

## HR 2424

To amend the Federal Food, Drug, and Cosmetic Act with respect to training and oversight in least burdensome appropriate means concept.

**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/2424>

### 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 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 require Food and Drug Administration (FDA) employees involved in reviewing premarket submissions of medical devices to receive training regarding the "least burdensome appropriate means" concept. (Currently, the FDA must consider evaluating medical devices by the least burdensome appropriate means that would have a reasonable likelihood of resulting in approval.) The ombudsman for the FDA unit responsible for the premarket review of devices must audit this training and include in the audit interviews with persons from industry regarding their experience in the device premarket review process.

When the FDA requests additional information about a medical device that is required to have premarket approval, it must consider the least burdensome appropriate means necessary for an applicant to demonstrate the safety and effectiveness of the device.

### **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.