HR 2422

To amend the Federal Food, Drug, and Cosmetic Act with respect to third-party quality system assessment.

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/2422

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 S 2187	Related bill	**Oct 21, 2015:** 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) to establish a third-party quality system assessment program to accredit persons to assess whether a medical device manufacturer's quality system can ensure the safety and effectiveness of an approved medical device after certain changes, including changes in manufacturing or changes to enhance device safety.

Device manufacturers are allowed to make changes to a device without submitting to the FDA the 30-day notice required for manufacturing changes or a premarket approval supplement if their quality system has been certified by an accredited person.

An accredited person who assesses a device manufacturer's quality system must submit a summary of their assessment and, as appropriate, a certification to the FDA within 30 days of the assessment. An assessment summary and certification is deemed accepted by the FDA 30 days after submission unless the FDA determines that additional information is needed to support certification, the assessment or certification is unwarranted, or an action other than acceptance of the certification is otherwise justified.

Periodic reports by device manufacturers must describe any changes made to a device without submission of the 30-day notice or the premarket approval supplement.

Certifications accepted by the FDA remain in effect for two years.
The FDA must report on this quality system assessment program no later than January 31, 2022. The program is terminated at the end of FY2022.

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.