research designs are needed, such as considering subgroups of responders versus the aggregate treatment response. Recognize that treatment response can

11. Inform phenotype studies. Shared treatment databases will move the field forward. More treatment research is needed among youths and adults, as is research that improves quality of life and enhances the strengths of the autistic person (as opposed to just 'normalizing deficits').

12. Parents should be included in research as partners and collaborators, and a participatory model adopted. Recognize that parents are astute observers of their child's response to intervention. A bed-to-bench + bench-to-bed approach will be productive. Dismissive wording when referring to parent observations should be removed.

13. The draft is biased toward characterizing autism as just a brain disorder. It should be reworded to recognize multisystem involvement.

14. Biomarkers should be recognized as a critical infrastructure need. Biomarkers will inform early detection. Biomarkers should be made a short term objective.

15. Tissue banking should expand beyond post-mortem brain to include stem cells/skin fibroblasts, other organs/tissues, and biopsy banking. Samples from youth and adults should be included.

16. The immune system should be characterized as a legitimate study area and not discounted just because immune dysfunction is common to other diseases (speech problems and repetitive behaviors are also common to other disorders).

17. The plan wording should not assume that autism is immutable and will not change over the lifespan.

18. The draft should place more emphasis on the environment. There should be a separate initiative on environmental factors, separate from gene x environment, recognizing that alterations resulting in autism can arise from genes, from environment, or from a combination. The document should balance what is already known from environmental research relative to what is known in genetics. The existence of toxicological databases should be recognized, that predictive models of toxicants can be created using stem cells, that the reasons why autism cells are more sensitive to toxicants should be determined, that high throughput toxicological studies that are specific to autism can be implemented.

19. The draft must specifically include vaccine research as this is what is stipulated by the CM and the intent of Congress. The document should reference the shortfalls of the epidemiological studies commonly cited to rule out vaccines in autism and state that the issue is open.

20. The need for more bioinformatics and bibliometrics should be added.

21. The word "pre-emptive" should be clarified so it does not connote pregnancy termination or genetics counseling for high risk pregnancies, should a biomarker be found.

22. Statements about the increasing rates of autism should acknowledge the growing consensus that the increase in cases is real. Statements that reduce a sense of urgency by casting doubt on the reality of the increases should be excluded.
23. It is important for policy makers to be informed of scientific progress in autism, so that policy can be evidence-based.

24. The idea of rapid acceleration of the science, with a sense of urgency and attendant mechanisms to achieve acceleration, should be built into the SP. The timelines assigned to initiatives should consider this urgency assigned to initiatives should consider this urgency.