HR 7383

RARE Act

Congress: 118 (2023–2025, Ended)
Chamber: House
Policy Area: Health
Introduced: Feb 15, 2024
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Feb 16, 2024)
Official Text: https://www.congress.gov/bill/118th-congress/house-bill/7383

Sponsor

Name: Rep. Matsui, Doris O. [D-CA-7]
Party: Democratic • **State:** CA • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Bilirakis, Gus M. [R-FL-12]	R · FL		Feb 15, 2024
Rep. Hudson, Richard [R-NC-9]	R · NC		Mar 5, 2024

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Feb 16, 2024

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
118 HR 3433	Related bill	**Sep 24, 2024:** Received in the Senate and Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
118 S 1214	Related bill	**Jun 22, 2023:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 109.

Summary (as of Feb 15, 2024)

Retaining Access and Restoring Exclusivity Act or the RARE Act

This bill specifies that the seven-year market exclusivity period for drugs for rare diseases or conditions (i.e., orphan drug exclusivity period) prohibits the approval of the same drug for the same approved use or indication with respect to the disease or condition.

Current law grants a seven-year period of market exclusivity for an approved orphan drug, during which the Food and Drug Administration (FDA) may not approve an application from another manufacturer for the same drug for the same disease or condition. The FDA's regulations provide that this exclusivity is specific to the same approved use or indication of the drug, rather than all uses or indications, for the disease or condition. However, in *Catalyst Pharmaceuticals, Inc. v. Becerra,* a court held that exclusivity did extend to all uses or indications for the disease or condition.

The bill provides statutory authority for the FDA's regulations.

Actions Timeline

- **Feb 16, 2024:** Referred to the Subcommittee on Health.
- **Feb 15, 2024:** Introduced in House
- **Feb 15, 2024:** Referred to the House Committee on Energy and Commerce.