

Immunization Safety Office

Additional Q&As and Hot Topics for Dr. Gerberding's Appropriations Briefing Materials

National Vaccine Injury Compensation Program

Q: Last week I heard that the federal government conceded and settled a case that a child's autism was caused by mercury-containing vaccines. Are you aware of this? If so, what can you tell us about this specific case?

A: I am aware of a blog article that was posted last week on the internet that makes a claim that the federal government reviewed a child's claim that mercury-containing vaccines caused her autism and that she was being compensated under the National Vaccine Injury Compensation Program. This program is located in the Department of Health and Human Services Health Resources and Services Administration (HRSA). The U.S. Department of Justice and the U.S. Court of Federal Claims also have an important role in the National Vaccine Injury Compensation Program. CDC does not play a role in this program. I recommend that you direct any questions you may have about the current claim discussed in the article last week and the upcoming Omnibus Autism Proceeding in May to HRSA.

Background: HRSA Public Statement: Tina Cheatham, Director, Office of Communications, HRSA, released the following public statement in response to the blog article:

Under the National Childhood Vaccine Injury Act, the Health Resources and Services Administration (HRSA) is prohibited from publicly disclosing or discussing information related to individual claims filed under the Act without the express written consent of the person who submitted the information.

HRSA has reviewed the scientific information concerning the allegation that vaccines cause autism and has found no credible evidence to support the claim. Accordingly, in every claim submitted under the Act, HRSA has maintained and continues to maintain the position that vaccines do not cause autism, and has never concluded in any case that autism was caused by vaccination.

HRSA will present its views on the allegation that vaccines cause autism in an "omnibus" autism proceeding in May of this year. The expert testimony in that proceeding will be available to the public, with the consent of the parties.

We know that autism is a heart-wrenching condition that presents special challenges for many families. To that end, HRSA and its partner Federal agencies are committed to continuing our efforts to support research that will enable us to understand and prevent autism and autism spectrum disorders.

Background: National Vaccine Injury Compensation Program: On October 1, 1988, the National Childhood Vaccine Injury Act of 1986 (Public Law 99-660) created the National Vaccine Injury Compensation Program (VICP). The VICP was established to ensure an adequate supply of vaccines, stabilize vaccine costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines.

The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines. The U. S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the VICP:

- the U.S. Department of Health and Human Services (HHS);
- the U.S. Department of Justice (DOJ); and
- the U.S. Court of Federal Claims (the Court).

The VICP is located in the HHS, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Vaccine Injury Compensation.

There is a specific process for filing and reviewing petitions under the National Vaccine Injury Compensation Program. Upon filing in the U.S. Court of Federal Claims, the petition and accompanying documents are reviewed by HRSA. If HRSA agrees that statutory criteria for demonstrating a compensable injury have been met, entitlement to compensation is conceded and the case moves on to a determination of the appropriate amount of compensation. If HRSA does not concede liability, the special master conducts further proceedings to resolve that issue. Persons with pre-existing injuries can also obtain compensation under the Program, if they establish that their underlying condition was "significantly aggravated" by a vaccine.

If liability is conceded or resolved in a claimant's favor, the amount of compensation is determined on the basis of present and anticipated future needs. Claimants can recover compensation for future medical and rehabilitative expenses that can reasonably be linked to their injury. However, the Program is a secondary, not a primary, payer of expenses. Awards are paid from a trust fund, which is funded by an excise tax on vaccines.

Representatives of the federal government are not able to address specific cases. The Vaccine Act, by law, mandates that "information submitted . . . [in a Vaccine Act proceeding] may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information." 42 U.S.C. section 300aa-12(d)(4). This blanket limitation on disclosure is by operation of law, not through the actions of a party to a Vaccine Act proceeding.

As the medical facts of each case are typically based on medical information submitted by the petitioner, disclosure of case-specific information usually requires prior written consent of the petitioner.

Thimerosal and autism

Q: What is the CDC's position on the possibility of a possible connection between autism and vaccinations?

A: CDC places a high priority on vaccine safety and the integrity and credibility of its vaccine safety research. This commitment not only stems from our scientific and medical dedication, it is also personal—because most of us who work at CDC are also parents and

grandparents. And as such, we too, have high levels of personal interest and concern in the health and safety of children, families and communities. CDC is fully committed to the health and well-being of children. Our highest priority is to protect the health of children and to ensure that all children can live, play and learn to their fullest potential. We have learned a lot about the symptoms of autism spectrum disorders (ASDs) and have improved efforts to track the disorders, but we still don't know a lot about the causes of ASDs. Scientists think that both genes and the environment play a role, and there might be many causes that lead to ASDs.

There is, however, no convincing evidence that the low concentrations of thimerosal in vaccines have caused any harm other than minor reactions such as redness or swelling at the injection site. To date, the vast majority of science does not support an association between thimerosal in vaccines and autism. CDC believes that supporting comprehensive research is our best hope for understanding the causes of autism and other developmental disorders. CDC is focusing on three areas: 1) understanding the frequency and trends of autism, 2) advancing research in the search for causes and effective interventions, and 3) improving early detection and diagnosis so that affected children get interventions as soon as possible.

Parents have a right to expect the vaccines their children receive are safe and effective. That is why CDC continually evaluates the safety of vaccines and we are prepared to adjust our policies if allegations prove scientifically valid.

Q: Did CDC request vaccine manufacturers to voluntarily remove mercury derivatives from children's vaccines?

A: As a precautionary measure designed to help reduce children's exposure to mercury from all sources, the U.S. Public Health Service, CDC, the American Academy of Pediatrics, and vaccine manufacturers agreed in July 1999 that thimerosal should be reduced or eliminated from vaccines, one of the few sources where such action could be taken.

Q: Are there still children's vaccines in the United States market that contain mercury?

A: Today, with the exception of some influenza vaccines, none of the vaccines used in the U.S. to protect preschool children against infectious diseases contain thimerosal as a preservative. Many vaccines, including the Measles-Mumps-Rubella and chickenpox vaccine never contained thimerosal, and there are brands of influenza vaccine that are thimerosal preservative-free. All routinely recommended childhood vaccines, with the exception of some flu vaccines, have not contained thimerosal since 2002. Parents should talk with their child's healthcare provider if they have concerns about vaccines. The child's doctor is the person who best knows the child's health status and has the child's best interest at heart.

Benefits of immunization

Q: Do you feel the benefit of immunization outweighs the possible risks?

A: It is important to remember, vaccines protect and save lives. There are thousands of people alive today who would have died of disease before vaccines. Vaccines protect infants, children and adults from the unnecessary harm and premature death caused by vaccine-preventable diseases. The number of deaths and hospitalizations from vaccine preventable diseases are at an all time low. The world is free of smallpox; polio has been eliminated from the Western Hemisphere and we are on the verge of eradicating polio around the world; rubella, once a major cause of birth defects, has been eliminated in the US; and diseases and death from diphtheria, pertussis, tetanus, measles, mumps, rubella and Haemophilus influenzae type b are at or near record lows.

However, these diseases are still circulating in many parts of the world and only a plane ride away.