

**[DISCUSSION DRAFT]**

114<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

**H. R.** \_\_\_\_\_

To establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, and for other purposes.

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IN THE HOUSE OF REPRESENTATIVES

M. \_\_\_\_\_ introduced the following bill; which was referred to the  
Committee on \_\_\_\_\_

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**A BILL**

To establish a regulatory framework for in vitro clinical tests that advances innovation for patient benefit, protects patients, provides a predictable and timely path to market, ensures reasonable risk-based regulation, avoids duplicative regulation, advances precision medicine, and applies the same regulatory principles to the same activity regardless of entity type, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the  
3 “\_\_\_\_\_ Act of 2015”.

4 (b) TABLE OF CONTENTS.—The table of contents of  
5 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. In vitro clinical tests defined.
- Sec. 3. Regulation of in vitro clinical tests.
- Sec. 4. FDA fees.
- Sec. 5. Certification of laboratories (CLIA).
- Sec. 6. Transitional provisions.

6 **SEC. 2. IN VITRO CLINICAL TESTS DEFINED.**

7 (a) DEFINITIONS.—Section 201 of the Federal Food,  
8 Drug, and Cosmetic Act (21 U.S.C. 321) is amended by  
9 adding at the end the following:

10 “(ss)(1) The term ‘in vitro clinical test’—

11 “(A) means a laboratory test protocol or fin-  
12 ished product intended by its developer to be used  
13 in the collection, preparation, analysis, or in vitro  
14 clinical examination of specimens taken or derived  
15 from the human body, solely or principally for the  
16 purpose of identifying, measuring, predicting, moni-  
17 toring, or assisting in selecting treatment for, a dis-  
18 ease or other condition;

19 “(B) excludes any test that—

20 “(i) meets the definition of a ‘biological  
21 product’ under section 351 of the Public Health  
22 Service Act; and

1 “(ii) is intended to—

2 “(I) screen human blood, human cells,  
3 tissues, cellular or tissue-based products  
4 (HCT/Ps), or organs for infectious dis-  
5 eases; or

6 “(II) determine the compatibility of a  
7 donor or patient to ensure the safe trans-  
8 fusion or transplantation of blood, human  
9 cells, tissues, cellular or tissue-based prod-  
10 ucts (HCT/Ps), or organs; and

11 “(C) excludes any test intended by its developer  
12 solely for nonclinical use, such as a test intended by  
13 its developer solely for purposes of forensic testing,  
14 drugs-of-abuse testing for employment, insurance,  
15 and genetic testing for nonclinical purposes.

16 “(2) The term ‘laboratory test protocol’—

17 “(A) means the final design of a test not pro-  
18 duced, provided, purchased, or sold as a finished  
19 product; and

20 “(B) excludes standard operating procedures  
21 for performance of an in vitro clinical test.

22 “(3) The term ‘finished product’—

23 “(A) means an article of personal property  
24 other than a laboratory test protocol that is suitable

1 for use and capable of functioning for its intended  
2 purpose without further production activity; and

3 “(B) excludes any component, part, or raw ma-  
4 terial.”.

5 (b) EXCLUSION FROM DEFINITIONS OF DRUGS, DE-  
6 VICES, AND BIOLOGICAL PRODUCTS.—

7 (1) DRUG DEFINITION.—Section 201(g)(1) of  
8 the Federal Food, Drug, and Cosmetic Act (21  
9 U.S.C. 321(g)(1)) is amended by striking “means”  
10 and inserting “excludes any in vitro clinical test and  
11 any component, part, raw material, or accessory of  
12 an in vitro clinical test and means”.

13 (2) DEVICE DEFINITION.—Section 201(h) of  
14 the Federal Food, Drug, and Cosmetic Act (21  
15 U.S.C. 321(h)) is amended by inserting “excludes  
16 any in vitro clinical test and any component, part,  
17 raw material, or accessory of an in vitro clinical test  
18 and” before “(except when”.

19 (3) BIOLOGICAL PRODUCT.—Section 351(i)(1)  
20 of the Public Health Service Act (42 U.S.C.  
21 262(i)(1)) is amended by striking “means” and in-  
22 sserting “excludes any in vitro clinical test and any  
23 component, part, raw material, or accessory of an in  
24 vitro clinical test and means”.

1 **SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.**

2 (a) IN GENERAL.—Chapter V of the Federal Food,  
3 Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amend-  
4 ed by adding at the end the following new subchapter:

5 **“Subchapter J—In Vitro Clinical Tests**

6 **“SEC. 590. REGULATION OF IN VITRO CLINICAL TEST DE-**  
7 **VELOPMENT ACTIVITIES.**

8 “(a) IN GENERAL.—The Secretary of Health and  
9 Human Services shall, in accordance with the provisions  
10 of this subtitle, establish procedures and processes for the  
11 regulation of in vitro clinical tests.

12 “(b) SCOPE OF AUTHORITY.—

13 “(1) IN GENERAL.—The design, development,  
14 validation, production, manufacture, preparation,  
15 propagation, assembly, and processing of an in vitro  
16 clinical test—

17 “(A) shall be regulated by the Secretary  
18 under this subchapter; and

19 “(B) shall not be regulated by the Sec-  
20 retary under section 353 of the Public Health  
21 Service Act.

