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112TH CONGRESS
2D SESSION

H. R. 6288

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit provisional approval of fast track products.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2012

Mr. BILBRAY (for himself, Mr. GRIFFITH of Virginia, Mr. HUNTER, Mr. BOREN, and Mrs. SCHMIDT) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit provisional approval of fast track products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Patient Choice Act of 2012''.

SEC. 2. PROVISIONAL APPROVAL FOR FAST TRACK PRODUCTS.

(a) IN GENERAL.—Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(d)) is amended by adding at the end the following:

''(e) PROVISIONAL APPROVAL.—

''(1) PROVISIONAL APPROVAL FOR ADEQUATELY SAFE FAST TRACK PRODUCTS.—

''(A) IN GENERAL.—Subject to the requirements of this subsection, if the Secretary determines that a drug that is designated as a fast track product under this section is adequately safe (as such term is defined in paragraph (2)), the Secretary shall grant provisional approval and the drug may be introduced into interstate commerce on or after the date such provisional approval is granted.

''(B) TREATMENT OF PROVISIONAL APPROVAL STATUS.—The provisional approval of a drug under subparagraph (A) shall be treated in the same manner as approval of a drug under section 505 or section 351 of the Public Health Service Act, except that such provisional approval shall be subject to the requirements of this section, including the following:

''(i) The requirements under paragraph (3), including requirements related to—

''(I) informed consent; and

''(II) continued pursuit of safety and efficacy data for purposes of gaining approval for such drug under section 505 or section 351 of the Public Health Service Act.

''(ii) The rules under paragraphs (4) and (5) relating to the length of the termination of the provisional approval and withdrawal of a drug subject to provisional approval.

''(C) REQUEST FOR PROVISIONAL APPROVAL.—

''(i) IN GENERAL.—The sponsor of a drug that is designated as a fast track product under this section may request that the Secretary grant provisional approval for such drug under subparagraph (A).

''(ii) RESPONSE TO REQUEST.—Not later than 90 days after receiving such a request, the Secretary shall either—

''(I) grant provisional approval for the drug under subparagraph (A); or

''(II) provide notice to the sponsor of the drug that such request is denied.

''(2) ADEQUATELY SAFE DEFINED.—

''(A) IN GENERAL.—For purposes of this subsection, with respect to a drug, the term 'adequately safe' means that—

''(i) for at least one population, the risk of death or morbidity caused directly by an adverse effect of the drug, as determined in one or more safety studies or through other data that the Secretary determines are sufficient, is unlikely to be greater than the combined direct and secondary risks of death or morbidity, as established in the literature or historical data, of—

''(I) the disease that such drug is intended to treat; and

''(II) existing therapies (including infection) for such disease; or

"(ii) the drug has had a valid marketing authorization, for a period of at least 4 years, by an authority in a country described in section 802(b)(1)(A), or designated by the Secretary under section 802(b)(1)(B), and data adequate for the approval of such marketing authorization for such drug in such country have been submitted to the Secretary.

"(B) LIMITATION.—The Secretary may not impose any requirements for purposes of the safety studies or data under subparagraph (A)(i) that are in addition to, or different than, the requirements for studies to establish safety for purposes of Phase 1 or Phase 2, as such terms are described in subsection (a) and (b), respectively, of section 312.21 of title 21, Code of Federal Regulations.

"(3) REQUIREMENTS.—Provisional approval of a fast track product under this subsection shall be subject to the following requirements:

"(A) INFORMED CONSENT.—

"(i) IN GENERAL.—As a condition of provisional approval under paragraph (1), the sponsor of a drug shall ensure that, be-

fore such drug is dispensed to an individual—

"(I) the individual shall be informed that the drug is subject to provisional approval based on limited safety data and that the efficacy of the drug has not been proven;

"(II) the individual shall be informed of the known risks of the drug and any unknown but reasonably predictable risks of the drug, including, as appropriate, potential risks of death, complications, or injury resulting from use of the drug, and risks related to the potential ineffectiveness of the drug, including progression of the disease that may result in death or morbidity, or the potential for the drug to accelerate or exacerbate the disease process; and

"(III) the individual provides written informed consent acknowledging that individual has been provided with and understands the information under subclauses (I) or (II).

"(ii) REGULATIONS.—The Secretary shall issue regulations on the requirements for informed consent under clause (i). Such regulations shall be similar to the requirements for informed consent for human subjects under subpart B of part 50 of title 21, Code of Federal Regulations, adjusted as appropriate for purposes of this subsection.

"(B) PURSUIT OF FULL APPROVAL REQUIRED.—A sponsor of a drug that receives a provisional approval under paragraph (1) shall continue to diligently conduct appropriate studies, after such provisional approval is granted, to—

"(i) establish that the drug has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit; and

"(ii) collect the data necessary to demonstrate that the drug is safe and effective (or, in the case of a biologic, safe and potent) for purpose of obtaining approval for such drug under section 505(c)

or section 351 of the Public Health Service Act.

