

# Calendar No. 426

114TH CONGRESS  
2D SESSION

# S. 1622

To amend the Federal Food, Drug, and Cosmetic Act with respect to devices.

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## IN THE SENATE OF THE UNITED STATES

JUNE 18, 2015

Mr. BURR (for himself, Mr. FRANKEN, Mr. KIRK, Mr. ENZI, and Mr. ALEXANDER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

APRIL 18, 2016

Reported by Mr. ALEXANDER, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italie*]

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## A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to devices.

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 “FDA Device Account-  
5 ability Act of 2015”.

1 **SEC. 2. ENSURING LEAST BURDENSOME MEANS OF EVALU-**  
 2 **ATING DEVICES.**

3 (a) TRAINING AND OVERSIGHT OF LEAST BURDEN-  
 4 SOME REQUIREMENTS.—Section 513 of the Federal Food,  
 5 Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by  
 6 adding at the end the following:

7 “(j) TRAINING AND OVERSIGHT OF LEAST BURDEN-  
 8 SOME REQUIREMENTS.—

9 “(1) TRAINING AND ASSESSMENT.—The Sec-  
 10 retary shall—

11 “(A) ensure that each employee of the  
 12 Food and Drug Administration who is involved  
 13 in the review of premarket submissions, includ-  
 14 ing supervisors, receives training regarding the  
 15 meaning and implementation of the least bur-  
 16 densome requirements under subsections  
 17 (a)(3)(D) and (i)(1)(D) and section 515(e)(5);  
 18 and

19 “(B) periodically assess the implementa-  
 20 tion of the least burdensome requirements, in-  
 21 cluding the employee training under subpara-  
 22 graph (A) to ensure that the least burdensome  
 23 requirements are fully and consistently applied.

24 “(2) OMBUDSMAN AUDIT.—Not later than 180  
 25 calendar days after the date of enactment of the  
 26 FDA Device Accountability Act of 2015, the om-

1       budsman for any organizational unit of the Food  
2       and Drug Administration responsible for the pre-  
3       market review of devices shall—

4               “(A) conduct an audit of the training de-  
5               scribed in paragraph (1)(A);

6               “(B) include in such audit interviews of  
7               persons who are representatives of the device  
8               industry regarding their experience in the de-  
9               vice premarket review process, including with  
10              respect to the application of least burdensome  
11              concepts to premarket review and the applica-  
12              tion of postmarket requirements to facilitate  
13              premarket decisionmaking;

14              “(C) include in such audit an assessment  
15              of the measurement tools the Secretary uses to  
16              assess the implementation of the least burden-  
17              some requirements, including the effectiveness  
18              of such tools and the effectiveness of the imple-  
19              mentation of the least burdensome require-  
20              ments; and

21              “(D) within 30 calendar days of comple-  
22              tion of the audit, make such audit available—

23                      “(i) to the Committee on Health,  
24                      Education, Labor, and Pensions of the  
25                      Senate and the Committee on Energy and

1 Commerce of the House of Representa-  
2 tives; and

3 “(ii) on the Internet website of the  
4 Food and Drug Administration.”

5 (b) **PREMARKET APPLICATIONS.**—Section 515(e) of  
6 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
7 360e(e)) is amended by adding at the end the following:

8 “(5)(A) In requesting additional information with re-  
9 spect to an application under this section, the Secretary  
10 shall consider the least burdensome appropriate means  
11 necessary to demonstrate a reasonable assurance of device  
12 safety and effectiveness.

13 “(B) For purposes of subparagraph (A) the term  
14 ‘necessary’ means the minimum required information that  
15 would support a determination by the Secretary that an  
16 application provides a reasonable assurance of the safety  
17 and effectiveness of the device.

18 “(C) Nothing in this paragraph alters the standards  
19 for premarket approval of a device.

20 “(D) For purposes of this paragraph, the Secretary  
21 shall consider whether the least burdensome means of  
22 demonstrating a reasonable assurance of device safety and  
23 effectiveness would be achieved through reliance on  
24 postmarket information.”

1       (e) **RATIONALE FOR SIGNIFICANT DECISIONS RE-**  
 2 **GARDING DEVICES.**—Section 517A(a) of the Federal  
 3 Food, Drug, and Cosmetic Act (21 U.S.C. 360g-1(a)) is  
 4 amended by adding at the end the following:

5           “(3) **APPLICATION OF LEAST BURDENSOME RE-**  
 6 **QUIREMENTS.**—The substantive summary required  
 7 under this subsection shall include an explanation of  
 8 how the least burdensome requirements were consid-  
 9 ered and applied consistent with section  
 10 513(i)(1)(D) and section 513(a)(3)(D) and section  
 11 515(e)(5), as applicable.”.

