

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6288

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

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## 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.

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”.

○