

HR 4511

FACTS Act

Congress: 117 (2021–2023, Ended)

Chamber: House

Policy Area: Health

Introduced: Jul 19, 2021

Current Status: Referred to the Subcommittee on Health.

Latest Action: Referred to the Subcommittee on Health. (Jul 20, 2021)

Official Text: <https://www.congress.gov/bill/117th-congress/house-bill/4511>

Sponsor

Name: Rep. Burgess, Michael C. [R-TX-26]

Party: Republican • **State:** TX • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Craig, Angie [D-MN-2]	D · MN		Jul 19, 2021
Rep. Carter, Earl L. "Buddy" [R-GA-1]	R · GA		Jul 30, 2021

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Jul 20, 2021

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

FDA Advancing Collection of Transformative Science Act or the FACTS Act

This bill establishes that certain data and determinations from a request for emergency use authorization for a drug, biological product, or medical device may apply to later regulatory procedures for that product.

Specifically, data generated to support a request for emergency use authorization may constitute valid scientific evidence to be considered for various later submissions to the Food and Drug Administration (FDA), including a request for market approval.

Also, when granting emergency use authorization for a medical device, if the FDA determines that the device performs certain simple low-risk examinations or procedures, that determination shall apply to certain other regulatory submissions unless additional information contradicts that determination.

Actions Timeline

- **Jul 20, 2021:** Referred to the Subcommittee on Health.
- **Jul 19, 2021:** Introduced in House
- **Jul 19, 2021:** Referred to the House Committee on Energy and Commerce.