

The Coalition for Vaccine Safety (CVS) calls for independent vaccine safety agency and Congressional hearings on government's lax record on safety issues.

A three-part investigative series on Merck's cervical cancer vaccine, Gardasil®, highlights serious conflicts of interest across agencies of the Department of Health and Human Services (DHHS) in the development, approval and safety surveillance of vaccines. The series, by Mark Blaxill, Editor-at-Large for the Internet newspaper Age of Autism and a Director of SafeMinds, was posted on the newspaper's site on May 12-13 (<a href="http://www.ageofautism.com/mark\_blaxill">www.ageofautism.com/mark\_blaxill</a>). It preceded the announcement on May 14 that FDA, a DHHS agency, is allowing use of rotavirus vaccines despite their contamination with viral particles from pigs. (<a href="http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm212149.htm">http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm212149.htm</a>)

Blaxill's investigation found an unprecedented vaccine "public-private partnership" between drug companies and DHHS' National Institutes of Health (NIH). NIH researchers developed key technology underpinning cervical cancer vaccines. The technology was patented and licensed to pharmaceutical giants Merck and GlaxoSmithKline through the NIH Office of Technology Transfer (OTT). When new products invented at NIH clear the regulatory hurdles at FDA and reach market, OTT shares in the profits and distributes them back to NIH and its staff inventors.

Despite clinical trials lacking a true placebo, FDA approved it for use. The CDC's vaccine advisory committee then recommended Gardasil for universal use by girls. The FDA and CDC jointly conduct the surveillance to decide whether the NIH-invented Gardasil is safe once licensed. Dr. Julie Gerberding served as the Director of the CDC when it approved Gardasil. She is now the president of Merck Vaccines. According to Blaxill, this situation creates "an unprecedented web of conflict, one in which the same departments that are tasked with regulating the health and safety of medical products are also profiting from them."

There have been hundreds of claims of injury or death from Gardasil. Some of these claims are now reaching the Court of Federal Claims, where vaccine injured petitioners are required to bring claims. Here too there are serious potential conflicts of interest as DHHS jointly administers the Vaccine Injury Compensation Program and is also the defendant against the claims of vaccine injury instead of the vaccine manufacturer Merck.

"DHHS has chosen to minimize other safety issues like mercury and viral contamination in vaccines," stated Mary Holland of CVS. "We need a stronger vaccine safety oversight agency which is independent of DHHS." CVS calls on Congress, as it has in recent letters, to hold hearings to investigate the agencies responsible for the national vaccine program. These federal agencies have failed to comply with the terms of the 1986 Vaccine Injury Compensation Act (VICA) to provide critical vaccine safety science.