

## S 1439

### FDA Accountability for Public Safety Act

**Congress:** 117 (2021–2023, Ended)

**Chamber:** Senate

**Policy Area:** Health

**Introduced:** Apr 28, 2021

**Current Status:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

**Latest Action:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions. (Apr 28, 2021)

**Official Text:** <https://www.congress.gov/bill/117th-congress/senate-bill/1439>

### Sponsor

**Name:** Sen. Manchin, Joe, III [D-WV]

**Party:** Independent • **State:** WV • **Chamber:** Senate

### Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Capito, Shelley Moore [R-WV]	R · WV		Apr 28, 2021
Sen. King, Angus S., Jr. [I-ME]	I · ME		Apr 28, 2021

### Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 28, 2021

### Subjects & Policy Tags

#### Policy Area:

Health

### Related Bills

*No related bills are listed.*

## **FDA Accountability for Public Safety Act**

This bill establishes additional procedures related to the market approval process for opioids.

Under the bill, a Food and Drug Administration (FDA) advisory committee must make recommendations regarding supplemental applications for opioids. Current law requires only that an FDA committee make recommendations on new drug applications.

The bill specifies that only the Commissioner of Food and Drugs may approve an opioid-related application against the recommendation of the committee. If the Commissioner approves such an application against a committee recommendation, the Commissioner must submit a report to Congress that includes (1) the evidence regarding patient safety that supports the Commissioner's decision, and (2) a disclosure of any potential conflicts of interest of FDA officials involved in the decision. The Commissioner must also testify before Congress regarding the decision, upon request. The drug in question may not be sold until the Commissioner has submitted the required report.

## **Actions Timeline**

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- **Apr 28, 2021:** Introduced in Senate
- **Apr 28, 2021:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.