22 “(2) LIMITATIONS.—

23 “(A) LABORATORY OPERATIONS.—The  
24 provisions of this subchapter shall not apply to  
25 laboratory operations, as defined in section 353  
26 of the Public Health Service Act.

1                   “(B) PUBLIC HEALTH SURVEILLANCE AC-  
2                   TIVITIES.—

3                   “(i) IN GENERAL.—The provisions of  
4                   this subchapter shall not apply to a test in-  
5                   tended to be used solely for public health  
6                   surveillance.

7                   “(ii) DEFINITION.—In this subpara-  
8                   graph, the term ‘public health surveillance’  
9                   means ongoing systematic activities, in-  
10                  cluding collection, analysis, and interpreta-  
11                  tion of health-related data, essential to  
12                  planning, implementing, and evaluating  
13                  public health practice.

14                  “(C) OTHER LIMITATIONS.—

15                  “(i) NO INTERFERENCE WITH  
16                  HEALTH CARE PRACTICE.—Nothing in this  
17                  subchapter shall be construed to limit or  
18                  interfere with the authority of a health  
19                  care practitioner to prescribe, order, or use  
20                  the results of an in vitro clinical test for  
21                  any condition or disease within a legitimate  
22                  health care practitioner-patient relation-  
23                  ship.

24                  “(ii) OTHER ACTIVITIES.—The Sec-  
25                  retary shall not regulate the following ac-

1                   activities under this subchapter when under-  
2                   taken by a pathologist, laboratory physi-  
3                   cian, other physician, laboratory scientist,  
4                   or other health care practitioner:

5                   “(I) Recommending appropriate  
6                   patient-specific in vitro clinical tests.

7                   “(II) Rendering a diagnosis as a  
8                   result of a specimen review.

9                   “(III) Interpreting data gen-  
10                  erated by an in vitro clinical test.

11                  “(IV) Dialog with a health care  
12                  practitioner regarding scientific infor-  
13                  mation about an in vitro clinical test.

14                  “(V) Assessing in vitro clinical  
15                  test output related to a specific pa-  
16                  tient.

17                  “(c) AGENCY CENTER.—Not later than 90 calendar  
18                  days after the date of enactment of the \_\_\_\_\_ Act of  
19                  2015, the Secretary shall establish within the Food and  
20                  Drug Administration the Center for In Vitro Clinical  
21                  Tests, which shall report to the Commissioner of Food and  
22                  Drugs in the same manner as the other agency centers  
23                  within the Food and Drug Administration. The Center  
24                  shall be responsible for the implementation of this sub-  
25                  chapter and closely related matters assigned by the Com-

1 missioner. Senior management of the Center shall include  
2 at least one person with management experience in clinical  
3 laboratory operations.

4 “(d) DEFINITIONS.—In this subchapter:

5 “(1) The terms ‘analytical validity’ and ‘analytically valid’ mean, with respect to an in vitro clinical  
6 test, the ability of the test to identify, measure, calculate, or analyze one or more analytes, biomarkers,  
7 substances, or other targets sought to be identified,  
8 measured, calculated, or analyzed by the test, as  
9 measured by, for example, sensitivity, specificity, accuracy, precision, reference range, and reportable  
10 range.  
11 range.

12 “(2) The terms ‘clinical validity’ and ‘clinically valid’—

13 “(A) mean, with respect to an in vitro clinical test, the reliability and accuracy with which  
14 the test—  
15 the test—

16 “(i) identifies, measures, predicts, monitors, or assists in selecting treatment  
17 for, a disease or condition in humans; or  
18

19 “(ii) identifies, measures, predicts, or monitors characteristics related to an individual’s clinical status; and  
20  
21

22 “(B) excludes clinical utility.  
23  
24  
25

1           “(3) The term ‘developer’ means the person re-  
2           sponsible for the design, development, validation,  
3           production, manufacture, preparation, propagation,  
4           assembly, processing, or initial importation of an in  
5           vitro clinical test.

6           “(4)(A) The term ‘intended use’ means the de-  
7           veloper’s stated purpose for the in vitro clinical test.

8           “(B) The intended use of an in vitro clinical  
9           test shall not be determined using any of the fol-  
10          lowing:

11           “(i) Scientific or medical communication or  
12           collaboration between the developer of the in  
13           vitro clinical test and the operator of a labora-  
14           tory or another health care practitioner that  
15           uses or may use the test.

16           “(ii) Communication between the developer  
17           of an in vitro clinical test and a prospective  
18           purchaser or user regarding the developer’s in  
19           vitro clinical test then in development.

20           “(iii)(I) Health care economic information  
21           provided to an entity for the purpose of car-  
22           rying out such entity’s responsibilities for the  
23           selection of in vitro clinical tests for coverage,  
24           reimbursement, or inclusion in a formulary.

1           “(II) In this clause, the term ‘health care  
2           economic information’ means any analysis that  
3           identifies, measures, or compares the economic  
4           consequences of the use of an in vitro clinical  
5           test to—

6                   “(aa) another in vitro clinical test;

7                   “(bb) another test or intervention; or

8                   “(cc) no test or intervention.

9           “(5) The terms ‘laboratory’, ‘laboratory oper-  
10          ations’, and ‘standard operating procedures’ have  
11          the meanings given to such terms in section  
12          353(a)(2) of the Public Health Service Act.

