

## HR 2425

To amend the Federal Food, Drug, and Cosmetic Act with respect to the recognition of standards.

**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/2425>

### 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 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.

This bill amends the Federal Food, Drug, and Cosmetic Act to allow a person to request that the Food and Drug Administration (FDA) recognize all or part of a performance standard established by a nationally or internationally recognized standard organization as a standard to which a medical device may conform in order to meet an FDA requirement. When a request to recognize a standard is received, the FDA must determine whether to recognize all, part, or none of the standard and publish the rationale for that determination. (Currently, the FDA recognizes certain performance standards, but it is not required to respond to requests or publish rationales for recognizing standards.)

The FDA must: (1) publish the rationale for recognizing only part of a standard, (2) periodically train employees who review premarket submissions for medical devices on the concept and use of recognized standards for purposes of meeting requirements, and (3) publish its principles for recognizing standards.

### **Actions Timeline**

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- **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.