Children's Health Defense

March 5th, 2019

Senate Hearing: Vaccines Save Lives. What is Driving Preventable Disease Outbreaks?

This Hearing Should Be About Vaccine Safety

Inadequate Pre-Licensure Safety Testing - Vaccines are regulated by the FDA's CBER division as "biologics" and are not always put through the same level of safety testing as new drugs. Inadequate testing currently ensures that the **true risk/benefit assessments for the safety and cost of vaccines are impossible to calculate accurately.** Safety problems in vaccine licensing include inadequate follow up for adverse events (2-5 days), lack of placebo controls and lack of studies of vaccinated vs. unvaccinated children. In addition, the FDA's approval of new products is largely funded by industry.

Inadequate Post-Licensure Safety Testing - There is no requirement to report adverse events and deaths due to vaccines so there is inadequate post-licensure safety surveillance through the **Vaccine Adverse Event Reporting System** which HHS admits gathers only about 1% of the actual injuries and deaths. The system cannot provide information on long-term or rare effects. The **Vaccine Safety Datalink,** a publicly-funded database which has collected information from HMOs for 28 years ostensibly for these purposes, is currently hampered by variability of reporting, its statistical structure and the inability of independent researchers to access its data.

Inadequate Research on Adverse Events from Vaccines - The Institute of Medicine has issued three reports on the evidence for suspected and/or reported vaccine adverse events. In summary, **it investigated 231 injuries associated with vaccines and found that for 184 (80%) there wasn't enough research evidence to accept or reject vaccine causation.** Of the reviews that did have sufficient evidence, 72% found that the vaccine likely did cause the injury. In 2013, the IOM studied the entire Childhood Immunization schedule and stated: **"No studies have compared the differences in health outcomes… between entirely unimmunized populations of children and fully immunized children…. Furthermore, studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted."**

Lack of Congressional Oversight – When Congress passed the National Childhood Vaccine Injury Act in 1986 and gave companies full immunity from injury claims, it also required HHS to assure vaccine safety and file biennial reports to Congress on its efforts to improve vaccine safety. **CHD's recent lawsuit forced HHS to admit that it has not fulfilled these duties even once in the 32 years since the NCVIA was passed.** Nine vaccines have been added to the childhood schedule since 1986 but HHS has failed to properly oversee their safety.

Further information and full references are available on our website or by contacting CHD.

1227 North Peachtree Parkway, Suite 202. Peachtree City, GA 30269
www.childrenshealthdefense.org