13          “(6) The term ‘mitigating measures’ means,  
14          with respect to an in vitro clinical test, one or more  
15          measures that the Secretary determines, based on  
16          available evidence, are necessary to provide a reason-  
17          able assurance of the analytical validity and clinical  
18          validity, or probable clinical validity, as applicable, of  
19          an in vitro clinical test for its intended use, in a par-  
20          ticular risk classification.

21          “(7) The term ‘offer’ means to make available  
22          for purchase, order, prescription, or use.

23          “(8) The term ‘platform’ means an in vitro clin-  
24          ical test that is hardware intended by the hardware’s  
25          developer to be used with one or more in vitro clin-

1 ical tests to generate a clinical test result, including  
2 software used to effectuate the hardware's  
3 functionality.

4 “(9) The term ‘reasonable assurance’ means the  
5 degree of valid scientific evidence for in vitro clinical  
6 tests needed to demonstrate analytical validity or  
7 clinical validity, for the intended use of the in vitro  
8 clinical test, as applicable, which may vary based  
9 upon the relevant—

10 “(A) population size;

11 “(B) disease state;

12 “(C) demographic representation;

13 “(D) limit of detection or analytical sensi-  
14 tivity;

15 “(E) disease or condition;

16 “(F) type of use claim (such as predictive,  
17 prognostic, diagnostic, monitoring, treatment  
18 selection, and screening uses);

19 “(G) risk classification;

20 “(H) availability of warnings and restric-  
21 tions or other mitigating measures;

22 “(I) use environment;

23 “(J) user;

24 “(K) feasibility of data collection;

1           “(L) impact of requiring additional data  
2           collection on innovation;

3           “(M) experience with similar in vitro clin-  
4           ical tests;

5           “(N) ease of use; or

6           “(O) other factors.

7           “(10)(A) The term ‘valid scientific evidence’  
8           means, with respect to an in vitro clinical test, evi-  
9           dence—

10           “(i) which has been generated and  
11           evaluated by persons qualified by training  
12           and experience to do so, using procedures  
13           generally accepted by other persons so  
14           qualified; and

15           “(ii) for which it can be fairly and re-  
16           sponsibly concluded by qualified experts  
17           that there is a reasonable assurance of an-  
18           alytical validity and clinical validity, or  
19           probable clinical validity where applicable,  
20           of the in vitro clinical test for its intended  
21           use.

22           “(B) Subject to subparagraph (A), the term  
23           ‘valid scientific evidence’ may, with respect to an in  
24           vitro clinical test, include, alone or in combination—

25           “(i) peer reviewed literature;

- 1 “(ii) clinical guidelines;
- 2 “(iii) reports of significant human experi-
- 3 ence with an offered in vitro clinical test;
- 4 “(iv) bench studies;
- 5 “(v) case studies or histories;
- 6 “(vi) clinical data;
- 7 “(vii) consensus standards;
- 8 “(viii) reference standards;
- 9 “(ix) data registries;
- 10 “(x) postmarket data; and
- 11 “(xi) clinical trials.

12 **“SEC. 590A. CLASSIFICATION OF IN VITRO CLINICAL TESTS.**

13 “(a) RISK CLASSIFICATION.—

14 “(1) IN GENERAL.—The Secretary shall, based

15 on the intended use of an in vitro clinical test, estab-

16 lish the following risk classes:

17 “(A) High-risk.

18 “(B) Moderate-risk.

19 “(C) Low-risk.

20 “(2) HIGH-RISK CLASS.—An in vitro clinical

21 test shall be regulated as high-risk if—

22 “(A) a clinically significant inaccurate re-

23 sult for the intended use would cause serious or

24 irreversible harm, or death, to the patient or

25 public based on failure to treat, incorrect treat-

1           ment, invasive procedures, or prolonged dis-  
2           ability if such inaccurate result were undetected  
3           when used as intended in medical practice;

4           “(B) none of the factors specified in para-  
5           graph (5) are available to prevent or detect  
6           such inaccurate result or otherwise mitigate the  
7           risk of such inaccurate result; and

8           “(C) the risk of adverse patient impact or  
9           adverse public health impact caused by an inac-  
10          curate result is not remote.

11          “(3) MODERATE-RISK CLASS.—An in vitro clin-  
12          ical test shall be regulated as moderate-risk if—

13               “(A) the test meets the criteria specified in  
14               paragraph (2)(A) for classification as high-risk,  
15               but one or more mitigating factors described in  
16               paragraph (5) is available to prevent or detect  
17               the clinically significant inaccurate result or  
18               otherwise mitigate the risk; or

19               “(B)(i) a clinically significant inaccurate  
20               result for the intended use would cause non-life-  
21               threatening injury, injury that is medically re-  
22               versible, or delay in necessary treatment if such  
23               inaccurate result were undetected when used as  
24               intended in medical practice;

1           “(ii) none of the mitigating factors de-  
2           scribed in paragraph (5) are available to pre-  
3           vent or detect such inaccurate result or other-  
4           wise mitigate the risk of such inaccurate result;  
5           and

6           “(iii) the risk of adverse patient impact or  
7           adverse public health impact caused by an inac-  
8           curate result is not remote.

