

**Congress of the United States**  
**Washington, DC 20515**

June 10, 2009

Hon. Kathleen Sebelius  
Secretary, Health and Human Services  
200 Independence Avenue SW  
Room 615-F  
Washington, DC 20201

Dear Secretary Sebelius,

We are writing to ask your support in furthering the goals of the “Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act,” a bill that we plan to reintroduce in the 111<sup>th</sup> Congress in the coming weeks. The bill, as introduced in 2007 with 21 co-sponsors, would direct the Secretary of the Department of Health and Human Services (DHHS) “to conduct or support a comprehensive study comparing total health outcomes, including risk of autism, in vaccinated populations in the United States with such outcomes in unvaccinated populations in the United States, and for other purposes.” In the intervening time period, there have been two primary concerns that have slowed progress towards accomplishing this goal.

The first concern is that the total population of unvaccinated children would be too small or too different to permit a valid study. We believe that these concerns are increasingly unfounded.

- As for size, Duane Alexander, Director of the National Institute of Child Health and Human Development, commented recently that the study population in the National Children’s Study alone--a sample of 100,000 children--may itself contain several thousand unvaccinated children. In addition, families from targeted populations, e.g., the home-schooled, the Amish or those pursuing anthroposophic lifestyles, with known reduced vaccination rates could be recruited to expand the sample.
- As for difference, there is increasing evidence that vaccine refusals are rising among the most affluent, educated and professional parents (many of whom I represent in my Manhattan district). Indeed, it is the rise of such refusals that lends urgency to the need to investigate the safety of our current childhood vaccine program so that policy can be formed with full knowledge of any and all valid safety issues.

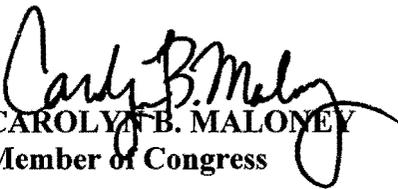
The second concern is that appropriating the resources necessary to complete such a comprehensive study would be too difficult (estimates of the cost of the study fall in the range of \$5-20 million). Indeed, this was part of the rationale provided by Dr. Thomas Insel, Director of the National Institute of Mental Health, when he obtained a reversal of a previous vote to include such a study in the NIH Strategic Plan for autism research. Since then, however, the American Recovery and Reinvestment Act has authorized \$300 million in *new funding* to promote the purchasing and distribution of vaccines. Surely, dedicating resources to fundamental safety

research should command as high a priority as increasing our already generous purchasing practices for childhood vaccines.

The questions raised by an increasing number of families, those affected by autism, learning disabilities and a rising toll of chronic disease, deserve immediate attention by the DHHS. Given the ongoing debate among parents and the medical establishment about the safe use of vaccines and the current vaccine schedule, it is likely that everyone will benefit from additional information and understanding of the outcomes of this study.

We are very grateful for your attention to this important matter.

Sincerely,

  
CAROLYN B. MALONEY  
Member of Congress

  
CHRISTOPHER H. SMITH  
Member of Congress