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December 10, 2002

Update on Vaccine Safety

Dear Colleague,

The homeland security bill that Congress passed at the end of the session contained a number of irrelevant provisions involving vaccines that had never been part of the deliberations on the bill. For example, one provision that received particular attention blocks pending litigation against manufacturers of a preservative formerly used in childhood vaccines, thimerosal. I objected to the inclusion of these provisions because of the manner in which and means by which they were raised, and I continue to do so.

Having said that, this letter is not about how the vaccine provisions got inserted in the bill. I am writing today to ensure that Members have good information about an issue of vital public health significance: childhood immunization. There continues to be serious confusion and misinformation about vaccine safety, the Vaccine Injury Compensation Program (VICP), and the vaccine preservative thimerosal. It is important that members have correct information about these topics in order to prepare for future legislative efforts in this area and to respond to constituents' concerns.

Childhood Vaccines

While vaccines are essential for public health, no vaccine is 100% safe. There are rare, but sometimes serious, side effects associated with all vaccines. The overall advantage of vaccines, however, far outweighs the risks. Because of the polio vaccine, parents no longer fear that letting their children swim in public swimming pools (a once widely held and mistaken view of how the disease was spread) could lead to a life in an iron lung. Universal immunization against rubella has nearly eliminated congenital rubella syndrome, which can cause deafness, mental retardation, and autism. In the last decade, new vaccines against bacterial meningitis have saved thousands of children's lives.

Because vaccines are given to healthy children, and because they have been associated with rare, but sometimes serious, side effects, vaccines undergo constant scrutiny. Doctors are required to report vaccine adverse events to the Food and Drug Administration (FDA). The

Centers for Disease Control and Prevention (CDC) have also contracted with a number of health maintenance organizations (HMOs) to create a large, linked database—the Vaccine Safety Database (VSD)—to monitor vaccine safety. The Department of Health and Human Services (HHS) has three advisory committees that monitor vaccine safety issues:

- FDA’s Vaccine and Related Biologic Products Advisory Committee, which recommends whether or not FDA should license a particular vaccine;
- CDC’s Advisory Committee on Immunization Practices, which recommends whether a particular vaccine should be added or removed from the childhood immunization schedule;
- HHS’s National Vaccine Advisory Committee, which recommends research priorities to enhance vaccine safety and effectiveness.

In addition, the Institute of Medicine (IOM) has convened an Immunization Safety Review Committee, which is charged with reviewing the science of current and emerging vaccine safety concerns. This committee, which first met in January 2001, has issued reports on five different vaccine safety concerns, and will issue another four over the next year.

These safety systems have detected problems with vaccines. Most recently, the rotavirus vaccine was withdrawn in 1999, soon after marketing began, when vaccine safety experts at the CDC and FDA identified an association between vaccination and intestinal obstruction in infants.

In other instances, these safety systems provide reassuring evidence to counter unsubstantiated concerns. One recent theory, which alleges that the combination vaccine for measles, mumps, and rubella, the MMR vaccine, may cause autism, has led many parents in the United Kingdom to refuse vaccination in recent years and caused measles cases there to surge. After reviewing all relevant data however, the panel convened by the IOM concluded that the evidence favored rejection of a connection between autism and the MMR vaccine. This conclusion was reinforced by a recent large epidemiological study from Denmark, published in the *New England Journal of Medicine*, that found no association between the MMR vaccine and autism.

Safety Concerns over Thimerosal

Another theory alleges that autism and other neurological problems have been caused by thimerosal, a mercury-containing preservative that was used, until recently, in some routine childhood vaccines in the United States. This theory, which has been dubbed the “not so crackpot autism theory” by the *New York Times Magazine*, has its base in the well-known fact that mercury in *high* doses is toxic to the brain.

The key question for vaccine safety is whether mercury in the doses that were present in childhood vaccines ever harmed children. In 2001, the independent expert committee on vaccine safety convened by IOM examined this question. The IOM's conclusion was that there was not enough evidence either to confirm or to reject a relationship between thimerosal and injury to children. Recognizing the fact that mercury in high doses is known to be toxic to the brain, IOM recommended that further research on the safety of thimerosal be conducted.

