safeMinds
Sensible Action For Ending Mercury-Induced Neurological Disorders

July 10, 2008

Thomas Insel, 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. Insel:

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 next week.

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. 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 research budget based on 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 (as measured in part by meritorious grant applications that were not funded due to lack of resources).

    b. Priorities among the research projects set forth in the plan.

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

    d. Changes in funding mechanisms to reflect the urgency of treating existing cases and preventing new cases.

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e. Changes in the mission, vision and funding mechanisms, including 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.

f. Incorporation of broad community participation in funding decisions, including both scientific merit and programmatic relevance.

g. 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.

h. Mechanisms to facilitate coordination between public and private funders of autism research.

5. 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.

6. 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

Theresa K. Wrangham,
President

safeMinds
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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 webconference 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 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').
11. 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.
12. The draft is biased toward characterizing autism as just a brain disorder. It should be reworded to recognize multisystem involvement.
13. Biomarkers should be recognized as a critical infrastructure need. Biomarkers will inform early detection. Biomarkers should be made a short term objective.
14. 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.
15. 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).
16. The plan wording should not assume that autism is immutable and will not change over the lifespan.
17. 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.
18. The draft must specifically include vaccine research as this is what is stipulated by the CAA 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.

19. The need for more bioinformatics and bibliometrics should be added.
20. 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.
21. 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.
22. It is important for policy makers to be informed of scientific progress in autism, so that policy can be evidence-based.
23. 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.