

112TH CONGRESS
2^D 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

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patient Choice Act
5 of 2012”.

1 **SEC. 2. PROVISIONAL APPROVAL FOR FAST TRACK PROD-**
2 **UCTS.**

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

6 “(e) PROVISIONAL APPROVAL.—

7 “(1) PROVISIONAL APPROVAL FOR ADEQUATELY
8 SAFE FAST TRACK PRODUCTS.—

9 “(A) IN GENERAL.—Subject to the re-
10 quirements of this subsection, if the Secretary
11 determines that a drug that is designated as a
12 fast track product under this section is ade-
13 quately safe (as such term is defined in para-
14 graph (2)), the Secretary shall grant provisional
15 approval and the drug may be introduced into
16 interstate commerce on or after the date such
17 provisional approval is granted.

18 “(B) TREATMENT OF PROVISIONAL AP-
19 PROVAL STATUS.—The provisional approval of a
20 drug under subparagraph (A) shall be treated
21 in the same manner as approval of a drug
22 under section 505 or section 351 of the Public
23 Health Service Act, except that such provisional
24 approval shall be subject to the requirements of
25 this section, including the following:

1 “(i) The requirements under para-
2 graph (3), including requirements related
3 to—

4 “(I) informed consent; and

5 “(II) continued pursuit of safety
6 and efficacy data for purposes of
7 gaining approval for such drug under
8 section 505 or section 351 of the Pub-
9 lic Health Service Act.

10 “(ii) The rules under paragraphs (4)
11 and (5) relating to the length of the termi-
12 nation of the provisional approval and
13 withdrawal of a drug subject to provisional
14 approval.

15 “(C) REQUEST FOR PROVISIONAL AP-
16 PROVAL.—

17 “(i) IN GENERAL.—The sponsor of a
18 drug that is designated as a fast track
19 product under this section may request
20 that the Secretary grant provisional ap-
21 proval for such drug under subparagraph
22 (A).

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

1 “(I) grant provisional approval
2 for the drug under subparagraph (A);
3 or

4 “(II) provide notice to the spon-
5 sor of the drug that such request is
6 denied.

7 “(2) ADEQUATELY SAFE DEFINED.—

8 “(A) IN GENERAL.—For purposes of this
9 subsection, with respect to a drug, the term
10 ‘adequately safe’ means that—

11 “(i) for at least one population, the
12 risk of death or morbidity caused directly
13 by an adverse effect of the drug, as deter-
14 mined in one or more safety studies or
15 through other data that the Secretary de-
16 termines are sufficient, is unlikely to be
17 greater than the combined direct and sec-
18 ondary risks of death or morbidity, as es-
19 tablished in the literature or historical
20 data, of—

21 “(I) the disease that such drug is
22 intended to treat; and

23 “(II) existing therapies (includ-
24 ing infection) for such disease; or

1 “(ii) the drug has had a valid mar-
2 keting authorization, for a period of at
3 least 4 years, by an authority in a country
4 described in section 802(b)(1)(A), or des-
5 ignated by the Secretary under section
6 802(b)(1)(B), and data adequate for the
7 approval of such marketing authorization
8 for such drug in such country have been
9 submitted to the Secretary.

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

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

22 “(A) INFORMED CONSENT.—

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

1 fore such drug is dispensed to an indi-
2 vidual—

3 “(I) the individual shall be in-
4 formed that the drug is subject to
5 provisional approval based on limited
6 safety data and that the efficacy of
7 the drug has not been proven;

8 “(II) the individual shall be in-
9 formed of the known risks of the drug
10 and any unknown but reasonably pre-
11 dictable risks of the drug, including,
12 as appropriate, potential risks of
13 death, complications, or injury result-
14 ing from use of the drug, and risks
15 related to the potential ineffectiveness
16 of the drug, including progression of
17 the disease that may result in death
18 or morbidity, or the potential for the
19 drug to accelerate or exacerbate the
20 disease process; and

21 “(III) the individual provides
22 written informed consent acknowl-
23 edging that individual has been pro-
24 vided with and understands the infor-
25 mation under subclauses (I) or (II).

1 “(ii) REGULATIONS.—The Secretary
2 shall issue regulations on the requirements
3 for informed consent under clause (i).
4 Such regulations shall be similar to the re-
5 quirements for informed consent for
6 human subjects under subpart B of part
7 50 of title 21, Code of Federal Regula-
8 tions, adjusted as appropriate for purposes
9 of this subsection.

10 “(B) PURSUIT OF FULL APPROVAL RE-
11 QUIRED.—A sponsor of a drug that receives a
12 provisional approval under paragraph (1) shall
13 continue to diligently conduct appropriate stud-
14 ies, after such provisional approval is granted,
15 to—

16 “(i) establish that the drug has an ef-
17 fect on a clinical endpoint or on a surro-
18 gate endpoint that is reasonably likely to
19 predict clinical benefit; and

20 “(ii) collect the data necessary to
21 demonstrate that the drug is safe and ef-
22 fective (or, in the case of a biologic, safe
23 and potent) for purpose of obtaining ap-
24 proval for such drug under section 505(c)

1 or section 351 of the Public Health Service
2 Act.