12 **SEC. 3. PERMITTING NON-LOCAL INSTITUTIONAL REVIEW**  
 13 **BOARDS.**

14       (a) **IN GENERAL.**—Section 520 of the Federal Food,  
 15 Drug, and Cosmetic Act (21 U.S.C. 360(j)) is amended—

16           (1) in subsection (g)(3)—

17               (A) by striking “local” each place it ap-  
 18 pears; and

19               (B) in subparagraph (A)(i), by striking  
 20 “which has been”; and

21           (2) in subsection (m)(4)—

22               (A) by striking “local” each place it ap-  
 23 pears; and

24               (B) by amending subparagraph (A) to read  
 25 as follows:

1           “(A) in facilities in which clinical testing of de-  
2           vices is supervised by an institutional review com-  
3           mittee established in accordance with the regulations  
4           of the Secretary; and”.

5           (b) REGULATIONS.—Not later than 1 year after the  
6           date of the enactment of this Act, the Secretary of Health  
7           and Human Services shall revise or issue such regulations  
8           or guidance as may be necessary to carry out the amend-  
9           ments made by subsection (a).

10 **SEC. 4. CLARIFYING CLIA WAIVER STUDY DESIGN GUID-**  
11 **ANCE FOR IN VITRO DIAGNOSTICS.**

12           (a) DRAFT REVISED GUIDANCE.—Not later than 1  
13           year after the date of the enactment of this Act, the Sec-  
14           retary of Health and Human Services shall publish a draft  
15           guidance that—

16           (1) revises section “V. Demonstrating Insignifi-  
17           cant Risk of an Erroneous Result” – “Accuracy” of  
18           the guidance entitled “Recommendations for Clinical  
19           Laboratory Improvement Amendments of 1988  
20           (CLIA) Waiver Applications for Manufacturers of In  
21           Vitro Diagnostic Devices” and dated January 30,  
22           2008; and

23           (2) includes guidance on the appropriate use of  
24           comparable performance between a waived user and

1 a moderately complex laboratory user to dem-  
2 onstrate accuracy.

3 (b) ~~FINAL REVISED GUIDANCE.~~—The Secretary of  
4 Health and Human Services shall finalize the draft guid-  
5 ance published under subsection (a) not later than 1 year  
6 after the comment period for such draft guidance closes.

7 **SECTION 1. SHORT TITLE.**

8 *This Act may be cited as the “FDA Device Account-*  
9 *ability Act of 2016”.*

10 **SEC. 2. USE OF NONLOCAL INSTITUTIONAL REVIEW**  
11 **BOARDS FOR REVIEW OF INVESTIGATIONAL**  
12 **DEVICE EXEMPTIONS AND HUMAN DEVICE**  
13 **EXEMPTIONS.**

14 *Section 520 of the Federal Food, Drug, and Cosmetic*  
15 *Act (21 U.S.C. 360j) is amended—*

16 (1) *in subsection (g)(3)—*

17 (A) *in subparagraph (A)(i)—*

18 (i) *by striking “local”; and*

19 (ii) *by striking “which has been”; and*

20 (B) *in subparagraph (B), by striking “a*  
21 *local institutional” and inserting “an institu-*  
22 *tional”; and*

23 (2) *in subsection (m)(4)—*

24 (A) *by striking subparagraph (A) and in-*  
25 *serting the following new subparagraph:*

1           “(A) in facilities in which clinical testing of  
2           devices is supervised by an institutional review  
3           committee established in accordance with the reg-  
4           ulations of the Secretary, and”;

5           (B) in subparagraph (B), by striking “a  
6           local institutional” and inserting “an institu-  
7           tional”; and

8           (C) in the matter following subparagraph  
9           (B), by striking “local”.

10 **SEC. 3. CLIA WAIVER STUDY DESIGN GUIDANCE FOR IN**  
11 **VITRO DIAGNOSTICS.**

12           (a) *DRAFT REVISED GUIDANCE*.—Not later than 1  
13 year after the date of the enactment of this Act, the Sec-  
14 retary of Health and Human Services, acting through the  
15 Commissioner of Food and Drugs, shall publish a draft  
16 guidance that—

17           (1) revises section “V. Demonstrating Insignifi-  
18 cant Risk of an Erroneous Result” – “Accuracy” of  
19 the guidance entitled “Recommendations for Clinical  
20 Laboratory Improvement Amendments of 1988  
21 (CLIA) Waiver Applications for Manufacturers of In  
22 Vitro Diagnostic Devices” and dated January 30,  
23 2008; and



1           (2) *includes the appropriate use of comparable*  
 2           *performance between a waived user and a moderately*  
 3           *complex laboratory user to demonstrate accuracy.*

4           (b) *FINAL REVISED GUIDANCE.*—*The Secretary of*  
 5           *Health and Human Services, acting through the Commis-*  
 6           *sioner of Food and Drugs, shall finalize the draft guidance*  
 7           *published under subsection (a) not later than 1 year after*  
 8           *the comment period for such draft guidance closes.*

