

110TH CONGRESS  
2D SESSION

# H. R. 6378

To expand the authority of the Secretary of Health and Human Services to impose debarments in order to ensure the integrity of drug, biological product, and device regulation, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 26, 2008

Mr. BARTON of Texas (for himself, Mr. DEAL of Georgia, Mr. WHITFIELD of Kentucky, Mr. SHIMKUS, Mrs. WILSON of New Mexico, Mr. PICKERING, Mrs. BONO MACK, Mr. WALDEN of Oregon, Mr. TERRY, Mr. SULLIVAN, and Mrs. BLACKBURN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To expand the authority of the Secretary of Health and Human Services to impose debarments in order to ensure the integrity of drug, biological product, and device regulation, and for other purposes.

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 “Strengthening of FDA  
5 Integrity Act of 2008”.

1 **SEC. 2. DEBARMENT.**

2 (a) APPLICATION TO DRUGS, BIOLOGICAL PROD-  
3 UCTS, AND DEVICES.—The Federal Food, Drug, and Cos-  
4 metic Act (21 U.S.C. 301 et seq.) is amended—

5 (1) in section 201, by amending subsection (dd)  
6 to read as follows:

7 “(dd) The term ‘drug product’—

8 “(1) for purposes of sections 306 and 307,  
9 means a drug subject to regulation under section  
10 505, 512, or 802 of this Act or under section 351  
11 of the Public Health Service Act; and

12 “(2) for purposes of section 306, includes a de-  
13 vice subject to regulation under section 513 of this  
14 Act.”; and

15 (2) in section 306—

16 (A) by striking the term “an abbreviated  
17 drug application” each place such term appears  
18 and inserting “a covered application”;

19 (B) by striking the terms “abbreviated  
20 drug application” and “abbreviated drug appli-  
21 cations” each place either such term appears  
22 and inserting “covered application” and “cov-  
23 ered applications”, respectively;

24 (C) by striking the term “drug product ap-  
25 plication” each place such term appears and in-  
26 serting “covered application”;

1 (D) in the heading of subsections (a) and  
2 (b), by striking “CERTAIN DRUG APPLICA-  
3 TIONS” and inserting “CERTAIN DRUG PROD-  
4 UCT APPLICATIONS”;

5 (E) in subsection (b)(2)(B)(i), by striking  
6 “the process for the regulation of drugs” and  
7 inserting “the process for the regulation of drug  
8 products”;

9 (F) in subsection (d)(4)(B)(ii), by striking  
10 “of any drug subject to sections 505” and in-  
11 sserting “of any drug product”;

12 (G) in subsections (b)(2)(A), (b)(2)(B)(iv),  
13 (c)(3)(C), (c)(3)(E), (d)(3)(A)(ii)(II),  
14 (d)(3)(B)(ii), (d)(4)(B)(iv), (d)(4)(D)(ii),  
15 (f)(1)(B)(ii), (g), and (h), by striking the terms  
16 “drug” and “drugs” each place either such  
17 term appears and inserting “drug product” and  
18 “drug products”, respectively; and

19 (H) by adding at the end the following:

20 “(n) COVERED APPLICATION DEFINED.—In this sec-  
21 tion, the term ‘covered application’ means—

22 “(1) an application for approval or licensure of  
23 a drug under section 505 of this Act or section 351  
24 of the Public Health Service Act, respectively; or

1           “(2) an application for clearance or approval of  
2           a device under section 510(k) or 515 of this Act, re-  
3           spectively.”.

4           (b) MANDATORY DEBARMENT.—Section 306(a) of  
5           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
6           335a(a)) is amended—

7           (1) by amending paragraph (1) to read as fol-  
8           lows:

9           “(1) CORPORATIONS, PARTNERSHIPS, AND AS-  
10          SOCIATIONS.—If the Secretary finds that a person  
11          other than an individual has been convicted, after  
12          May 13, 1992, of a felony under Federal law for  
13          conduct—

14                 “(A) relating to the development or ap-  
15                 proval, including the process for development or  
16                 approval, of any drug product, or

17                 “(B) otherwise relating to the regulation of  
18                 any drug product under this Act or subpart 1  
19                 of part F of title III of the Public Health Serv-  
20                 ice Act,

21                 the Secretary shall debar such person from submit-  
22                 ting, or assisting in the submission of, any covered  
23                 application.”; and

24           (2) by adding at the end the following new  
25           paragraph:

1           “(3) INITIATION OF DEBARMENT.—The Sec-  
2           retary shall initiate a debarment of a person or indi-  
3           vidual under paragraph (1) or (2), respectively, not  
4           later than the date that is one year after the date  
5           such person or individual is convicted of the felony  
6           described in such respective paragraph.”.

7           (c) PERMISSIVE DEBARMENT.—Section 306(b)(2) of  
8           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
9           335a(b)(2)) is amended—

10           (1) in subparagraph (A)(i), by amending sub-  
11           clause (I) to read as follows:

12   “(I) relates to the development or  
13   approval, including the process for de-  
14   velopment or approval, of any drug  
15   product or otherwise relates to the  
16   regulation of drug products under this  
17   Act or subpart 1 of part F of title III  
18   of the Public Health Service Act,  
19   and”;

20           (2) in subparagraph (B)—

21   (A) by striking clauses (ii) and (iii); and

22   (B) by redesignating clause (iv) as clause  
23   (ii); and

24           (3) by adding at the end the following:

1           “(C) BRIBERY, FRAUD, AND OTHER SUCH  
2 CRIMES.—Any person (including any individual)  
3 whom the Secretary finds has been convicted  
4 of—

5           “(i) a felony which is not described in  
6 paragraph (1) or (2) of subsection (a) or  
7 in subparagraph (A) or (B)(i) of this sub-  
8 section and which involves bribery, pay-  
9 ment of illegal gratuities, fraud, perjury,  
10 false statement, racketeering, blackmail,  
11 extortion, falsification or destruction of  
12 records, or interference with or obstruction  
13 of an investigation into, or prosecution of,  
14 any criminal offense, or

15           “(ii) a conspiracy to commit, or aiding  
16 or abetting such felony,

17 if the Secretary finds, on the basis of the con-  
18 viction of such person and other information,  
19 that such person has demonstrated a pattern of  
20 conduct sufficient to find that there is reason to  
21 believe that such person may violate require-  
22 ments under this Act or subpart 1 of part F of  
23 title III of the Public Health Service Act relat-  
24 ing to drug products.

