

HR 2618

Vaccine Safety and Public Confidence Assurance Act of 2009

Congress: 111 (2009–2011, Ended)

Chamber: House

Policy Area: Health

Introduced: May 21, 2009

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jun 2, 2009)

Official Text: <https://www.congress.gov/bill/111th-congress/house-bill/2618>

Sponsor

Name: Rep. Maloney, Carolyn B. [D-NY-14]

Party: Democratic • **State:** NY • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Smith, Christopher H. [R-NJ-4]	R · NJ		May 21, 2009

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jun 2, 2009

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Vaccine Safety and Public Confidence Assurance Act of 2009 - Amends the Public Health Service Act to establish the Agency for Vaccine Safety Evaluation in the Office of the Secretary of Health and Human Services (HHS). Requires the Director for Vaccine Safety Evaluation to: (1) conduct or support safety research and monitor licensed vaccines; (2) develop a vaccine safety research agenda; (3) evaluate means to promote compliance with federal adverse reaction reporting requirements; (4) provide a clearinghouse for vaccine studies; (5) ensure that functions relating to vaccine monitoring or research on adverse reactions are not carried out by anyone with a conflict of interest; (6) oversee the Vaccine Safety Datalink Project; and (7) resolve U.S. conflicts of interest related to international agreements, partnerships, and activities.

Allows the Director to establish a program of awarding fellowships for research on vaccine safety.

Requires the Commissioner of Food and Drugs to provide the Director, upon request, with complete access to all vaccine-related information submitted to the Food and Drug Administration (FDA) by vaccine manufacturers.

Requires the Director to require vaccine manufacturers to: (1) provide for postmarketing surveillance and clinical testing for any acute or chronic adverse reactions associated with the vaccine; and (2) register in a qualified public registry each clinical trial conducted or supported by the manufacturer with respect to the vaccine.

Transfers to the Agency Centers for Disease Control and Prevention (CDC) responsibilities for the Vaccine Safety Datalink Project, the Clinical Immunization Safety Assessment Centers, or any other post-licensure vaccine safety monitoring activities.

Requires the Secretary to establish an advisory council in the Agency.

Actions Timeline

- **Jun 2, 2009:** Referred to the Subcommittee on Health.
- **May 21, 2009:** Introduced in House
- **May 21, 2009:** Sponsor introductory remarks on measure. (CR E1240)
- **May 21, 2009:** Referred to the House Committee on Energy and Commerce.