Congress of the United States Washington, DC 20515

February 22, 2006

Director David A. Schwartz, MD National Institute of Environmental Health Sciences National Toxicology Program P.O. Box 12233 Research Triangle Park, NC 27709-2233

Dear Director Schwartz:

We write to congratulate you on your appointment as NIEHS director and to bring to your attention report language contained in the FY06 Labor, Health and Human Services (HHS), and Education Appropriations conference report. This provision asks NIEHS to investigate a possible association between thimerosal in vaccines and the risk of autism.

NIEHS is a well respected institute entrusted with the important task of better elucidating the links between the environment and human health. We applaud NIEHS' work within the areas of breast cancer, asthma, and Parkinson's. We particularly commend your efforts to involve communities in the design, implementation and interpretation of research projects. This research will not only help us acquire essential environmental health knowledge, but simultaneously build the capacity of communities to take charge of their own health in a way that is culturally compatible, empowering, and most importantly, effective.

We hope that NIEHS can bring its expertise to the issue of thimerosal. Many of us in Congress are concerned about the possibility of an association between autism and thimerosal in vaccines. While we understand that the Institute of Medicine (IOM) has determined that the evidence thus far does not support an association, we know that for too many the issue is still not resolved. The exposure of American children from 1990to 2001 to thimerosal was unique – it was 75 percent greater than their European counterparts who are the focus of the majority of the epidemiological research on this issue upon which the IOM relied. This period coincided with an autism epidemic now affecting 1 out of every 166 children. Additionally, thimerosal is by weight 50 percent ethyl-mercury, which is a potent neurotoxin. The level of thimerosal in these vaccines exceeded the EPA *oral* daily dose limit for methyl-mercury by over 120 times at the 2, 4, and 6 month pediatric visit. Therefore, we believe that there is room for a closer look on any potential association between thimerosal exposure and the risk of autism, both to

learn new information and to solidify the public's trust in vaccines.

We note the existence and importance of the Vaccine Safety Datalink (VSD), a computerized Centers for Disease Control and Prevention (CDC) database that has followed 7 million vaccinated children in 7 managed care organizations throughout the United States from 1990 onwards. The VSD could be a valuable resource in investigating diseases of any type, including neuro-developmental disorders. Some experts suggest this database could provide answers regarding any thimerosal-autism link. The IOM regards the VSD as a unique data base with which the public should become familiar. We would expect that the VSD would be used in further studies.

Thus far, with regard to thimerosal and autism, the CDC has studied and reported on this database only once. That study was based on data collected prior to the removal of thimerosal and failed to explicity compare the outcomes of children who received thimerosal-containing vaccines (TCVs) with those who did not. The VSD now includes five years of additional data. We are aware that the CDC is presently preparing to conduct further analysis of the VSD to investigate the post-thimerosal data. Unfortunately, as the IOM pointed out in its April 2005 report on VSD access, a CDC-led study on thimerosal and autism could be viewed with much skepticism and may not be accepted by the growing number of parents with concerns about vaccine safety and the possible links between thimerosal and autism. If the federal government is going to have a study whose results will be broadly accepted, such a study cannot be led by the CDC. It is for these reasons we believe that NIEHS is the most appropriate entity to lead such an investigation.

Accordingly, Congress included in the FY 06 Labor, HHS, and Education Appropriations the following report language:

The conferees urge NIEHS to work with CDC and expert independent researchers on research that could identify or rule out any association between thimerosal exposure in pediatric vaccines and increased rates of autism. The conferees believe that the Vaccine Safety Datalink (VSD), a CDC-constructed database that follows 7 million immunized children from 1990 to present, could be helpful in the research, especially regarding pre-2001 VSD data and post-2000 VSD data, since thimerosal was removed from most childhood vaccines in 2001. The conferees urge NIEHS and CDC to organize a workshop by May 2006 to explore the research possibilities and scientific feasibility of such a study and report back to the House and Senate Appropriations Committees soon after.

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We ask that NIEHS adhere to Congressional intent to convene a workshop bringing together the various thimerosal-autism stakeholders, including the CDC, the autism community, members of the public concerned about vaccine safety research, and external academic researchers, to discuss how best to proceed with an NIEHS study of the VSD in a way that best addresses the various stakeholders' concerns. Our request is consistent with the NIEHS mission and with the type of expenditure the public expects. We were pleased that NIEHS provided a grant for a workshop on thimerosal last summer and believe this was good first and important step in investigating the role and effects of environmental exposures to mercury and neuro-developmental disorders. The directive language included in this year's Labor/HHS bill is a logical next step as NIEHS is the most appropriate entity to investigate this matter.

In the following weeks, we will follow up this letter with a phone contact. We request that our staff be briefed on the status of NIEHS acting on the FY 06 Labor, HHS, and Education Appropriations report language and progress in meeting the May deadline for the workshop.

Once again, congratulations on your new role as director. We look forward to working with you.

Sincerely,

Senator Joseph I. Lieberman

Congressman Dave Weldon

Congressman Carolyn Majoney

Congressman Chris Smith

Congressman Dan Burton

Congressman Joseph Crowley

Congressman Maurice Hinchey