HR 1376

Patient Choice Act of 2015

Congress: 114 (2015–2017, Ended)
Chamber: House
Policy Area: Health
Introduced: Mar 16, 2015
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Mar 20, 2015)
Official Text: https://www.congress.gov/bill/114th-congress/house-bill/1376

Sponsor

Name: Rep. Griffith, H. Morgan [R-VA-9]
Party: Republican • **State:** VA • **Chamber:** House

Cosponsors (2 total)

Cosponsor	Party / State	Role	Date Joined
Rep. McCaul, Michael T. [R-TX-10]	R · TX		Mar 16, 2015
Rep. Peters, Scott H. [D-CA-52]	D · CA		Mar 16, 2015

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Mar 20, 2015

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Mar 16, 2015)

Patient Choice Act of 2015

Amends the Federal Food, Drug, and Cosmetic Act to authorize provisional approval of fast track products determined by the Department of Health and Human Services (HHS) to be adequately safe. Treats provisional approval in the same manner as approval of a drug, except that provisional approval is subject to requirements related to informed consent and continued pursuit of safety and efficacy data for purposes of gaining approval for the drug.

Defines the term “adequately safe” to mean that: (1) for at least one population, the risk of death or morbidity of the drug is unlikely to be greater than the combined risks of death or morbidity of the disease and existing therapies; or (2) the drug has had a valid marketing authorization for at least four years in one of the countries specified and data adequate for the approval of that marketing authorization has been submitted to HHS.

Prohibits HHS from imposing any requirements for safety studies or data in addition to, or different than, the requirements for studies to establish safety for purposes of Phase 1 (initial introduction of an investigational new drug into humans) or Phase 2 (controlled clinical studies to evaluate the effectiveness of the drug for a particular indication in patients with the disease or condition under study and to determine the common short-term side effects and risks associated with the drug).

Applies the provisional approval only to the indication for which the drug was: (1) designated as a fast track product, and (2) demonstrated to be adequately safe.

Prescribes requirements for termination of provisional approval, withdrawal of provisional approval, and application of market exclusivity to fast-track approval products.

Actions Timeline

- **Mar 20, 2015:** Referred to the Subcommittee on Health.
- **Mar 16, 2015:** Introduced in House
- **Mar 16, 2015:** Referred to the House Committee on Energy and Commerce.