

111TH CONGRESS
1ST SESSION

H. R. 3932

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.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 27, 2009

Mr. BARTON of Texas (for himself, Mr. SHIMKUS, Mrs. BONO MACK, Mr. TERRY, Mr. SULLIVAN, Mr. BURGESS, Mrs. BLACKBURN, and Mr. WALDEN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 2009”.

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.—Paragraph (1) of
5 section 306(a) of the Federal Food, Drug, and Cosmetic
6 Act (21 U.S.C. 335a(a)) is amended to read as follows:

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

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

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

19 the Secretary shall debar such person from submit-
20 ting, or assisting in the submission of, any covered
21 application.”.

22 (c) PERMISSIVE DEBARMENT.—Section 306(b)(2) of
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
24 335a(b)(2)) is amended—

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

3 “(I) relates to the development or
4 approval, including the process for de-
5 velopment or approval, of any drug
6 product or otherwise relates to the
7 regulation of drug products under this
8 Act or subpart 1 of part F of title III
9 of the Public Health Service Act,
10 and”;

11 (2) in subparagraph (B)—

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

13 (B) by redesignating clause (iv) as clause
14 (ii); and

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

16 “(C) BRIBERY, FRAUD, AND OTHER SUCH
17 CRIMES.—Any person (including any individual)
18 whom the Secretary finds has been convicted
19 of—

20 “(i) a felony which is not described in
21 paragraph (1) or (2) of subsection (a) or
22 in subparagraph (A) or (B)(i) of this sub-
23 section and which involves bribery, pay-
24 ment of illegal gratuities, fraud, perjury,
25 false statement, racketeering, blackmail,

1 extortion, falsification or destruction of
2 records, or interference with or obstruction
3 of an investigation into, or prosecution of,
4 any criminal offense, or

5 “(ii) a conspiracy to commit, or aiding
6 or abetting such felony,

7 if the Secretary finds, on the basis of the con-
8 viction of such person and other information,
9 that such person has demonstrated a pattern of
10 conduct sufficient to find that there is reason to
11 believe that such person may violate require-
12 ments under this Act or subpart 1 of part F of
13 title III of the Public Health Service Act relat-
14 ing to drug products.

15 “(D) MATERIAL PARTICIPATION.—Any
16 person (including any individual) whom the
17 Secretary finds materially participated in acts
18 that were the basis for a conviction for an of-
19 fense described in paragraph (1) or (2) of sub-
20 section (a) or in subparagraph (A), (B)(i), or
21 (C) of this subsection for which a conviction
22 was obtained, if the Secretary finds, on the
23 basis of such participation and other informa-
24 tion, that such individual has demonstrated a
25 pattern of conduct sufficient to find that there

1 is reason to believe that such person may vio-
2 late requirements under this Act or subpart 1
3 of part F of title III of the Public Health Serv-
4 ice Act relating to drug products.”.

5 (d) ADDITIONAL DEBARMENT CONSIDERATION.—
6 Paragraph (3) of subsection (c) of section 306 of the Fed-
7 eral Food, Drug, and Cosmetic Act (21 U.S.C.
8 335a(c)(3)) is amended—

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

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

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(G) whether debarment of the person will
16 affect the public health because sufficient quan-
17 tities of the drug product would not be avail-
18 able.”.

19 (e) EFFECTIVE DATES.—Paragraph (2) of section
20 306(l) of the Federal Food, Drug, and Cosmetic Act (21
21 U.S.C. 335a(l)) is amended by striking the phrase “oc-
22 curred more than 5 years before” each place such phrase
23 appears and inserting “occurred more than 1 year before”.

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

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

7 “(1) debarment proceedings mandated under
8 subsection (a) or (m);

9 “(2) debarment proceedings initiated under
10 subsection (a), (b), or (m);

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

13 “(4) debarments imposed under this section;
14 and

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

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

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

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

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

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

7 (5) in subsection (c)(1)(B), by striking “sub-
8 section (a)(2) or (b)(2)(B)” and inserting “sub-
9 section (a)(2) or (b)(1)(B)”;

10 (6) in subsection (d)(3)(A)(i), by striking “or
11 paragraph (2)(A) or (3) of subsection (b)” and in-
12 serting “subparagraph (A) or (C) of subsection
13 (b)(1)”;

14 (7) in subsection (d)(3)(B)(i), by striking
15 “clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B)
16 or subsection (b)(3)” and inserting “subparagraph
17 (B) or (C) of subsection (b)(1)”;

18 (8) in subsection (d)(3)(B)(ii), by striking
19 “under subsection (b)(2)(B) or subsection (b)(3)”
20 and inserting “under subparagraph (B) or (C) of
21 subsection (b)(1)”;

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

25 (10) in subsection (l)(2)—

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

4 (B) by striking “Clauses (iii) and (iv) of
5 subsection (b)(2)(B)” and inserting “Subpara-
6 graphs (B)(ii) and (D) of subsection (b)(2)”;
7 and

8 (C) by striking “Clause (iv) of subsection
9 (b)(2)(B)” and inserting “Subparagraph (B)(ii)
10 of subsection (b)(2)”.

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