

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.

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.