3 “(C) PROMOTIONAL MATERIALS.—During
4 the period that provisional approval under para-
5 graph (1) applies to a drug, the sponsor of the
6 drug shall submit copies of all promotional ma-
7 terials related to the drug at least 30 days prior
8 to dissemination of the materials.

9 “(D) RISK EVALUATION AND MITIGATION
10 STRATEGY.—

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

17 “(ii) RULE OF CONSTRUCTION.—
18 Nothing in this subparagraph shall be con-
19 strued to limit the Secretary’s authority
20 under section 505–1 to determine if a risk
21 evaluation and mitigation strategy is nec-
22 essary.

23 “(E) INDICATION OF USE.—The provi-
24 sional approval under paragraph (1) shall only
25 apply to the indication of use for the drug—

1 “(i) which is related to the treatment
2 of the condition with respect to which such
3 drug was designated as a fast track prod-
4 uct; and

5 “(ii) for which the drug is dem-
6 onstrated to be adequately safe.

7 “(4) TERMINATION OF PROVISIONAL AP-
8 PROVAL.—

9 “(A) IN GENERAL.—In the case of a drug
10 that is not designated under section 526, the
11 provisional approval of the drug under para-
12 graph (1) shall terminate on the earlier of the
13 following:

14 “(i) The date that the drug is ap-
15 proved under section 505(c) or section 351
16 of the Public Health Service Act.

17 “(ii) At the end of the 5-year period
18 beginning on the date on which provisional
19 approval was granted for such drug, ex-
20 cept—

21 “(I) if the Secretary determines
22 that the sponsor of the drug is dili-
23 gently engaging in actions (including
24 conducting clinical trials) for the pur-
25 pose of seeking approval under section

1 505(c) or section 351 of the Public
2 Health Service Act (excluding provi-
3 sional approval under paragraph (1))
4 and the Secretary determines that the
5 sponsor requires additional time to
6 complete such actions and attain such
7 approval, the Secretary may extend
8 such period for an appropriate length
9 of time to allow the sponsor to com-
10 plete such actions and attain such ap-
11 proval; or

12 “(II) if the Secretary determines
13 that the termination of the provisional
14 approval is adverse to protecting or
15 promoting the public health, the Sec-
16 retary may extend such period for an
17 appropriate length of time to protect
18 or promote the public health.

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

1 “(C) RULE OF CONSTRUCTION.—For pur-
2 poses of this paragraph, the phrase ‘approved
3 under section 505(e) or section 351 of the Pub-
4 lic Health Service Act’ shall not be construed to
5 include a provisional approval under paragraph
6 (1).

7 “(5) WITHDRAWAL.—

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

13 “(B) ADDITIONAL WITHDRAWAL AUTHOR-
14 ITY.—In addition to subparagraph (A), the Sec-
15 retary may withdraw approval of a fast track
16 product using the expedited procedures applied
17 under subsection (b)(3) if the requirements of
18 paragraph (3)(A) have not been met with re-
19 spect to the drug.

20 “(6) IMPACT ON MARKETING EXCLUSIVITY.—

21 The rules related to marketing exclusivity under sec-
22 tions 505(e)(3)(E), 505(j)(5)(F), 505A, and 527
23 shall apply to a drug subject to provisional approval
24 under this subsection in the same manner that such
25 rules apply to drugs approved under section 505 or

1 section 351 of the Public Health Service Act, except
2 that the period of provisional approval under this
3 subsection for a drug shall be an addition to the ap-
4 plicable period of marketing exclusivity for such
5 drug.”.

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

9 “(aa) If it is a drug that is introduced or delivered
10 for introduction into interstate commerce after the date
11 of the termination of the provisional approval for such
12 drug under section 506(e), unless, on or before the date
13 such drug is so introduced or delivered, such drug is ap-
14 proved under section 505(c) or section 351 of the Public
15 Health Service Act.”.

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

19 (1) in section 502(a), by inserting “(or an indi-
20 cation subject to a provisional approval under sec-
21 tion 506(e))” after “an indication approved under
22 section 505 or under section 351(a) of the Public
23 Health Service Act”;

24 (2) in section 506A—

1 (A) in subsection (a), by inserting “(or a
2 provisional approval under section 506(e))”
3 after “a license under section 351 of the Public
4 Health Service Act”; and

5 (B) by adding at the end the following:

6 “(e) SPECIAL RULE FOR DRUGS SUBJECT TO PROVI-
7 SIONAL APPROVAL.—In the case of a drug subject to a
8 provisional approval under section 506(e), any reference
9 to safety and efficacy under this section shall be treated
10 as a reference to adequate safety, as such term is defined
11 for purposes of such section 506(e).”;

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

14 “(3) SPECIAL RULE FOR PROVISIONAL AP-
15 PROVAL.—A sponsor of a drug that is subject to a
16 provisional approval under section 506(e) shall sub-
17 mit the reports required under this section on the
18 studies conducted on such drug that are described in
19 section 506(e)(3)(B). For purposes of this section,
20 such reports shall be treated as reports on post-
21 marketing studies described in paragraph (1).”;

22 (4) in section 506(a)(2), by inserting “(or that
23 is subject to a provisional approval under section
24 506(e))” after “505(j)”; and

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

○