HR 4965

Disclosure; and Encouragement of Verification, Innovation, Cleaning, and Efficiency Act of 2016

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Apr 15, 2016
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Apr 22, 2016)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/4965

Sponsor

Name: Rep. Lieu, Ted [D-CA-33]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (6 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Cummings, Elijah E. [D-MD-7]	D · MD		Apr 21, 2016
Del. Norton, Eleanor Holmes [D-DC-At Large]	D · DC		May 6, 2016
Rep. Moore, Gwen [D-WI-4]	D · WI		May 6, 2016
Rep. Chu, Judy [D-CA-27]	D · CA		May 11, 2016
Rep. Hastings, Alcee L. [D-FL-20]	D · FL		May 13, 2016
Rep. Slaughter, Louise McIntosh [D-NY-25]	D · NY		Jun 3, 2016

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Apr 22, 2016

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 15, 2016)

Disclosure; and Encouragement of Verification, Innovation, Cleaning, and Efficiency Act of 2016

This bill amends the Federal Food, Drug, and Cosmetic Act by requiring a manufacturer of a medical device to give the Food and Drug Administration (FDA) premarket notification of changes to the design or reprocessing instructions of its device.

Medical device manufacturers must also notify the FDA within five days of widely disseminating to health care providers in a foreign country communications relating to a change to the recommended reprocessing protocols, if any, for their device, or a safety concern about the device.

The bill bans the devices if the manufacturers violate the notification requirements concerning those design or reprocessing changes or communications to foreign health care providers.

The FDA must publish a list of the types of rapid assessment tests of reusable devices for which premarket notification must include proposed labeling, including validated instructions regarding sanitizing reusable devices.

Actions Timeline

- **Apr 22, 2016:** Referred to the Subcommittee on Health.
- **Apr 15, 2016:** Introduced in House
- **Apr 15, 2016:** Referred to the House Committee on Energy and Commerce.

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