HR 2426

To amend the Federal Food, Drug, and Cosmetic Act with respect to easing regulatory burden with respect to certain class I and class II devices.

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: May 19, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 22, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/2426

Sponsor

Name: Rep. Shimkus, John [R-IL-15]
Party: Republican • **State:** IL • **Chamber:** House

Cosponsors

No cosponsors are listed for this bill.

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 22, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
114 HR 34	Related bill	**Dec 13, 2016:** Became Public Law No: 114-255.
114 S 2737	Related bill	**Mar 17, 2016:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
114 HR 6	Related bill	**Jul 13, 2015:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of May 19, 2015)

This bill amends the Federal Food, Drug, and Cosmetic Act to require the Food and Drug Administration (FDA), not later than 120 days after enactment of the 21st Century Cures Act (H.R. 6, a bill introduced on May 19, 2015), to identify types of class I medical devices (devices that do not need special controls to assure their safety and effectiveness) for which a report is no longer needed prior to marketing to provide reasonable assurance of safety and effectiveness. (Currently, a report is needed for a class I device only if the device is of substantial importance in preventing impairment of human health or if it presents a potential unreasonable risk of illness or injury.)

Not later than 180 days after enactment of the 21st Century Cures Act, the FDA must publish a list of types of class II medical devices (devices that need special controls to assure their safety and effectiveness) for which a report is no longer needed prior to marketing to provide reasonable assurance of safety and effectiveness. (Currently, such a list must be published each time the FDA exempts a type of class II device from the reporting requirement.) The public comment period for such an exemption is extended to 60 days.

Actions Timeline

- **May 22, 2015:** Referred to the Subcommittee on Health.
- **May 19, 2015:** Introduced in House
- **May 19, 2015:** Referred to the House Committee on Energy and Commerce.