HR 6047

Early Access to Treatment Act

Congress: 110 (2007–2009, Ended)
Chamber: House
Policy Area: Health
Introduced: May 14, 2008
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (May 15, 2008)
Official Text: https://www.congress.gov/bill/110th-congress/house-bill/6047

Sponsor

Name: Rep. Jones, Walter B., Jr. [R-NC-3]
Party: Republican • **State:** NC • **Chamber:** House

Cosponsors (1 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Jackson-Lee, Sheila [D-TX-18]	D · TX		May 21, 2008

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	May 15, 2008

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of May 14, 2008)

Early Access to Treatment Act - Amends the Federal Food, Drug, and Cosmetic Act to require a drug that is not approved for marketing, but that is under clinical investigation for a serious or immediately life-threatening disease condition in patients for whom no comparable or satisfactory alternative drug or other therapy is available, to be made available for treatment use by an individual patient if: (1) the drug is intended to treat such condition; (2) there is no comparable or satisfactory alternative available to treat that stage of the disease; (3) the drug is under investigation in a controlled clinical trial as an investigational new drug or all clinical trials have been completed; and (4) an application for treatment use has been filed with the Food and Drug Administration (FDA) by a licensed practitioner which sets forth the intended use of the drug, an explanation of the rationale for its use, the treatment protocol, statements of the practitioner's qualifications to use the drug and familiarity with its safety and effectiveness, and a notarized statement of the patient's informed consent.

Requires the Secretary of Health and Human Services, within 30 days after an application is filed, to grant permission to the sponsor to furnish such drug to the practitioner under such terms as the sponsor, practitioner, and patient determine to be appropriate, including any agreement to waive liability. Provides for application transmission by telephone or other means of rapid communication and for rapid action on it in an emergency situation.

Requires (current law authorizes) the Secretary to approve an application under the Public Health Service Act for a fast track product determined to have an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

Actions Timeline

- **May 15, 2008:** Referred to the Subcommittee on Health.
- **May 14, 2008:** Introduced in House
- **May 14, 2008:** Referred to the House Committee on Energy and Commerce.