HR 3207

Modernizing Laboratory Test Standards for Patients Act of 2011

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Oct 14, 2011
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Oct 14, 2011)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/3207

Sponsor

Name: Rep. Burgess, Michael C. [R-TX-26]
Party: Republican • **State:** TX • **Chamber:** House

Cosponsors (18 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Oct 14, 2011
Rep. Latta, Robert E. [R-OH-5]	R · OH		Oct 14, 2011
Rep. Paulsen, Erik [R-MN-3]	R · MN		Oct 14, 2011
Rep. Coble, Howard [R-NC-6]	R · NC		Nov 18, 2011
Rep. Lance, Leonard [R-NJ-7]	R · NJ		Dec 7, 2011
Rep. McMorris Rodgers, Cathy [R-WA-5]	R · WA		Dec 7, 2011
Rep. Guthrie, Brett [R-KY-2]	R · KY		Dec 8, 2011
Rep. McKinley, David B. [R-WV-1]	R · WV		Dec 8, 2011
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Dec 13, 2011
Rep. Yoder, Kevin [R-KS-3]	R · KS		Dec 13, 2011
Rep. Tiberi, Patrick J. [R-OH-12]	R · OH		Dec 14, 2011
Rep. Murphy, Tim [R-PA-18]	R · PA		Jan 27, 2012
Rep. Sessions, Pete [R-TX-32]	R · TX		Jan 27, 2012
Rep. Stearns, Cliff [R-FL-6]	R · FL		Feb 8, 2012
Rep. Filner, Bob [D-CA-51]	D · CA		Feb 13, 2012
Rep. Meehan, Patrick [R-PA-7]	R · PA		Feb 27, 2012
Rep. Culberson, John Abney [R-TX-7]	R · TX		Apr 16, 2012
Rep. Miller, Brad [D-NC-13]	D · NC		Sep 11, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Oct 14, 2011

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Oct 14, 2011)

Modernizing Laboratory Test Standards for Patients Act of 2011 - Amends the Public Health Service Act to require the Secretary of Health and Human Services (HHS) to establish a single publicly accessible test registry data bank of laboratory-developed tests and direct-to-consumer DNA tests, which shall include information on the purpose of each test, the claimed use or uses of each test, and information regarding the analytical validity of each test.

Requires notification to the Secretary: (1) before marketing such a test, (2) after any significant modification of such a test, or (3) if the evidence of clinical validity is inadequate to support one or more of the claimed uses.

Requires the Secretary, within 90 days of receiving such notification, to determine whether the notification demonstrates clinical validity. Deems the Secretary to have authorized marketing of the test if no response is received within 90 days.

Gives the Secretary authority to order a laboratory or test-offering entity to cease offering or marketing a test if the information submitted in notifications does not demonstrate the clinical validity of the claimed uses and the test poses a risk of immediate harm to the public health.

Sets forth requirements for: (1) registration of a test-offering entity, (2) information that must be included in disseminated materials and advertising, (3) notice to the Secretary if a test may have caused or contributed to a death or serious bodily injury, and (4) sanctions for violations of this Act.

Requires the Secretary to administer this section solely through the Centers for Medicare and Medicaid Services (CMS).

Actions Timeline

- **Oct 14, 2011:** Introduced in House
- **Oct 14, 2011:** Referred to the House Committee on Energy and Commerce.
- **Oct 14, 2011:** Referred to the Subcommittee on Health.