HR 6272

TEST Act

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Aug 2, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Aug 3, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/6272

Sponsor

Name: Rep. Markey, Edward J. [D-MA-7]
Party: Democratic • **State:** MA • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. DeLauro, Rosa L. [D-CT-3]	D · CT		Aug 2, 2012
Rep. Schakowsky, Janice D. [D-IL-9]	D · IL		Aug 2, 2012
Rep. Waxman, Henry A. [D-CA-30]	D · CA		Aug 2, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 3, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 2, 2012)

Trial and Experimental Studies Transparency Act of 2012 or TEST Act - Amends the Public Health Service Act to expand the clinical trials that must be reported to the clinical trial registry data bank to include: (1) any interventional study of a drug, device, or biological product conducted outside of the United States the results of which are submitted to the Secretary of Health and Human Services (HHS) as support for approval of an application; and (2) postmarket surveillance of a class II or class III device that involves data collection from human subjects. Defines "interventional study" to mean a study in human beings in which individuals are assigned by an investigator, based on a protocol, to receive specific interventions to evaluate their effects on biomedical health-related outcomes.

Requires submission to the data bank of supporting documents, including protocol documents and consent documents used to enroll subjects into the trial. Requires the responsible party for a clinical trial to submit clinical trial information to the data bank before the first patient is enrolled in the trial.

Requires the Director of the National Institutes of Health (NIH) to post the information submitted to the data bank within 30 days after the submission is determined to meet the quality criteria established by the Director.

Revises time frames for the reporting of results data to the clinical trial registry.

Requires the Director and the Commissioner of Food and Drugs (FDA) to report on the number of clinical trials with information submitted to the registry and steps taken to enforce compliance with such reporting requirements.

Actions Timeline

- **Aug 3, 2012:** Referred to the Subcommittee on Health.
- **Aug 2, 2012:** Introduced in House
- **Aug 2, 2012:** Referred to the House Committee on Energy and Commerce.