9           “(4) LOW-RISK CLASS.—An in vitro clinical test  
10          shall be regulated as low risk if—

11           “(A) the test meets the criteria for classi-  
12           fication as moderate-risk specified in subpara-  
13           graph (3)(B)(i), but one or more mitigating fac-  
14           tors described in paragraph (5) is available to  
15           prevent or detect the clinically significant inac-  
16           curate result or otherwise mitigate the risk;

17           “(B) a clinically significant inaccurate re-  
18           sult for the intended use would cause minimal  
19           or no harm, immediately reversible harm, or no  
20           disability if such inaccurate result were unde-  
21           tected when used as intended in medical prac-  
22           tice; or

23           “(C) the risk of adverse patient impact or  
24           adverse public health impact caused by an inac-  
25           curate result is remote.

1           “(5) MITIGATING FACTORS.—A mitigating fac-  
2           tor described in this paragraph is one of the fol-  
3           lowing:

4                   “(A) The test’s technology and clinical use  
5           are well characterized.

6                   “(B) Clinical presentation.

7                   “(C) The availability of—

8                           “(i) other tests, such as confirmatory  
9                           or adjunctive tests; or

10                           “(ii) relevant materials standards.

11                   “(D) Such other factors as the Secretary  
12           considers necessary.

13                   “(E) Mitigating measures.

14           “(b) PRECLASSIFICATION MEETING.—Before submit-  
15           ting a request under subsection (c) or (d) for classification  
16           or reclassification, as applicable, of an in vitro clinical  
17           test—

18                   “(1) the developer of the test may submit to the  
19           Secretary a written request for a meeting to discuss  
20           and provide information relating to classification or  
21           reclassification of the test; and

22                   “(2) upon receipt of such a request, the Sec-  
23           retary shall—

1           “(A) within 30 calendar days after such  
2 receipt, meet with the developer submitting the  
3 request; and

4           “(B) within 30 calendar days after such  
5 meeting, provide a written record or response  
6 describing the issues discussed and conclusions  
7 reached in the meeting.

8           “(c) CLASSIFICATION PROCESS.—

9           “(1) CLASSIFICATION BY OPERATION OF  
10 LAW.—If a type of in vitro clinical test has been  
11 classified by the Secretary under this section, and  
12 such classification remains in effect, any in vitro  
13 clinical test within such type is deemed to be in the  
14 same class.

15           “(2) CLASSIFICATION BY SECRETARY.—

16           “(A) SUBMISSION OF REQUEST.—In the  
17 case of an in vitro clinical test that is not clas-  
18 sified pursuant to paragraph (1) or subsection  
19 (e), the developer of the in vitro clinical test  
20 may submit a request to the Secretary for clas-  
21 sification of the in vitro clinical test.

22           “(B) FORM OF REQUEST.—A request  
23 under subparagraph (A) shall be in such form,  
24 submitted in such manner, and contain such in-  
25 formation as the Secretary may require. At a

1           minimum, any such request shall contain each  
2           of the following:

3                   “(i) A detailed description of the in  
4                   vitro clinical test, including its intended  
5                   uses, a description of its composition, and  
6                   an explanation of the mechanism by which  
7                   it functions.

8                   “(ii) A recommended classification, in-  
9                   cluding a rationale for the recommended  
10                  classification.

11                  “(iii) Proposed mitigating measures, if  
12                  any, and an explanation of how the pro-  
13                  posed mitigating measures support the rec-  
14                  ommended classification.

15                  “(C) DISPOSITION OF REQUEST.—The  
16                  Secretary shall—

17                   “(i) not later than 60 calendar days  
18                   after receiving a request under subpara-  
19                   graph (B), issue an administrative order—

20                           “(I) rejecting, modifying, or ac-  
21                           cepting the recommended classifica-  
22                           tion of the in vitro clinical test; and

23                           “(II) explaining the reasons for  
24                           such decision and in the case of a  
25                           modification or rejection, the reason

1 for the modification or rejection, in-  
2 cluding the reasons why the informa-  
3 tion and explanations submitted by  
4 the developer (including any valid sci-  
5 entific evidence for the in vitro clinical  
6 test involved) do not support the rec-  
7 ommended classification; and

8 “(ii) not later than 60 calendar days  
9 after issuing an order under clause (i) with  
10 respect to a recommended classification for  
11 an in vitro clinical test—

12 “(I) publish a notice in the Fed-  
13 eral Register announcing the classi-  
14 fication; and

15 “(II) revise, as appropriate, regu-  
16 lations to include such classification.

17 “(iii) revoke or revise, as appropriate,  
18 any regulation or requirement issued in  
19 connection with the in vitro clinical test’s  
20 previous classification

21 “(D) CLASSIFICATION APPEALS.—In the  
22 case of a modification or rejection of a rec-  
23 ommended classification of an in vitro clinical  
24 test by order issued by the Secretary under sub-  
25 paragraph (C)(i) or the Secretary’s failure to

1 issue an order within the timeframes specified  
2 in such subparagraph—

3 “(i) such modification or rejection or  
4 failure shall be treated as final and imme-  
5 diately subject to appeal under section  
6 590G; and

7 “(ii) not later than 180 calendar days  
8 after the date on which such modification  
9 or rejection is issued, the developer of the  
10 test may, as part of such an appeal, re-  
11 quest review of the recommended classi-  
12 fication by an advisory panel.

