

March 14, 2008

Talking Points: Vaccine Injury Compensation Case in the News

- **No federal court has conceded that there is a link between vaccines and autism.** On March 3, the Health Resources and Services Administration (HRSA) released the following statement regarding the National Vaccine Childhood Injury Act: “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.”
- **CDC has no role in the HRSA National Vaccine Injury Compensation Program.** The VICP was established under the HRSA National Vaccine Childhood Injury Act 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 compensating vaccine injury claims. 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;
 - the U.S. Department of Justice; and
 - the U.S. Court of Federal Claims.
- **CDC believes that supporting comprehensive research is our best hope for understanding the causes of autism and other developmental disorders.** Comprehensive, population-based studies conducted in the United States and around the world have not concluded that vaccines contributed to the rise in autism in the United States. CDC is focusing on three areas: 1) understanding the frequency and trends of autism, 2) advancing research into potential risk factors and causes, and 3) improving early identification/diagnosis so affected children receive care as soon as possible.
- **Vaccines are held to the highest standard of safety.** Years of testing are required by law before a vaccine can be licensed. Once licensed, the United States has a comprehensive vaccine safety monitoring system in place; vaccine safety issues are investigated and studied, and action is taken when vaccine recommendations need to be changed.
- **CDC places a high priority on vaccine safety and the integrity and credibility of its vaccine safety research.** Sound immunization policies and recommendations affecting the health of our nation depend on continuous monitoring of vaccines and ongoing research to assess immunization benefits and risks. Serious vaccine side effects are rare and difficult to detect even with the well-designed large clinical trials that are conducted on vaccines before they are licensed. That is why CDC continually evaluates the safety of vaccines, and is prepared to adjust its policies on the basis of new scientific evidence.
- **CDC strongly recommends vaccinating young children against 14 diseases before age 2.** Vaccines are a proven and essential component of protecting the health of children and adults in the United States and around the world.
- **Studies show the benefits of immunization outweigh the risks.** A large body of scientific evidence shows that vaccines are overwhelmingly safe medical products; they are, and have to be, held to high standards of safety because they are given to millions of people.

- **Vaccines prevent serious illness and save lives.** In the United States, the number of cases of most vaccine-preventable is at an all-time low, and hospitalizations and deaths have shown amazing decreases due to vaccination. Smallpox is gone from the globe. Polio, measles, and rubella viruses can no longer circulate in the U.S. population due to high immunity from vaccination; however, cases can and do still occur here, since in other parts of the world, these diseases are still circulating—making them only a plane ride away. Thus, we must remain vigilant, keeping childhood vaccination rates high to prevent the return or resurgence of vaccine-preventable diseases.
- **CDC’s Advisory Committee on Immunization Practices (ACIP) makes sound immunization recommendations for the United States.** ACIP was established to guide CDC and the Department of Health and Human Services regarding the most effective selection of vaccines to control diseases in the civilian population. It consists of 15 voting members who are not employees of the U.S. government. The members are drawn from diverse backgrounds and pool their expertise in immunization, pediatrics, vaccine safety, internal medicine, and economics. One member of the board is a consumer representative.
- **To ensure safety, vaccines are tested and monitored.** The United States has a comprehensive vaccine safety monitoring system in place; vaccine safety issues are investigated and studied, and action is taken when vaccine recommendations need to be changed.
 - *Testing Vaccines Before Licensing.* Vaccines must be licensed by the U.S. Food and Drug Administration (FDA) before they can be used in the United States. Before the FDA approves a license, vaccines are tested extensively to ensure they are safe. For vaccines in development today, the first step in the process is using computers to find promising vaccine formulas. Then researchers test a vaccine on animals. When the vaccine completes these laboratory tests successfully, the FDA allows it to be tested on people during clinical trials. If the clinical trials show the vaccine works and is safe, the manufacturer asks for a license. The FDA reviews the clinical trial results and the proposed vaccine label, and inspects the plant where the vaccine will be made. When the FDA is satisfied it is safe and effective in preventing disease, the vaccine is licensed for public use. This process can take 10 years or longer.
 - *Monitoring Vaccines After Licensing.* After a vaccine is licensed for public use, its safety is monitored. As one part of this, the FDA requires all manufacturers to submit samples from each vaccine lot before its release. In addition, manufacturers must give the FDA their test results for vaccine safety, potency, and purity. Other monitoring includes assessing how much the vaccine is used and what impact the vaccine has on the incidence of the disease it is intended to prevent; CDC takes a lead role in these studies. Of course, studies are constantly ongoing for every vaccine to watch for reports of adverse events and to follow up on them to determine if vaccine recommendations need to be changed.
- **It is important to monitor vaccine safety for three primary reasons—**
 - *Rare reactions.* The most important reason is to detect rare reactions. Not enough people are included in clinical trials to detect rare reactions.
 - *Higher risk groups.* Because vaccine trials may not include members of high-risk groups, such as the elderly or those with chronic medical conditions, vaccine safety monitoring also makes sure new vaccines are safe for such persons.
 - *Public confidence.* Monitoring vaccine safety also helps to maintain public confidence needed to keep enough people vaccinated to prevent disease outbreaks.