



July 13, 2009

\*\*\*\*\*VIA EMAIL\*\*\*\*\*

Dr. Bruce Gellin, Director  
National Vaccine Program Office  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW., Room 715-H  
Washington, DC 20201

Re: Recommendations to the IACC at July 15<sup>th</sup> Joint Meeting of NVAC and IACC

Dear Dr. Gellin,

IACC Chairman Dr. Insel wrote to you in January proposing a "mutually informative dialogue" to address "public concerns regarding a possible vaccine/ASD link." We recognize and appreciate the efforts of NVAC's Vaccine Safety Working Group and its recent report which was approved unanimously by NVAC on June 2nd. We note that many of the critical gaps in vaccine safety science identified in the report and many of the report's recommendations have implications for IACC's autism research agenda.

The most important of these recommendations in our opinion is number seven, comparing health outcomes of vaccinated vs. unvaccinated (and alternatively vaccinated) children. We note that this recommendation is essentially the same as the research objective approved in December by the IACC for inclusion in their Strategic Plan for Autism Research, along with a similar objective for studies in animals. Unfortunately, these objectives were deleted from the Strategic Plan at IACC's meeting in January over the objection of the majority of the IACC's public members. For your reference, the deleted IACC objectives (Question 3, Objectives 4 and 5) are contained in the footnote below.<sup>1</sup>

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<sup>1</sup> Question 3, Short-Term Objective 4: Study the effect of vaccines, vaccine components, and multiple vaccine administration through a variety of approaches, including cell and animal studies, and understand whether and how certain subpopulations in humans may be more susceptible to adverse effects of vaccines by 2011. Duration 2 years, budget \$6 million.

Question 3, Short-Term Objective 5: Determine the feasibility and design an epidemiological study to determine if the health outcomes, including ASD, among various populations with vaccinated, unvaccinated and alternatively vaccinated groups by 2011. Duration 2 years, budget \$10 million.

Given the recommendations contained in the NVAC report, we believe that the IACC should restore the deleted research objectives to the Strategic Plan in order for the plan to contain a comprehensive research agenda regarding the potential role of vaccination in triggering, or exacerbating, conditions associated with the diagnosis of autism.

Accordingly, we seek your assistance at the upcoming joint NVAC/IACC meeting on July 15th to ensure that the IACC, pursuant to its statutory responsibility under the Combating Autism Act, and in alignment with the VSWG's recommendations, include the vaccine-related research objectives approved in December 2008 in the autism research strategic plan as soon as possible.

As you are aware, vaccine-associated ASD remains a matter of intense controversy since it was first suggested in a 1994 paper by Sir Michael Rutter, and which must be resolved through sound science. Numerous public figures, including Dr. Bernadine Healey and Dr. Louis Cooper have called for additional research. IACC Chairman Dr. Insel conceded during a 2007 Senate Appropriations hearing that vaccine-autism question has not been resolved.

Additionally, the Vaccine Injury Compensation Program (VICP) has been compensating children who reported suffering vaccine-related injuries which were also temporally associated with ASD. Some of these cases were simply conceded by Department of Justice lawyers. Thus, the question is not whether vaccines "can" cause autism, instead, the question is how many children are affected and how can new cases be prevented and/or existing cases treated? In addition to these questions is the primary question of when will our Government pursue a "Safety First" agenda and invest the research dollars needed to answer these and other vaccine related questions?

Obtaining baseline data on the health of unvaccinated (and alternately vaccinated) children is the most obvious first step in filling crucial vaccine safety research gaps. These data are needed not just to address the autism issue but for all other conditions potentially associated with vaccination. Just as important is the dire need for research required to identify the fundamental mechanism by which vaccination is associated with neuroinflammation and auto-immune reactions.

Congress tasked IACC with finding the causes of and treatments for autism. Vaccines were the only cause specifically singled out in the legislative history. The IACC is required to develop an annual strategic research plan and budget to accomplish the mission set by Congress. Thus, Congress did not task NVAC with this specific responsibility. Moreover, we understand that NVAC does not fund or supervise research, nor does it directly establish the research activities of NIH, CDC, or other federal agencies. We greatly appreciate NVAC's work to identify vaccine safety research gaps. We believe that at this point, IACC should be responsible and accountable for seeing that the appropriate studies investigate the role of vaccination in

ASD are funded and conducted as soon as possible. Far too much time has been wasted already.

The health and safety of children and the future of the vaccine program must not be held hostage in a game of "kick the can" between NVAC and IACC. As such, we respectfully request that the recommendation(s) made to the IACC at the upcoming meeting on the 15<sup>th</sup> be:

- 1) that IACC reinstate the vaccine-autism objectives that were approved in December 2008; and
- 2) that the IACC review the NVAC report in its entirety and include in their research agenda those items specific to autism.

Thank you in advance for your prompt consideration and response to our request.

Sincerely,



Theresa K. Wrangham,  
President