HR 6288

Patient Choice Act of 2012

Congress: 112 (2011–2013, Ended)
Chamber: House
Policy Area: Health
Introduced: Aug 2, 2012
Current Status: Referred to the Subcommittee on Health.
Latest Action: Referred to the Subcommittee on Health. (Aug 3, 2012)
Official Text: https://www.congress.gov/bill/112th-congress/house-bill/6288

Sponsor

Name: Rep. Bilbray, Brian P. [R-CA-50]
Party: Republican • **State:** CA • **Chamber:** House

Cosponsors (4 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Boren, Dan [D-OK-2]	D · OK		Aug 2, 2012
Rep. Griffith, H. Morgan [R-VA-9]	R · VA		Aug 2, 2012
Rep. Hunter, Duncan D. [R-CA-52]	R · CA		Aug 2, 2012
Rep. Schmidt, Jean [R-OH-2]	R · OH		Aug 2, 2012

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Referred to	Aug 3, 2012

Subjects & Policy Tags

Policy Area:

Health

Related Bills

No related bills are listed.

Summary (as of Aug 2, 2012)

Patient Choice Act of 2012 - Amends the Federal Food, Drug, and Cosmetic Act to authorize provisional approval of fast track products determined by the Secretary 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 caused directly by an adverse effect of the drug is unlikely to be greater than the combined direct and secondary 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 specified countries and data adequate for the approval of such marketing authorization has been submitted to the Secretary.

Prohibits the Secretary 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 the drug: (1) which is related to the treatment of the condition with respect to which the drug was designated as a fast track product, and (2) for which the drug is demonstrated to be adequately safety.

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

Actions Timeline

- **Aug 3, 2012:** Referred to the Subcommittee on Health.
- **Aug 2, 2012:** Introduced in House
- **Aug 2, 2012:** Referred to the House Committee on Energy and Commerce.