



Press Release

FDA User Fee Reauthorization in the House and the Senate

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The Food and Drug Administration (FDA) user fee programs—which, among other things, are used to fund the agency’s technology and workforce—must be reauthorized for the next five years by September 30.

Accordingly, both the House and the Senate have advanced different versions of a user fee reauthorization package. In a new insight, Health Care Policy Fellow Margaret Barnhorst explores areas of agreement between the two bills, as well as several of the various riders included in each package that lawmakers must reconcile in the final text.

Key points:

- The FDA user fee programs for prescription drugs, medical devices, generic drugs, and biosimilars will require congressional reauthorization by the end of the fiscal year.
- The Senate Committee on Health, Education, Labor, and Pensions recently marked up its version of the “must-pass” legislation, which, like the House-passed bill, contains several riders unrelated to the user fees that would expand the FDA’s authority.
- Both bills would reauthorize user fee programs and reform the accelerated approval process, though the House bill also seeks to improve clinical trial diversity and manufacturing inspections, while the Senate bill would address the infant formula crisis and increase regulation of cosmetics, dietary supplements, and in-vitro tests.

[Read the analysis](#)