I

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.

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 ''Strengthening of FDA Integrity Act of 2009''.

SEC. 2. DEBARMENT.

(a) APPLICATION TO DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

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

''(dd) The term 'drug product'—

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

''(2) for purposes of section 306, includes a device subject to regulation under section 513 of this Act.''; and

(2) in section 306—

(A) by striking the term ''an abbreviated drug application'' each place such term appears and inserting ''a covered application'';

(B) by striking the terms ''abbreviated drug application'' and ''abbreviated drug applications'' each place either such term appears and inserting ''covered application'' and ''covered applications'', respectively;

(C) by striking the term ''drug product application'' each place such term appears and inserting ''covered application'';

(D) in the heading of subsections (a) and (b), by striking ''CERTAIN DRUG APPLICATIONS'' and inserting ''CERTAIN DRUG PRODUCT APPLICATIONS'';

(E) in subsection (b)(2)(B)(i), by striking ''the process for the regulation of drugs'' and inserting ''the process for the regulation of drug products'';

(F) in subsection (d)(4)(B)(ii), by striking ''of any drug subject to sections 505'' and inserting ''of any drug product'';

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

(H) by adding at the end the following:

''(n) COVERED APPLICATION DEFINED.—In this section, the term 'covered application' means—

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

''(2) an application for clearance or approval of a device under section 510(k) or 515 of this Act, respectively.''.

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

''(1) CORPORATIONS, PARTNERSHIPS, AND ASSOCIATIONS.—If the Secretary finds that a person other than an individual has been convicted, after May 13, 1992, of a felony under Federal law for conduct—

''(A) relating to the development or approval, including the process for development or approval, of any drug product, or

''(B) otherwise relating to the regulation of any drug product under this Act or subpart 1 of part F of title III of the Public Health Service Act,

the Secretary shall debar such person from submitting, or assisting in the submission of, any covered application.''.

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

(1) in subparagraph (A)(i), by amending subclause (I) to read as follows:

''(I) relates to the development or approval, including the process for development or approval, of any drug product or otherwise relates to the regulation of drug products under this Act or subpart 1 of part F of title III of the Public Health Service Act, and'';

(2) in subparagraph (B)—

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

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

(3) by adding at the end the following:

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

''(i) a felony which is not described in paragraph (1) or (2) of subsection (a) or in subparagraph (A) or (B)(i) of this subsection and which involves bribery, payment of illegal gratuities, fraud, perjury, false statement, racketeering, blackmail,

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

"(ii) a conspiracy to commit, or aiding or abetting such felony,

if the Secretary finds, on the basis of the conviction of such person and other information, that such person has demonstrated a pattern of conduct sufficient to find that there is reason to believe that such person may violate requirements under this Act or subpart 1 of part F of title III of the Public Health Service Act relating to drug products.

"(D) MATERIAL PARTICIPATION.—Any person (including any individual) whom the Secretary finds materially participated in acts that were the basis for a conviction for an offense described in paragraph (1) or (2) of subsection (a) or in subparagraph (A), (B)(i), or (C) of this subsection for which a conviction was obtained, if the Secretary finds, on the basis of such participation and other information, that such individual has demonstrated a pattern of conduct sufficient to find that there

is reason to believe that such person may violate requirements under this Act or subpart 1 of part F of title III of the Public Health Service Act relating to drug products.''.

(d) ADDITIONAL DEBARMENT CONSIDERATION.—Paragraph (3) of subsection (c) of section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a(c)(3)) is amended—

(1) by striking ''and'' at the end of subparagraph (E);

(2) by striking the period at the end of subparagraph (F) and inserting '', and''; and

(3) by adding at the end the following new subparagraph:

''(G) whether debarment of the person will affect the public health because sufficient quantities of the drug product would not be available.''.

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

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

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

''(1) debarment proceedings mandated under subsection (a) or (m);

''(2) debarment proceedings initiated under subsection (a), (b), or (m);

''(3) the status of debarment proceedings so initiated or pending from a previous year;

''(4) debarments imposed under this section; and

''(5) debarments declined under this section.''.

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

(1) in subsections (a)(2)(B) and (h)(1)(A), by striking ''this Act'' and inserting ''this Act or subpart 1 of part F of title III of the Public Health Service Act'';

(2) in subsection (b)(2)(A)(i)(II), by striking ''the date of the enactment of this section'' and inserting ''May 13, 1992'';

(3) in subsection (b)(4), by striking ''clause (iii) or (iv) of paragraph (2)(B)'' and inserting ''subparagraph (B)(ii) or (D) of paragraph (2)'';

(4) in subsection (c)(1)(A), by striking ''subsection (a)(1) or (b)(2)(A)'' and inserting ''subsection (a)(1) or (b)(1)(A)'';

(5) in subsection (c)(1)(B), by striking ''subsection (a)(2) or (b)(2)(B)'' and inserting ''subsection (a)(2) or (b)(1)(B)'';

(6) in subsection (d)(3)(A)(i), by striking ''or paragraph (2)(A) or (3) of subsection (b)'' and inserting ''subparagraph (A) or (C) of subsection (b)(1)'';

(7) in subsection (d)(3)(B)(i), by striking ''clause (i), (ii), (iii), or (iv) of subsection (b)(2)(B) or subsection (b)(3)'' and inserting ''subparagraph (B) or (C) of subsection (b)(1)'';

(8) in subsection (d)(3)(B)(ii), by striking ''under subsection (b)(2)(B) or subsection (b)(3)'' and inserting ''under subparagraph (B) or (C) of subsection (b)(1)'';

(9) in subsection (j)(2), by striking ''clause (iii) or (iv) of subsection (b)(2)(B)'' and inserting ''subparagraph (B)(ii) or (D) of subsection (b)(2)''; and

(10) in subsection (l)(2)—

(A) by striking ''clauses (i) and (ii) of subsection (b)(2)(B)'' and inserting ''subparagraphs (B)(i) and (C) of subsection (b)(2)'';

(B) by striking ''Clauses (iii) and (iv) of subsection (b)(2)(B)'' and inserting ''Subparagraphs (B)(ii) and (D) of subsection (b)(2)''; and

(C) by striking ''Clause (iv) of subsection (b)(2)(B)'' and inserting ''Subparagraph (B)(ii) of subsection (b)(2)''.

○