9           **SEC. 4. ENSURING LEAST BURDENSOME MEANS OF EVALU-**  
 10           **ATING DEVICES.**

11           (a) *TRAINING AND OVERSIGHT OF LEAST BURDEN-*  
 12           *SOME REQUIREMENTS.*—*Section 513 of the Federal Food,*  
 13           *Drug, and Cosmetic Act (21 U.S.C. 360c) is amended by*  
 14           *adding at the end the following:*

15           “(j) *TRAINING AND OVERSIGHT OF LEAST BURDEN-*  
 16           *SOME REQUIREMENTS.*—

17           “(1) *TRAINING AND ASSESSMENT.*—*The Sec-*  
 18           *retary shall—*

19           “(A) *ensure that each employee of the Food*  
 20           *and Drug Administration who is involved in the*  
 21           *review of premarket submissions, including su-*  
 22           *pervisors, receives training regarding the mean-*  
 23           *ing and implementation of the least burdensome*  
 24           *requirements under subsections (a)(3)(D) and*  
 25           *(i)(1)(D) and section 515(c)(5); and*

1           “(B) periodically assess the implementation  
2 of the least burdensome requirements, including  
3 the employee training under subparagraph (A)  
4 to ensure that the least burdensome requirements  
5 are fully and consistently applied.

6           “(2) OMBUDSMAN AUDIT.—Not later than 18  
7 months after the date of enactment of the FDA Device  
8 Accountability Act of 2016, the ombudsman for any  
9 organizational unit of the Food and Drug Adminis-  
10 tration responsible for the premarket review of devices  
11 shall—

12           “(A) conduct an audit of the training de-  
13 scribed in paragraph (1)(A), including the effec-  
14 tiveness of such training in implementing the  
15 least burdensome requirements;

16           “(B) include in such audit interviews of  
17 persons who are representatives of the device in-  
18 dustry regarding their experience in the device  
19 premarket review process, including with respect  
20 to the application of least burdensome concepts  
21 to premarket review and decisionmaking;

22           “(C) include in such audit a list of the  
23 measurement tools the Secretary uses to assess  
24 the implementation of the least burdensome re-  
25 quirements, including those referenced in para-

1 *graph (1)(B) and section 517A(a)(3), and may*  
2 *also provide feedback on the effectiveness of such*  
3 *tools in the implementation of the least burden-*  
4 *some requirements;*

5 *“(D) summarize the findings of such audit*  
6 *in a final audit report; and*

7 *“(E) within 30 calendar days of completion*  
8 *of such final audit report, make such final audit*  
9 *report available—*

10 *“(i) to the Committee on Health, Edu-*  
11 *cation, Labor, and Pensions of the Senate*  
12 *and the Committee on Energy and Com-*  
13 *merce of the House of Representatives; and*

14 *“(ii) on the Internet website of the*  
15 *Food and Drug Administration.”.*

16 *(b) PREMARKET APPLICATIONS.—Section 515(c) of the*  
17 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e(c))*  
18 *is amended by adding at the end the following:*

19 *“(5)(A) In requesting additional information*  
20 *with respect to an application under this section, the*  
21 *Secretary shall consider the least burdensome appro-*  
22 *priate means necessary to demonstrate a reasonable*  
23 *assurance of device safety and effectiveness.*

24 *“(B) For purposes of subparagraph (A), the*  
25 *term ‘necessary’ means the minimum required*

1           *information that would support a determination*  
2           *by the Secretary that an application provides a*  
3           *reasonable assurance of the safety and effective-*  
4           *ness of the device.*

5           “(C) *For purposes of this paragraph, the*  
6           *Secretary shall consider the role of postmarket*  
7           *information in determining the least burdensome*  
8           *means of demonstrating a reasonable assurance*  
9           *of device safety and effectiveness.*

10           “(D) *Nothing in this paragraph may alter*  
11           *the standards for premarket approval of a de-*  
12           *vice.”.*

13           *(c) RATIONALE FOR SIGNIFICANT DECISIONS REGARD-*  
14           *ING DEVICES.—Section 517A(a) of the Federal Food, Drug,*  
15           *and Cosmetic Act (21 U.S.C. 360g–1(a)) is amended by*  
16           *adding at the end the following:*

17           “(3) *APPLICATION OF LEAST BURDENSOME RE-*  
18           *QUIREMENTS.—The substantive summary required*  
19           *under this subsection shall include a brief statement*  
20           *regarding how the least burdensome requirements*  
21           *were considered and applied consistent with section*  
22           *513(i)(1)(D), section 513(a)(3)(D), and section*  
23           *515(c)(5), as applicable.”.*



Calendar No. 426

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

**S. 1622**

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**A BILL**

To amend the Federal Food, Drug, and Cosmetic  
Act with respect to devices.

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APRIL 18, 2016

Reported with an amendment