1           “(D) MATERIAL PARTICIPATION.—Any  
2           person (including any individual) whom the  
3           Secretary finds materially participated in acts  
4           that were the basis for a conviction for an of-  
5           fense described in paragraph (1) or (2) of sub-  
6           section (a) or in subparagraph (A), (B)(i), or  
7           (C) of this subsection for which a conviction  
8           was obtained, if the Secretary finds, on the  
9           basis of such participation and other informa-  
10          tion, that such individual has demonstrated a  
11          pattern of conduct sufficient to find that there  
12          is reason to believe that such person may vio-  
13          late requirements under this Act or subpart 1  
14          of part F of title III of the Public Health Serv-  
15          ice Act relating to drug products.”.

16          (d) ADDITIONAL DEPARTMENT CONSIDERATION.—  
17          Paragraph (3) of subsection (c) of section 306 of the Fed-  
18          eral Food, Drug, and Cosmetic Act (21 U.S.C.  
19          335a(c)(3)) is amended—

20                 (1) by striking “and” at the end of subpara-  
21                 graph (E);

22                 (2) by striking the period at the end of sub-  
23                 paragraph (F) and inserting “, and”; and

24                 (3) by adding at the end the following new sub-  
25                 paragraph:

1           “(G) whether debarment of the person will  
2           affect the public health because sufficient quan-  
3           tities of the drug product would not be avail-  
4           able.”.

5           (e) EFFECTIVE DATES.—Paragraph (2) of section  
6 306(l) of the Federal Food, Drug, and Cosmetic Act (21  
7 U.S.C. 335a(l)) is amended by striking the phrase “oc-  
8 curred more than 5 years before” each place such phrase  
9 appears and inserting “occurred more than 1 year before”.

10          (f) ANNUAL REPORT.—Section 306 of the Federal  
11 Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is  
12 amended by adding at the end the following:

13          “(o) ANNUAL REPORT.—Each year, the Secretary  
14 shall submit a report to the Congress on implementation  
15 of this section. Each such report shall identify—

16           “(1) debarment proceedings mandated under  
17 subsection (a) or (m);

18           “(2) debarment proceedings initiated under  
19 subsection (a), (b), or (m);

20           “(3) the status of debarment proceedings so ini-  
21 tiated or pending from a previous year;

22           “(4) debarments imposed under this section;  
23 and

24           “(5) debarments declined under this section.”.

1 (g) CONFORMING AMENDMENTS.—Section 306 of the  
2 Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a)  
3 is amended—

4 (1) in subsections (a)(2)(B) and (h)(1)(A), by  
5 striking “this Act” and inserting “this Act or sub-  
6 part 1 of part F of title III of the Public Health  
7 Service Act”;

8 (2) in subsection (b)(2)(A)(i)(II), by striking  
9 “the date of the enactment of this section” and in-  
10 serting “May 13, 1992”;

11 (3) in subsection (b)(4), by striking “clause (iii)  
12 or (iv) of paragraph (2)(B)” and inserting “subpara-  
13 graph (B)(ii) or (D) of paragraph (2)”;

14 (4) in subsection (c)(1)(A), by striking “sub-  
15 section (a)(1) or (b)(2)(A)” and inserting “sub-  
16 section (a)(1) or (b)(1)(A)”;

17 (5) in subsection (c)(1)(B), by striking “sub-  
18 section (a)(2) or (b)(2)(B)” and inserting “sub-  
19 section (a)(2) or (b)(1)(B)”;

20 (6) in subsection (d)(3)(A)(i), by striking “or  
21 paragraph (2)(A) or (3) of subsection (b)” and in-  
22 serting “subparagraph (A) or (C) of subsection  
23 (b)(1)”;

24 (7) in subsection (d)(3)(B)(i), by striking  
25 “clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B)

1 or subsection (b)(3)” and inserting “subparagraph  
2 (B) or (C) of subsection (b)(1)”;

3 (8) in subsection (d)(3)(B)(ii), by striking  
4 “under subsection (b)(2)(B) or subsection (b)(3)”  
5 and inserting “under subparagraph (B) or (C) of  
6 subsection (b)(1)”;

7 (9) in subsection (j)(2), by striking “clause (iii)  
8 or (iv) of subsection (b)(2)(B)” and inserting “sub-  
9 paragraph (B)(ii) or (D) of subsection (b)(2)”;

10 (10) in subsection (l)(2)—

11 (A) by striking “clauses (i) and (ii) of sub-  
12 section (b)(2)(B)” and inserting “subpara-  
13 graphs (B)(i) and (C) of subsection (b)(2)”;

14 (B) by striking “Clauses (iii) and (iv) of  
15 subsection (b)(2)(B)” and inserting “Subpara-  
16 graphs (B)(ii) and (D) of subsection (b)(2)”;  
17 and

18 (C) by striking “Clause (iv) of subsection  
19 (b)(2)(B)” and inserting “Subparagraph (B)(ii)  
20 of subsection (b)(2)”.

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