S 954

FDA Accountability for Public Safety Act

Congress: 114 (2015–2017, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Apr 15, 2015
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 15, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/senate-bill/954

Sponsor

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

Cosponsors (5 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Capito, Shelley Moore [R-WV]	R · WV		Apr 15, 2015
Sen. Kaine, Tim [D-VA]	D · VA		Apr 15, 2015
Sen. Vitter, David [R-LA]	R · LA		Apr 15, 2015
Sen. McCaskill, Claire [D-MO]	D · MO		Sep 9, 2015
Sen. King, Angus S., Jr. [I-ME]	I · ME		Nov 19, 2015

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Apr 15, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Apr 15, 2015)

FDA Accountability for Public Safety Act

This bill requires the Commissioner of Food and Drugs to ensure that an advisory committee of the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) evaluates each new drug application for an opioid (a drug with effects similar to opium, such as morphine) and issues a recommendation regarding approval of the drug. If the decision to approve the drug is inconsistent with the committee's recommendation, the Commissioner must make the final decision on approval.

If the committee recommends a drug not be approved but the Commissioner decides to approve the drug, 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 to approve the drug; and (2) testify before Congress regarding the decision, upon request. Such a drug cannot be sold until the Commissioner has submitted the required report.

Actions Timeline

- **Apr 15, 2015:** Introduced in Senate
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