S 3576

ADAPT 2.0 Act

Congress: 117 (2021–2023, Ended)
Chamber: Senate
Policy Area: Health
Introduced: Feb 3, 2022
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. (Feb 3, 2022)
Official Text: https://www.congress.gov/bill/117th-congress/senate-bill/3576

Sponsor

Name: Sen. Braun, Mike [R-IN]
Party: Republican • **State:** IN • **Chamber:** Senate

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Sen. Paul, Rand [R-KY]	R · KY		Feb 3, 2022

Committee Activity

Committee	Chamber	Activity	Date
Health, Education, Labor, and Pensions Committee	Senate	Referred To	Feb 3, 2022

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Feb 3, 2022)

Accelerated Drug Approval for Prescription Therapies 2.0 Act or the ADAPT 2.0 Act

This bill allows applicants seeking Food and Drug Administration (FDA) approval to market a new drug to rely on investigations conducted in certain other countries and addresses related issues.

If an applicant seeks market approval for a new drug with an application that relies on at least one investigation that the applicant did not conduct and did not obtain approval to use, the applicant may rely on an investigation that was conducted in certain foreign countries if the drug in question has already been approved in that country. The investigation must have been conducted in Australia, Canada, Israel, Japan, New Zealand, Switzerland, South Africa, the United Kingdom, the European Union, a country in the European Economic Area, or another country that the FDA has found to meet certain requirements.

The FDA must make a decision on such an application within 90 days of the application's filing. If the FDA does not take certain actions within that period, the application shall be considered approved. The FDA may require the applicant to conduct postapproval studies of the drug and to submit copies of all promotional materials.

The bill also establishes an advisory committee to provide the FDA with recommendations as to each application that relies on a foreign investigation. The FDA must make available on its public website each decision on such an application, including the rationale for the decision and the advisory committee's recommendations.

Actions Timeline

- **Feb 3, 2022:** Introduced in Senate
- **Feb 3, 2022:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

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