

HR 1016

Biological Implant Tracking and Veteran Safety Act of 2015

Congress: 114 (2015–2017, Ended)

Chamber: House

Policy Area: Armed Forces and National Security

Introduced: Feb 20, 2015

Current Status: Forwarded by Subcommittee to Full Committee in the Nature of a Substitute (Amended) by Voice Vote .

Latest Action: Forwarded by Subcommittee to Full Committee in the Nature of a Substitute (Amended) by Voice Vote . (Apr 21, 2015)

Official Text: <https://www.congress.gov/bill/114th-congress/house-bill/1016>

Sponsor

Name: Rep. Roe, David P. [R-TN-1]

Party: Republican • **State:** TN • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Blackburn, Marsha [R-TN-7]	R · TN		Apr 21, 2015
Rep. Coffman, Mike [R-CO-6]	R · CO		Apr 21, 2015
Rep. Johnson, Bill [R-OH-6]	R · OH		Apr 23, 2015
Rep. Heck, Joseph J. [R-NV-3]	R · NV		Sep 10, 2015

Committee Activity

Committee	Chamber	Activity	Date
Veterans' Affairs Committee	House	Discharged from	Mar 13, 2015
Veterans' Affairs Committee	House	Reported by	Apr 21, 2015

Subjects & Policy Tags

Policy Area:

Armed Forces and National Security

Related Bills

Bill	Relationship	Last Action
114 S 2334	Related bill	Nov 30, 2015: Read twice and referred to the Committee on Veterans' Affairs.

Biological Implant Tracking and Veteran Safety Act of 2015

Directs the Department of Veterans Affairs (VA) to: (1) adopt the unique device identification system developed for medical devices by the Food and Drug Administration (FDA), or implement a comparable standard identification system, for identifying biological implants intended for use in medical procedures conducted in VA medical facilities; (2) permit a vendor to use any of the accredited entities identified by the FDA as an issuing agency in adopting or implementing such a system; (3) implement a compatible system for tracking the implants from the human donor or animal source to implantation; and (4) implement inventory controls compatible with such tracking system so that all patients who have received, in a VA medical facility, a biological implant subject to a recall by the FDA can be notified of the recall.

Sets forth requirements for vendors from which the VA may procure biological implants of human origin, and for vendors from which the VA may procure biological implants of non-human origin, including that such a vendor:

- uses the standard identification system adopted or implemented by VA under this Act;
- is registered as required by FDA procedures;
- consents to periodic inspections and audits by the VA regarding the accuracy of records and the handling of products;
- agrees to cooperate with all biological implant recalls conducted on the vendor's own initiative, on the initiative of the original product manufacturer used by the vendor, by the request of the FDA, or by a statutory order of the FDA;
- agrees to notify the VA of any adverse event report it provides to the FDA, or of any warning letter from the FDA issued to the vendor, by not later than 60 days after the vendor receives such report or warning letter; and
- agrees to retain all records associated with the procurement of a biological implant by the VA for at least five years after the date of the procurement.

Requires the VA to: (1) procure such implants under General Services Administration Federal Supply Schedules if they are available under such Schedules, (2) accommodate reasonable vendor requests to undertake specified outreach efforts to educate VA medical professionals about the use and efficacy of implants that are listed on such Schedules, and (3) procure biological implants that are unavailable under such Schedules using competitive procedures in accordance with the Federal Acquisition Regulation.

Makes any VA procurement employee found responsible for a biological implant procurement transaction with intent to avoid, or with reckless disregard of, the requirements of this Act ineligible to hold a certificate of appointment as a contracting officer or to serve as the representative of an ordering officer, contracting officer, or purchase card holder.

Actions Timeline

- **Apr 21, 2015:** Subcommittee Consideration and Mark-up Session Held.
- **Apr 21, 2015:** Forwarded by Subcommittee to Full Committee in the Nature of a Substitute (Amended) by Voice Vote .
- **Mar 19, 2015:** Subcommittee Hearings Held.
- **Mar 13, 2015:** Subcommittee on Health Discharged.
- **Mar 13, 2015:** Referred to the Subcommittee on Oversight and Investigations.
- **Mar 6, 2015:** Referred to the Subcommittee on Health.
- **Feb 20, 2015:** Introduced in House
- **Feb 20, 2015:** Referred to the House Committee on Veterans' Affairs.