''(C) PROMOTIONAL MATERIALS.—During the period that provisional approval under paragraph (1) applies to a drug, the sponsor of the drug shall submit copies of all promotional materials related to the drug at least 30 days prior to dissemination of the materials.

''(D) RISK EVALUATION AND MITIGATION STRATEGY.—

''(i) IN GENERAL.—Section 505–1 shall apply to a drug subject to provisional approval under this subsection in the same manner that such section applies to a drug approved under section 505 or section 351 of the Public Health Service Act.

''(ii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to limit the Secretary's authority under section 505–1 to determine if a risk evaluation and mitigation strategy is necessary.

''(E) INDICATION OF USE.—The provisional approval under paragraph (1) shall only apply to the indication of use for the drug—

"(i) which is related to the treatment of the condition with respect to which such drug was designated as a fast track product; and

"(ii) for which the drug is demonstrated to be adequately safe.

"(4) TERMINATION OF PROVISIONAL APPROVAL.—

"(A) IN GENERAL.—In the case of a drug that is not designated under section 526, the provisional approval of the drug under paragraph (1) shall terminate on the earlier of the following:

"(i) The date that the drug is approved under section 505(c) or section 351 of the Public Health Service Act.

"(ii) At the end of the 5-year period beginning on the date on which provisional approval was granted for such drug, except—

"(I) if the Secretary determines that the sponsor of the drug is diligently engaging in actions (including conducting clinical trials) for the purpose of seeking approval under section

505(c) or section 351 of the Public Health Service Act (excluding provisional approval under paragraph (1)) and the Secretary determines that the sponsor requires additional time to complete such actions and attain such approval, the Secretary may extend such period for an appropriate length of time to allow the sponsor to complete such actions and attain such approval; or

"(II) if the Secretary determines that the termination of the provisional approval is adverse to protecting or promoting the public health, the Secretary may extend such period for an appropriate length of time to protect or promote the public health.

"(B) SPECIAL RULE FOR ORPHAN DRUGS.—In the case of a drug designated under section 526, the provisional approval of the drug under paragraph (1) shall terminate on the date that the drug is approved under section 505(c) or section 351 of the Public Health Service Act.

"(C) RULE OF CONSTRUCTION.—For purposes of this paragraph, the phrase 'approved under section 505(c) or section 351 of the Public Health Service Act' shall not be construed to include a provisional approval under paragraph (1).

"(5) WITHDRAWAL.—

"(A) IN GENERAL.—Subsection (b)(3) shall apply to a drug subject to a provisional approval under this subsection in the same manner as such subsection applies to any fast track product.

"(B) ADDITIONAL WITHDRAWAL AUTHORITY.—In addition to subparagraph (A), the Secretary may withdraw approval of a fast track product using the expedited procedures applied under subsection (b)(3) if the requirements of paragraph (3)(A) have not been met with respect to the drug.

"(6) IMPACT ON MARKETING EXCLUSIVITY.—The rules related to marketing exclusivity under sections 505(c)(3)(E), 505(j)(5)(F), 505A, and 527 shall apply to a drug subject to provisional approval under this subsection in the same manner that such rules apply to drugs approved under section 505 or

section 351 of the Public Health Service Act, except that the period of provisional approval under this subsection for a drug shall be an addition to the applicable period of marketing exclusivity for such drug.''.

(b) MISBRANDING FOR MARKETING OF TERMINATED DRUG.—Section 502 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''(aa) If it is a drug that is introduced or delivered for introduction into interstate commerce after the date of the termination of the provisional approval for such drug under section 506(e), unless, on or before the date such drug is so introduced or delivered, such drug is approved under section 505(c) or section 351 of the Public Health Service Act.''.

(c) CONFORMING AMENDMENTS.—The chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351) is further amended—

(1) in section 502(a), by inserting ''(or an indication subject to a provisional approval under section 506(e))'' after ''an indication approved under section 505 or under section 351(a) of the Public Health Service Act'';

(2) in section 506A—

(A) in subsection (a), by inserting ''(or a provisional approval under section 506(e))'' after ''a license under section 351 of the Public Health Service Act''; and

(B) by adding at the end the following:

''(e) SPECIAL RULE FOR DRUGS SUBJECT TO PROVISIONAL APPROVAL.—In the case of a drug subject to a provisional approval under section 506(e), any reference to safety and efficacy under this section shall be treated as a reference to adequate safety, as such term is defined for purposes of such section 506(e).'';

(3) in section 506B(a), by adding at the end the following:

''(3) SPECIAL RULE FOR PROVISIONAL APPROVAL.—A sponsor of a drug that is subject to a provisional approval under section 506(e) shall submit the reports required under this section on the studies conducted on such drug that are described in section 506(e)(3)(B). For purposes of this section, such reports shall be treated as reports on post-marketing studies described in paragraph (1).'';

(4) in section 506(a)(2), by inserting ''(or that is subject to a provisional approval under section 506(e))'' after ''505(j)''; and

(5) in section 551(b)(1)(A) by inserting ''(or a provisional approval under section 506(e))'' after ''Public Health Service Act''.

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