



By Fax – 202-690-7203

July 7, 2008

Hon. Michael O. Leavitt
Secretary, Health and Human Services
200 Independence Avenue SW
Room 615-F
Washington, DC 20201

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.

- 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 House³ and Senate⁴ 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 retraction⁷ of any “no causation” inference, and called for further research.

- 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 Congress⁸ that prevention is a goal of NIH autism research, a glaring absence from both the draft mission⁹ and vision¹⁰ 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 re-prioritized 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 R01 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 House¹⁴ and the Senate¹⁵ 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 consensus 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,

/s/ 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:

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

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

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

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.”

S. Rep. 109-318 at 13.

- 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 treatments 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 cure, 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 turn 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 turn 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-06-004, and Development of Innovative 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-VAC01.
- 13 <http://cdmrp.army.mil/arp/default.htm>. 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 IOM, 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 convened 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.