There have been three thimerosal safety studies conducted since the IOM committee met. In one study, published last week in the *Lancet*, researchers from the University of Rochester measured the amount of mercury in the blood of infants receiving thimerosal-containing vaccines. This study found, "Administration of vaccines containing [thimerosal] does not seem to raise blood concentrations of mercury above safe values in infants." An accompanying commentary concluded, "This study gives comforting reassurance about the safety of ethyl mercury as a preservative in childhood vaccines." (Ethyl mercury is the form of mercury found in thimerosal.)

Two additional studies, which have yet to be published, were submitted for the record at my request at a recent Government Reform Committee hearing. They were both conducted by Elizabeth Miller, a senior epidemiologist with the Public Health Laboratory Service in the United Kingdom. The first utilized the General Practice Research Database, a primary care database with information on more than 100,000 children. This study found no association between receipt of thimerosal and any neurological developmental disability. The second investigation utilized the Avon Longitudinal Study of Pregnancy and Childhood, a research project that has closely followed 14,000 children from birth. This investigation found "no evidence of association between early [thimerosal] exposure and specific behavior problems" through five years of age.

These three new studies, while reassuring, are not dispositive. The *Lancet* study was a relatively small study, and the children in the British studies were exposed to less mercury through vaccination than were some children in the United States. Other studies on the safety of thimerosal are pending, and we should wait for published results before reaching any final conclusions. Right now, vaccine safety experts believe that there is no evidence children were harmed by thimerosal.

The Vaccine Injury Compensation Program

In 1986, Congress addressed the twin problems of concerns about vaccine safety and litigation that threatened to drive vaccine manufacturers out of the business, by creating the VICP. The principle behind the VICP is that while there is a public interest in making sure that immunization rates are high, there are rare, but sometimes serious, risks associated with immunizations. Therefore, people who are injured from vaccines should be compensated quickly

and fairly without having to prove fault. If a person suffers an injury that is an established side effect of a vaccine in the program, causation is presumed. In the case of an injury that is not an established side effect of a vaccine, the claimant has to prove causation, but the standards of proof are less formal than they would be in civil litigation.

While awards for pain and suffering or death are limited to \$250,000, compensation for actual damages is not capped. Children who go through the program and whose injuries are deemed compensable will receive an award for their medical expenses, rehabilitation expenses, and their lost earnings.

The VICP is not an exclusive remedy. A claimant who goes through the process and is unhappy with the outcome can still sue in state court.

This program has worked well. To date, the program has paid about \$1.3 billion to approximately 1,775 claimants. And it is very rare that anyone who has gone through the VICP exercises their right to sue the vaccine manufacturers.

With time, however, it has become apparent that some refinements could improve the program. The advisory committee that oversees the program, the Advisory Commission on Childhood Vaccines (ACCV), has recommended a number of improvements. These changes include: allowing awards to pay for family counseling expenses; increasing the awards paid for pain and suffering, and in death cases; and extending the statute of limitations.

The ACCV also recommended that the liability protections of the VICP be tightened, and recommended that the thimerosal suits that are pending in state courts first go through the VICP. These recommendations were made in response to a growing number of cases being brought against vaccine manufacturers.

Conclusion

The available evidence does not support the allegation that vaccines can cause autism. Nonetheless, the thimerosal provisions certainly did not belong in the homeland security bill. The issues surrounding thimerosal, vaccine safety, and the VICP are complicated and deserve deliberate, well-informed debate.

If you would like more information on vaccine safety and the allegations regarding a connection between vaccines and autism, the following websites are very useful:

www.immunizationinfo.org

www.cdc.gov/nip

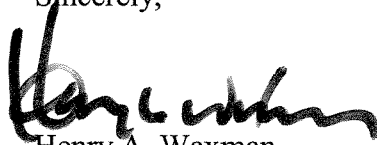
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www.aap.org

www.naar.org

If you or your staff have further questions, please feel free to call Sarah Despres or Josh Sharfstein of my staff at (202) 225-5420.

Sincerely,

A handwritten signature in black ink, appearing to read "Henry A. Waxman". The signature is written in a cursive, somewhat stylized font.

Henry A. Waxman
Ranking Minority Member