



August 5, 2008

By Fax and Email

Della Hann, PhD
National Institute of Mental Health
National Institutes of Health
6001 Executive Boulevard, Room 8235, MSC 9669
Bethesda, MD 20892-9669

Re: IACC Strategic Plan: Vote

Dear Dr. Hann:

Although the most recent version of the NIH Strategic Plan for autism research is an improvement over the previous draft, it continues to fall short in several crucial areas and needs additional work before broader distribution to the public or utilization by the Implementation Workgroup. Deficiencies include: lack of acknowledgment of the dramatic increase in the numbers of those suffering with ASDs; a corresponding lack of a sense of urgency in the treatment and prevention of this disorder as reflected by the research opportunities and objectives; selective and distorted representation of the public's input with regard to research priorities leading to the omission of vaccine and mercury specific research; and cursory, unsubstantiated and unbalanced science sections (What do we know, What do we need, Opportunities, and Objectives).

The plan states in the introduction that it is driven by a sense of urgency, but as a parent and member of the advocacy community, this urgency is not reflected in the actual document with regard to research opportunities and objectives. A child is diagnosed with autism every 20 minutes in our country today creating tremendous physical and emotional stressors for families in addition to the estimated 3.5 billion dollars spent annually to care for those with autism each year of their life. The current plan doesn't contain a cost of disease analysis or an in-depth review of past NIH autism research funding necessary to determine the performance of previous and current investments. There is no indication in the plan that increased resources will be allocated to autism treatment and prevention despite its considerable human and financial toll.

The research opportunities identified in the plan are oriented toward the existing research resources, that is, toward the scientists and organizations that have a stake in the existing research program and the types of projects that have been traditionally funded by NIH. This is demonstrated with the continued emphasis on genetics, even though the workgroup

acknowledged the need for more environmental research. While the latest version of the plan adds environmental activities, it includes two new large genetics projects. The environmental underpinnings of autism have been acknowledged as extremely underfunded to date (environmental studies have received less than 1/3 the amount spent on genetics), and the plan doesn't address this imbalance. Instead, it perpetuates and strengthens it.

In representing the status quo, the plan fails in capturing new and novel ideas suggested by the public that would focus on regenerative treatments that offer the opportunity of reversing the damage caused by autism. The proposed plan also fails to support the establishment of new "fast track" mechanisms necessary for ensuring that priority research initiatives are funded facilitating the translation of science into effective treatments. The number of projects ("Objectives") assigned to a given category appear to be completely arbitrary, with no rationale or priority for one area given one amount and another a different amount.

In an effort to obtain additional public input, the IACC sponsored a "Town Hall Meeting", which was well attended. One of the subjects that surfaced repeatedly was the need for research into vaccines as a trigger for autism. The need for vaccine research was also supported in the prior public RFIs. Clearly this research is seen by the public as a priority, was again restated in the second meeting of the workgroup (July 8th) as such, and was the intent of Congress in the Combating Autism Act, and yet it remains unaddressed in the proposed plan with the exception of a brief sentence that the scientific literature will be "monitored" for possible associations. If NIH fails to fund this research, it is unlikely that findings on it will enter "the literature"; which was the reasoning behind the public and members of Congress asking that NIH conduct research on the topic, not just "monitor the literature".

The section of the plan titled "What we know" is inadequate and barely scratches the surface of the current state of the science, or acknowledge new emerging ideas and research that advance our knowledge beyond the status quo. For example, the only mention of vaccine concerns with regard to autism cites an outdated IOM report from 2004 and fails to include more recent research supportive of a link between vaccines and adverse neurodevelopmental disorders like autism as well as several studies which support links between environmental mercury exposure and autism. This bias was also acknowledged by the workgroup, which recommended that the section reference the shortfalls in the epidemiological studies relied on by the IOM report of 2004 and state that the issue is still open for discussion and deserves additional investigation. This bias jeopardizes the strategic planning process in achieving the goals of preventing and treating autism and must be addressed.

As a public member of the IACC my job is to represent the public, and not just a certain segment of the public but the entirety of its views. The current plan reflects the input of the stakeholder sectors with which NIH is comfortable, that is, those who support the status quo. The public who wish to see autism research move forward with urgency and innovation is not represented.

Without the deficiencies noted above being addressed I cannot support this plan moving forward and I fear that members of the public, which worked so hard for the passage of the Combating Autism Act, will respond with heartfelt disappointment with the release of this plan.

At the last IACC meeting, only 40 minutes was allocated in the agenda to discuss the strategic plan, which was our most important agenda item. I stated that more time was needed for discussion, and at the very least, more comments should be allowed after the meeting for incorporation into the plan prior to it being released for public comment or moving to the implementation phase. This request was agreed to at the IACC meeting, yet many of my comments have not been included and a formal request made by my organization during the comment period to be included on the implementation workgroup has been denied. NIH has already scheduled an Implementation workgroup meeting for this Friday, before the IACC has even voted on this latest draft. I feel the IACC is being treated as a rubberstamp committee and that inadequate opportunity for the IACC to truly oversee the strategic planning process exists.

I must vote against the latest July 29, 2008 Strategic Plan Draft as well as register my disappointment in the strategic planning process.

Respectfully submitted,

Lyn Redwood, RN, MSN
IACC Public Member

Cc. Dr Thomas Insel