Congressional Budget Office
Cost Estimate

November 25, 2020

H.R.5663, Safeguarding Therapeutics Act

As passed by the House of Representatives on September 21, 2020

By Fiscal Year, Millions of Dollars	2021	2021-2025	2021-2030
Direct Spending (Outlays)	0	0	0
Revenues	*	*	*
Increase or Decrease (-) in the Deficit	*	*	*
Spending Subject to Appropriation (Outlays)	1	7	not estimated

Statutory pay-as-you-go procedures apply?	Yes	**Mandate Effects**	
Increases on-budget deficits in any of the four consecutive 10-year periods beginning in 2031?	No	Contains intergovernmental mandate?	No
		Contains private-sector mandate?	No

* = between -$500,000 and zero.

H.R. 5663 would extend the Food and Drug Administration's (FDA) authority to destroy certain imported products (known as administrative destruction authority) to include medical devices. Administrative destruction authority allows FDA to destroy certain imports when FDA believes such products are adulterated, misbranded, or unapproved and may pose a threat to public health. Under current law, FDA's destruction authority is limited to counterfeit drugs imported into the United States that are valued at $2,500 or less.

Based on information provided by FDA, CBO projects that about five full-time equivalent positions at an average cost of $300,000 each would be required each year to revise regulations, expand the agency's capacity to investigate counterfeit device cases, and exercise its administrative destruction authority. In total, CBO estimates that implementing H.R. 5663 would cost $7 million over the 2021-2025 period, reflecting both increased staffing and contracting expenses. Such spending would be subject to the availability of appropriated funds.

Following the implementation of the H.R. 5663, a reduced volume of counterfeit device imports may result in lower collections of customs duties. CBO expects any change in revenues to be insignificant.

The CBO staff contact for this estimate is Ryan Greenfield. The estimate was reviewed by Leo Lex, Deputy Director of Budget Analysis.