13 “(3) MULTIPLE INTENDED USES.—If a type of  
14 in vitro clinical test has multiple intended uses, any  
15 such test shall be classified based on the intended  
16 use of the highest risk class.

17 “(4) ACCESSORIES; PLATFORMS.—

18 “(A) ACCESSORIES.—

19 “(i) IN GENERAL.—An in vitro clinical  
20 test, that is intended by its developer to be  
21 used as an accessory to another in vitro  
22 clinical test, shall be classified according to  
23 its intended use and independently of any  
24 classification of any in vitro clinical test  
25 with which it is used.

1                   “(ii) DEFINITION.—In this subpara-  
2                   graph, the term ‘accessory’ means a stand-  
3                   alone item intended by its developer to be  
4                   used in conjunction with one or more par-  
5                   ticular in vitro clinical tests to enable or  
6                   assist the in vitro clinical test in per-  
7                   forming its intended use.

8                   “(B) PLATFORMS.—A platform shall be  
9                   classified and regulated under this title sepa-  
10                  rately from the in vitro clinical test with which  
11                  it is used and shall be classified as low-risk. An  
12                  in vitro clinical test intended to be performed  
13                  on the platform shall be classified according to  
14                  its intended use and independently of the plat-  
15                  form.

16                  “(d) RECLASSIFICATION PROCESS.—

17                  “(1) IN GENERAL.—Based on new information  
18                  respecting an in vitro clinical test when used in ac-  
19                  cordance with its intended use, the Secretary may,  
20                  upon the Secretary’s own initiative or upon petition  
21                  of an interested person, by administrative order pub-  
22                  lished in the Federal Register—

23                  “(A) change such in vitro clinical test’s  
24                  classification; and

1           “(B) revoke or revise, as appropriate, any  
2           regulation or requirement issued in connection  
3           with the in vitro clinical test’s previous classi-  
4           fication.

5           “(2) RECOMMENDATIONS OF ADVISORY  
6           PANEL.—In publishing an order under paragraph  
7           (1)—

8           “(A) the Secretary may secure, or the in-  
9           terested person may require that the Secretary  
10          secure, from an advisory panel, a recommenda-  
11          tion respecting the proposed change in the in  
12          vitro clinical test’s classification; and

13          “(B) the Secretary shall publish in the  
14          Federal Register any recommendation sub-  
15          mitted to the Secretary by the panel respecting  
16          such change.

17          “(3) MEMBERSHIP OF ADVISORY PANELS.—Any  
18          advisory panel convened to review the classification  
19          change shall include interested persons with knowl-  
20          edge of in vitro clinical tests, laboratory operations,  
21          and the use of in vitro clinical tests.

22          “(4) DOWN-CLASSIFICATION.—

23          “(A) IN GENERAL.—If the Secretary, upon  
24          the Secretary’s own initiative or upon petition,  
25          intends to make a down-classification of an in

1           in vitro clinical test, the Secretary shall publish a  
2           notice in the Federal Register of such intent.

3           Such notice shall—

4                   “(i) in the case of the Secretary in-  
5                   tending to modify or add mitigating meas-  
6                   ures applicable to the test involved—

7                           “(I) describe and provide jus-  
8                           tification for such mitigating meas-  
9                           ures; and

10                           “(II) provide for a 90-calendar-  
11                           day public comment period; and

12                           “(ii) in the case of the Secretary not  
13                           intending to modify or add any such miti-  
14                           gating measures, provide for a 60-cal-  
15                           endar-day public comment period.

16                   “(B) PREVENTION OF UP-CLASSIFICA-  
17                   TION.—In the case of an in vitro clinical test  
18                   that the Secretary determines would be up-clas-  
19                   sified but for the withdrawal, modification, or  
20                   addition of mitigating measures applicable to an  
21                   in vitro clinical test, the Secretary shall publish  
22                   in the Federal Register a notice of the Sec-  
23                   retary’s intent to withdraw, modify, or add such  
24                   mitigating measures. Such notice shall—

1 “(i) describe and provide justification  
2 for such mitigating measures; and

3 “(ii) provide for a 90-calendar-day  
4 public comment period.

5 “(C) FINAL DETERMINATION.—Not later  
6 than 60 calendar days after the close of the ap-  
7 plicable public comment period under subpara-  
8 graph (A) or (B), the Secretary shall—

9 “(i) decide whether to make the down-  
10 classification of the in vitro clinical test in-  
11 volved;

12 “(ii) publish a notice of such decision  
13 in the Federal Register;

14 “(iii) if the Secretary decides to make  
15 the down-classification, publish an admin-  
16 istrative order—

17 “(I) in accordance with para-  
18 graph (1); and

19 “(II) describing and providing  
20 justifications for any mitigating meas-  
21 ures applicable to such down-classi-  
22 fication; and

23 “(iv) revoke or revise, as appropriate,  
24 any regulation or requirement issued in

1 connection with the in vitro clinical test's  
2 previous classification.

