

## HR 5632

FDA Accountability for Public Safety Act

**Congress:** 116 (2019–2021, Ended)

**Chamber:** House

**Policy Area:** Health

**Introduced:** Jan 16, 2020

**Current Status:** Referred to the House Committee on Energy and Commerce.

**Latest Action:** Referred to the House Committee on Energy and Commerce. (Jan 16, 2020)

**Official Text:** <https://www.congress.gov/bill/116th-congress/house-bill/5632>

### Sponsor

**Name:** Rep. Kim, Andy [D-NJ-3]

**Party:** Democratic • **State:** NJ • **Chamber:** Senate

### Cosponsors

*No cosponsors are listed for this bill.*

### Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred To	Jan 16, 2020

### Subjects & Policy Tags

**Policy Area:**

Health

### Related Bills

Bill	Relationship	Last Action
116 S 418	Identical bill	<b>Feb 7, 2019:</b> Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

## **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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- **Jan 16, 2020:** Introduced in House
- **Jan 16, 2020:** Referred to the House Committee on Energy and Commerce.