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FDA Accountability for Public Safety Act

Congress: 116 (2019–2021, Ended)

Chamber: Senate

Policy Area: Health

Introduced: Feb 7, 2019

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. (Feb 7, 2019)

Official Text: <https://www.congress.gov/bill/116th-congress/senate-bill/418>

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		Feb 7, 2019
Sen. King, Angus S., Jr. [I-ME]	I · ME		Feb 7, 2019

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 7, 2019

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
116 HR 5632	Identical bill	Jan 16, 2020: Referred to the House Committee on Energy and Commerce.

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

- **Feb 7, 2019:** Introduced in Senate
- **Feb 7, 2019:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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