3 “(D) TRANSITION TO MITIGATING MEAS-  
4 URES.—When the Secretary establishes a miti-  
5 gating measure, including any mitigating meas-  
6 ure established pursuant to subsection (d)(4),  
7 specifying a new or different performance  
8 standard, the Secretary shall provide an appro-  
9 priate transition period with respect to—

10 “(i) in vitro clinical tests under pre-  
11 market review; and

12 “(ii) in vitro clinical tests not under  
13 premarket review, but for which the miti-  
14 gating measures are inconsistent with doc-  
15 umented advice provided to the developer  
16 by the Food and Drug Administration.

17 “(5) UP-CLASSIFICATION.—In the case of a  
18 proposed up-classification of an in vitro clinical test,  
19 the Secretary—

20 “(A) shall make the up-classification by  
21 administrative order;

22 “(B) shall revoke or revise, as appropriate,  
23 any regulation or requirement issued in connec-  
24 tion with the in vitro clinical test's previous  
25 classification; and

1           “(C) shall not delegate authority to make  
2           the up-classification to any employee or official  
3           other than the chief scientific officer of the  
4           Center for In Vitro Clinical Tests or another  
5           member of the senior management of such Cen-  
6           ter.

7           “(6) RECLASSIFICATION APPEALS.—In the case  
8           of a modification or rejection of a recommended  
9           classification change of an in vitro clinical test under  
10          paragraph (1) or failure to make a determination  
11          with respect to a down-classification within the time-  
12          frame specified in paragraph (4)(C)—

13           “(A) such modification, rejection, or failure  
14           shall be treated as final and immediately sub-  
15           ject to appeal under section 590G; and

16           “(B) not later than 180 calendar days  
17           after the date of such modification, rejection, or  
18           failure, the developer of the test may, as part  
19           of such an appeal, request review of the rec-  
20           ommended classification by an advisory panel.

21          “(e) INITIAL CLASSIFICATION OF PREVIOUSLY CLAS-  
22          SIFIED IN VITRO CLINICAL TESTS.—

23           “(1) IN GENERAL.—An in vitro clinical test  
24           classified under section 513(a) as of the date of en-

1 actment of the \_\_\_\_\_ Act of 2015 shall be  
2 classified as follows:

3 “(A) An in vitro clinical test classified in  
4 class I under section 513(a)(1)(A), as of such  
5 date, is deemed to be classified as a low-risk in  
6 vitro clinical test.

7 “(B) An in vitro clinical test classified as  
8 class II under section 513(a)(1)(B), as of such  
9 date, is deemed to be classified as a moderate-  
10 risk in vitro clinical test.

11 “(C) An in vitro clinical test classified as  
12 class III under section 513(a)(1)(C), as of such  
13 date, is deemed to be classified as a high-risk  
14 in vitro clinical test.

15 “(2) CONTINUED APPLICATION OF MITIGATING  
16 MEASURES.—An in vitro clinical test described in  
17 paragraph (1) that is subject to one or more miti-  
18 gating measures as of the date specified in such  
19 paragraph shall continue to be subject to such miti-  
20 gating measures after such date, unless—

21 “(A) the classification of the test is  
22 changed under this subsection; or

23 “(B) the mitigating measures applicable to  
24 such classification are changed pursuant to this  
25 subsection.

1           “(3) PUBLIC COMMENT.—Not later than 60  
2           calendar days after the date of enactment of the  
3           \_\_\_\_\_ Act of 2015, the Secretary shall—

4                   “(A) publish a notice in the Federal Reg-  
5           ister that—

6                           “(i) identifies, with supporting sci-  
7                           entific rationale, all in vitro clinical tests  
8                           for which the Secretary believes the classi-  
9                           fication pursuant to paragraph (1) is in-  
10                          correct;

11                           “(ii) requests that interested per-  
12                          sons—

13                                   “(I) notify the Secretary of any  
14                                   in vitro clinical test for which the in-  
15                                   terested person believes the classifica-  
16                                   tion pursuant to paragraph (1) is in-  
17                                   correct; and

18                                   “(II) provide supporting scientific  
19                                   rationale for such belief; and

20                           “(iii) requests that interested per-  
21                          sons—

22                                   “(I) notify the Secretary of any  
23                                   in vitro clinical test offered as of the  
24                                   date of the enactment of the \_\_\_\_\_  
25                                   Act of 2015, which was not classified

1 under section 513(a) as of such date;  
2 and

3 “(II) provide a suggested classi-  
4 fication with supporting scientific ra-  
5 tionale; and

6 “(B) provide a 120-calendar-day public  
7 comment period with respect to such notice.

8 “(4) REVIEW AND RECOMMENDATIONS BY AD-  
9 VISORY PANELS.—

10 “(A) IN GENERAL.—Not later than 90 cal-  
11 endar days after the date of enactment of the  
12 \_\_\_\_\_ Act of 2015, the Secretary shall iden-  
13 tify or establish one or more advisory panels (in  
14 this subsection referred to as an ‘advisory  
15 panel’)—

16 “(i) to review and consider the classi-  
17 fication of each in vitro clinical test identi-  
18 fied by the Secretary or an interested per-  
19 son pursuant to paragraph (3); and

20 “(ii) to recommend the appropriate  
21 classification of each such test in accord-  
22 ance with this section.

23 “(B) MEMBERSHIP.—The members of an  
24 advisory panel shall include a balanced rep-  
25 resentation of interested persons representing

1 physicians, consumers, and the in vitro clinical  
2 test manufacturing and laboratory industries.

