Rep. Weldon (cont. from page 3)

Mercury" *Associated Press* and *USA Today*,

• "Study Finds No Link Between Vaccines, Autism" *Reuters*

• "Vaccine-Autism Link Denied" *The Detroit News*

• "CDC Says Vaccines are Safe..." *The Seattle Times*

While the "spin" on the study misled the public to believe that this study concluded there was no link between mercury in vaccines and neurodevelopmental disorders, the principle author of that study recently wrote a different viewpoint in *Pediatrics* – four months after his study was first published.

Dr. Verstraeten writes, "The article does not state that we found evidence against an association, as a negative study would. It does state, on the contrary, that additional study is recommended...." Dr. Verstraeten goes on to state, "The authors could neither confirm nor exclude an association."

In other words, according to the principle author of that *Pediatrics* study, each of those headlines was wrong. The jury is still out on mercury.

Mercury from childhood vaccines continues to be a possible culprit:

• The CDC's own study – four years in the making - was unable to specifically exonerate mercury.

• Mercury is a neurotoxin and is particularly harmful to the developing central nervous system of fetuses and infants.

• The Deth study, published in Molecular Psychiatry earlier this year showed that concentrations of thimerosal of 1nm were inhibitory of critical enzymes involved in neurodevelopment.

• Studies of children with autism continue to show high levels of mercury – chelation studies show that children with autism excrete high levels of mercury compared to normal controls, suggesting that these children might have a problem handling mercury.

Given these concerns about mercury and the possibility that vaccine exposures to mercury may have been a contributing factor in the epidemic of autism and neurodevelopmental disorders, it is critical that we err on the side of caution. We have the ability to eliminate this mercury exposure for infants and we should do so.

We know mercury is a neurotoxin and we know that exposures for developing fetuses and infants can only cause harm. In January, the Environmental Protection Agency (EPA) issued a report finding that 1 in 6 infants is born with a blood mercury level above a level considered safe by the EPA.

Also recently, the U.S. Food and Drug Administration and the EPA warned pregnant women, nursing mothers, and young children to limit their consumption of certain fish that are high in mercury in order to reduce their mercury exposure.

Unfortunately, the CDC is now poised to adopt a recommendation from the Advisory Committee on Immunization Practices (ACIP) that infants 6, 7, and 23 months of age receive a flu vaccine which may contain mercury. I have urged the CDC to alter the ACIP recommendation to recommend that infants, children, and pregnant and nursing mothers receive the mercury-free dose of this vaccine. To date, the CDC has failed to adopt this recommendation.

In response, I have introduced, along with Rep. Carolyn Maloney of New York, H.R. 4169, the Mercury-Free Vaccine Act of 2004. This bill will phase out the use of mercury in vaccines over the next 3 years, giving particular attention to completely eliminating mercury from childhood vaccines on an expedited schedule. By January 1, 2006, mercury would be completely removed from all childhood vaccines – consistent with the goal stated by the AAP, PHS and AAFP back in 1999. Furthermore, H.R. 4169 provides that adult vaccines not contain more than 1microgram of mercury after January 1, 2007.

This is a very reasonable bill. It focuses on eliminating this exposure completely for children in the short-term, while also reducing this exposure for adults on a schedule that allows manufacturers to phase out its use in a reasonable timeframe but with a fixed date.

We have the ability to eliminate this exposure to mercury and it is inexcusable not to. We know that mercury is a neurotoxin. And, we know that mercury levels are too high. Vaccines can be made without mercury, so why not remove the mercury and remove any doubt?

There are three government agencies that have responsibilities related to monitoring vaccine safety – the FDA, the CDC, and the NIH.

The Food and Drug Administration (FDA) has a responsibility to monitor vaccine safety. However, their role is largely limited to ensuring that vaccine lots that are released meet FDA standards and collecting information to be entered into the Vaccine Adverse Events Reporting System (VAERS).

The FDA does conduct some monitoring of the VAERS data to track and understand adverse events. However, the CDC has a greater responsibility in this arena and the FDA largely defers to the CDC.

The Centers for Disease Control (CDC) has the greatest responsibility in this area. Unfortunately, they are also the agency with the greatest conflict of interest. The CDC's vaccine safety monitoring program amounts to between $20 and $30 million a year. However, it is housed within a $1 billion plus vaccine promotion program. In fact the CDC spends millions of dollars a year simply encouraging Americans to get vaccinated. The success of the CDC's vaccine promotion program is largely judged based on how high vaccination rates are. Here lies the greatest conflict. Any study raising concerns that there might be adverse reactions to a vaccine is likely to result in safety concerns which will lead to lower vaccination rates.

Lower vaccination rates are in direct conflict with one of the CDC's greatest measurements of their success. Clearly, due to its overwhelming size and the manner in which the agency measures its success, the vaccine promotion program overshadows and influences the CDC's vaccine safety monitoring program.

In fact, rightly or wrongly, the vaccine safety office within the CDC is largely viewed by outside observers as nothing more than another arm of the vaccine promotion program, giving support to vaccine promotion policies and doing very little to investigate and better understand acute and chronic adverse vaccine reactions.

Further complicating the CDC's role and undermining their research is the fact that the vaccine safety studies produced by the CDC are impossible to reproduce. External researchers are not granted the same level of access to the raw datasets that the CDC's internal researchers are granted. The bottom line is that the CDC's studies related to vaccine safety cannot be validated by external researchers – a critical component in demonstrating the validity of scientific findings.

On March 10, I discussed my concerns about a conflict of interest within the CDC's Director, Dr. Julie Gerberding. In that conversation she indicated to me that she recognized that there are problems and that she was taking several steps to try and address them. She is in the process of appointing a blue ribbon commission charged with reviewing the CDC's vaccine safety monitoring and research activities. One of the key responsibilities of this panel will be to assess the most appropriate organizational location of the vaccine safety-monitoring program. It is critical that this program be located outside of the CDC.

Conflicts of interest are not new to federal agencies and we have taken some positive steps to remove these conflicts. One of the most recent was moving the Office of Human Subjects Protection out of the NIH due to inherent conflicts. It is long overdue that we remove from the CDC the responsibility of monitoring for adverse outcomes from vaccines.

The National Institutes of Health has no coordinated program that is specifically charged with monitoring or funding research related to vaccine safety. The extent of involvement by the NIH, based on what they have told me thus far, is uncoordinated and limited to funding a study here or there that happens to pass peer review. Within the NIH there is very little if any coordinated effort to fund research aimed at examining the safety of particular vaccines.

continued on page 7