S 1078

FDA Accountability for Public Safety Act

Congress: 115 (2017–2019, Ended)
Chamber: Senate
Policy Area: Health
Introduced: May 9, 2017
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. (May 9, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/senate-bill/1078

Sponsor

Name: Sen. Manchin, Joe, III [D-WV]
Party: Independent • **State:** WV • **Chamber:** Senate

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Capito, Shelley Moore [R-WV]	R · WV		May 9, 2017
Sen. King, Angus S., Jr. [I-ME]	I · ME		May 9, 2017
Sen. McCaskill, Claire [D-MO]	D · MO		May 9, 2017

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	May 9, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 9, 2017)

FDA Accountability for Public Safety Act

This bill amends the Comprehensive Addiction and Recovery Act of 2016 to expand the scope of the Food and Drug Administration (FDA) advisory committee to make recommendations regarding supplemental applications for opioids. Currently, the committee only makes recommendations on new drug applications.

Only the Commissioner of Food and Drugs may approve a new drug application or supplement to an application for an opioid against the recommendation of the committee. If the Commissioner approves a drug against the recommendation of the committee, the Commissioner must: (1) submit a report to Congress that includes the evidence regarding patient safety that supports the Commissioner's decision and a disclosure of any potential conflicts of interest of FDA officials involved in the decision; and (2) testify before Congress regarding the decision, upon request. Such a drug cannot be sold until the Commissioner has submitted the report.

Actions Timeline

- **May 9, 2017:** Introduced in Senate
- **May 9, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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