3 “(C) INAPPLICABLE REQUIREMENTS.—  
4 Section 14 of the Federal Advisory Committee  
5 Act shall not apply to the duration of a panel  
6 established under this paragraph.

7 “(5) TIMING OF RECOMMENDATIONS.—

8 “(A) ASSIGNMENT TO ADVISORY PANEL.—  
9 Not later than 180 calendar days after the close  
10 of the public comment period under paragraph  
11 (3)(B) with respect to an in vitro clinical test,  
12 the Secretary shall direct the respective advi-  
13 sory panel to conduct the review required by  
14 paragraph (4).

15 “(B) ISSUANCE OF RECOMMENDATION.—  
16 Not later than 1 year after the Secretary di-  
17 rects an advisory panel to review the classifica-  
18 tion of an in vitro clinical test under subpara-  
19 graph (A), the advisory panel shall, after taking  
20 into consideration all public comments and, at  
21 the advisory panel’s discretion, holding public  
22 meetings, provide to the Secretary the advisory  
23 panel’s recommended classification of the in  
24 vitro clinical test.

25 “(6) CLASSIFICATION DETERMINATION.—

1           “(A) CLASSIFICATION.—Not later than  
2           180 calendar days after the date on which the  
3           Secretary receives the recommendation of an  
4           advisory panel with respect to the classification  
5           of an in vitro clinical test under paragraph (5),  
6           the Secretary shall by administrative order pub-  
7           lished in the Federal Register—

8                   “(i) classify the in vitro clinical test in  
9                   accordance with the classes specified in  
10                  this section and publish such classification  
11                  in the Federal Register;

12                   “(ii) if such classification differs from  
13                   the classification recommended by the ad-  
14                   visory panel, specifically rebut the  
15                   advisory’s panel’s classification with sci-  
16                   entific evidence;

17                   “(iii) in the case of an up-classifica-  
18                   tion, include a public health justification  
19                   demonstrating the need for up-classifica-  
20                   tion; and

21                   “(iv) subject to a final classification  
22                   determination under subparagraph (C)(iii),  
23                   revoke or revise, as appropriate, any regu-  
24                   lation or requirement issued in connection

1 with the in vitro clinical test's previous  
2 classification.

3 “(B) FINALITY OF CLASSIFICATION.—Sub-  
4 ject to subparagraph (C), a classification under  
5 subparagraph (A)(i) is deemed to be final upon  
6 publication.

7 “(C) EXCEPTION FOR UP-CLASSIFICA-  
8 TION.—With respect to any up-classification  
9 published under subparagraph (A), the Sec-  
10 retary—

11 “(i) shall provide a 60-calendar-day  
12 period for public comment;

13 “(ii) shall not delegate authority to  
14 make the up-classification to any employee  
15 or official other than the chief scientific of-  
16 ficer of the Center for In Vitro Clinical  
17 Tests or another member of the senior  
18 management of such Center; and

19 “(iii) not later than 90 calendar days  
20 after the close of the public comment pe-  
21 riod under clause (i), shall publish in the  
22 Federal Register the final classification for  
23 such in vitro clinical test.

24 “(7) INACTION BY THE SECRETARY.—If the  
25 Secretary fails to issue a final classification deter-

1       mination for an in vitro clinical test or type of in  
2       vitro clinical test within the timeframes described in  
3       paragraph (6), it shall be presumed that the classi-  
4       fication recommended by the advisory panel is the  
5       final classification of the in vitro clinical test or type  
6       of in vitro clinical test. Not later than 90 calendar  
7       days after the timeframes described in paragraph  
8       (6), the Secretary shall publish in the Federal Reg-  
9       ister final classification determinations for all such  
10      in vitro clinical tests and types of in vitro clinical  
11      tests taking into account the presumed classification.  
12      If the Secretary determines that the final classifica-  
13      tion differs from the presumed classification, the  
14      Secretary shall rebut such presumption using sci-  
15      entific evidence in the Federal Register.

16           “(8) DEEMED CLASSIFICATION TO BECOME  
17      FINAL.—The deemed classification under paragraph  
18      (1) shall be the final classification of any in vitro  
19      clinical test not submitted to an advisory panel pur-  
20      suant to paragraph (5).

21           “(9) APPEAL OF CLASSIFICATION.—Not later  
22      than 60 calendar days after the date of the final  
23      classification of an in vitro clinical test under para-  
24      graph (6) or (7), the developer of the test may ap-  
25      peal such classification under section 590F.

1 “(f) DEFINITIONS.—In this section:

2 “(1) DOWN-CLASSIFICATION.—The term ‘down-  
3 classification’ means—

4 “(A) reclassification from high-risk to  
5 moderate- or low-risk; or

6 “(B) reclassification from moderate-risk to  
7 low-risk.

8 “(2) UP-CLASSIFICATION.—The term ‘up-classi-  
9 fication’ means—

10 “(A) reclassification from low-risk to  
11 moderate- or high-risk; or

12 “(B) reclassification from moderate-risk to  
13 high-risk.

14 “(3) WELL-CHARACTERIZED.—The term ‘well-  
15 characterized’ means well-established and well-recog-  
16 nized by the medical community, as evidenced by  
17 one or more of the following:

18 “(A) Literature.

19 “(B) Practice Guidelines.

