

Oral Public Comments

**IACC Full Committee
Meeting**

July 15, 2009

List of Oral Public Comments

Geraldine Dawson.....	3
James Moody	4

Geraldine Dawson

July 15, 2009

I wish to comment on the IACC's discussion regarding the feasibility of using the National Children's Study as a platform for studying vaccines as a risk factor for ASD. Autism Speaks is leading an expert panel that is advising the National Children's Study regarding how to best leverage the National Children's Study to study a wide range of genetic and environmental risk factors for autism. One of the limitations of the current design of the study is that medical records are not collected. This precludes studying several important risk factors, including vaccines. The advisory panel strongly recommends that supplementary funding be provided to the study so that these additional risk factors can be studied. I wish to note that, although Autism Speaks is currently funding research on vaccines and autism, it remains a very small part of Autism Speaks' overall research portfolio – about 2% of Autism Speaks' research funding. This research focuses on identifying subgroups of children with specific medical or genetic conditions that might be susceptible to adverse effects of vaccines, including autism. The National Children's Study, which is a large population-based study, is much better suited to address questions regarding autism and vaccines than the smaller studies that Autism Speaks has funded. Such studies are best conducted by the federal government which has the resources needed for such large scale research.

Autism Speaks' expert panel that is advising the National Children's Study also is making recommendations regarding the ethical issues involved in studying autism in the context of the National Children's Study. Issues that are being considered include what referrals and monitoring should occur when children at risk for ASD are detected and issues related to risk communication, such as how to insure that rising questions about environmental risk factors, such as vaccines, doesn't alarm parents or discourage them from getting their child vaccinated.

James Moody

July 15, 2009

Subject: Feasibility of Vaccine Studies & Updating of IACC's Strategic Plan

Good afternoon. I am James Moody, a Director and Legal Counsel representing SafeMinds. I thank the committee for the opportunity to offer public comment on vaccine safety objectives. Our primary focus today is the need for the IACC's strategic plan to encompass autism specific vaccine safety research. The question of whether vaccines can cause autism has been answered by the Vaccine Injury Compensation Program's (VICP) compensation of vaccine injuries leading to an autism diagnosis, as well as the Government's concession of numerous cases of vaccine-induced autism. The questions that remain are how many children are affected and how can new cases be prevented and/or existing cases be treated.

Congress tasked this committee with finding the causes of and treatments for autism. Vaccines were the only cause specifically singled out in the legislative history. The unanimous passage of the National Vaccine Advisory Committee (NVAC) Vaccine Safety Working Group's Recommendations to the CDC's Immunization Safety Office identified crucial gaps in vaccine safety science. Many of the recommendations implicate IACC's research agenda where autism is a desired outcome. The continued growth in the body of research indicating that autism is environmentally triggered also supports the investigation of vaccine's role in autism. The Combating Autism Act's colloquy statements, IACC public comment statements and in correspondence to the IACC from many individuals and autism organizations leave no room for doubt as to the undeniable Congressional mandate and wishes of the public in this respect. The IACC must be accountable and responsible for autism specific vaccine research. As such, we ask that any applicable research objectives currently contained in the IACC's Strategic Plan encompass vaccines as a potential etiological factor worthy of study.

In addition to this request, the removal of previously approved vaccine objectives from the Strategic Plan under the false premise of NIH's lack of vaccine expertise, lack of support from the scientific workshops, and the acknowledged conflicts of interest must be righted. These same objectives were supported in the NVAC recommendations and NIH's expertise and historical involvement in vaccine research are a matter of public record and well known. The IACC transcripts document that such research was vetted and supported by the science workshops and strategic planning workgroups. An independent panel, as recommended by Dr. Mark Noble during his presentation to the IACC earlier this year, could easily overcome the acknowledged conflicts of interest existing within HHS in determining the feasibility of some of the vaccine research in question. Other vaccine research identified as necessary could also just as easily be required to be conducted by independent investigators who have no ties to industry and avoid conflicts of interest that have plagued this field of research previously. These steps would begin to assure a restoration of public confidence in the government's ability to conduct sound and necessary vaccine safety research. In short, given the latest recommendations from the NVAC, and the false premise put forward by Federal members of this committee, there is no logical reason or barrier preventing this much needed research and its inclusion in the IACC's Strategic Plan. Additionally, the scientific community involved in the strategic planning workgroup on numerous occasions, and in agreement with autism organizations and the majority of public IACC members, stated the need to acknowledge autism as a multi-system disorder, as well as the inclusion of limitations of studies used in the "What we know" section of Question 3 with the addition of research supporting vaccine and environmental concerns. We request that these items be corrected in the updating process

underway. The inaccuracies noted by the strategic planning workgroup and the autism community regarding vaccine research and the current plan's reference to the 2004 Institute of Medicine (IOM) Report are a matter of public record, not opinion, and must be corrected to remove the bias contained in the Strategic Plan in this regard.