20 “(C) Consensus standards.

21 “(D) Recognized standards of care.

22 “(E) Technology in use for many years.

23 “(F) Scientific publication by multiple  
24 sites.

1                   “(G) Wide recognition or adoption by the  
2                   medical community.

3                   “(H) Proficiency testing.

4   **“SEC. 590B. PREMARKET REVIEW.**

5           “(a) IN GENERAL.—The Secretary shall establish a  
6   process for the premarket review of in vitro clinical tests  
7   in accordance with this section.

8           “(b) PRESUBMISSION MEETING.—Before submitting  
9   an application or notification under subsection (c) or (d)  
10  for offering an in vitro clinical test—

11           “(1) the developer of the test may submit to the  
12   Secretary a written request for a meeting or con-  
13   ference to discuss and provide information relating  
14   to the submission process and the type and amount  
15   of evidence expected to demonstrate a reasonable as-  
16   surance of analytical validity and clinical validity, or  
17   probable clinical validity, as applicable; and

18           “(2) upon receipt of such a request, the Sec-  
19   retary shall—

20           “(A) within 30 calendar days after such  
21   receipt, meet or confer with the developer sub-  
22   mitting the request; and

23           “(B) within 30 calendar days after such  
24   meeting or conference, provide to the developer  
25   a written record or response describing the

1 issues discussed and conclusions reached in the  
2 meeting.

3 “(c) PREMARKET APPROVAL OF HIGH-RISK  
4 TESTS.—

5 “(1) IN GENERAL.—The Secretary shall ap-  
6 prove a high-risk in vitro clinical test (other than an  
7 in vitro clinical test submitted for approval under  
8 subsection (f)) if, upon the submission to the Sec-  
9 retary of an application by the developer of the test,  
10 the Secretary determines that the application dem-  
11 onstrates a reasonable assurance that the in vitro  
12 clinical test is analytically valid and clinically valid  
13 for its intended use.

14 “(2) APPLICATION CONTENTS.—An application  
15 submitted with respect to an in vitro clinical test  
16 under paragraph (1) shall include—

17 “(A) the name, address, and establishment  
18 registration number of the developer of the test;

19 “(B) in the case of an application sub-  
20 mitted by a person other than the developer,  
21 the name, address, and establishment registra-  
22 tion number, if applicable, of the applicant;

23 “(C) the name of the in vitro clinical test;

24 “(D) the intended use of the in vitro clin-  
25 ical test;

1                   “(E) a summary description of the in vitro  
2                   clinical test, including as applicable—

3                   “(i) the analyte, biomarker, substance,  
4                   or other target sought to be identified,  
5                   measured, calculated, or analyzed by the  
6                   test;

7                   “(ii) the specifications of the test;

8                   “(iii) specimen types to be analyzed  
9                   by the test;

10                  “(iv) the indications for use of the  
11                  test;

12                  “(v) the intended users of, and user  
13                  environments for, the test;

14                  “(vi) brief descriptions of components  
15                  of the test;

16                  “(vii) principles of properties of the  
17                  test or the principles of operation of the  
18                  test;

19                  “(viii) the software necessary for ap-  
20                  plication of the test, including risk mitiga-  
21                  tion for cybersecurity;

22                  “(ix) any quality controls applicable to  
23                  the use of the test; and

24                  “(x) the method of specimen collection  
25                  and transport to be used with the test;

1           “(F) applicable performance standards,  
2           voluntary standards, or mitigating measures re-  
3           lied upon by the developer in determining the  
4           analytical and clinical validity of the test;

5           “(G) a summary of design controls for the  
6           test and a declaration of the developer’s con-  
7           formity to such design controls;

8           “(H) in the case of an in vitro clinical test  
9           that is a finished product, a summary of rel-  
10          evant process controls used in manufacturing  
11          the test, a validation master plan for such pro-  
12          cess, any acceptance activities or statistical tech-  
13          niques used to ensure the validity of results  
14          generated by the test, and any purchasing con-  
15          trols applicable to the test;

16          “(I) proposed labeling for the test that ac-  
17          counts for the differences between an in vitro  
18          clinical test that is a laboratory test protocol  
19          and an in vitro clinical test that is a finished  
20          product, as appropriate;

21          “(J) a risk assessment for the test;

22          “(K) a statement attesting to the truthful-  
23          ness and accuracy of the submission;

24          “(L)(i) a summary of the valid scientific  
25          evidence that demonstrates a reasonable assur-

1           ance of analytical validity and clinical validity  
2           for the intended use of the in vitro clinical test;  
3           and

4                   “(ii) the protocol and summary of results  
5           and conclusions from any studies performed  
6           with respect to such test, including, if the Sec-  
7           retary determines that such summary of results  
8           and conclusions is insufficient to demonstrate a  
9           reasonable assurance of analytical validity and  
10          clinical validity, and the Secretary notifies the  
11          developer in writing setting forth with speci-  
12          ficity the basis for such insufficiency, the raw  
13          data from such studies.

14                   “(3) APPROVAL PROCESS.—Not later than 120  
15          calendar days after the date on which an application  
16          is submitted under paragraph (1), the Secretary  
17          shall—

18                           “(A) issue an order approving or dis-  
19                           approving the application; and

20                           “(B) in the case of an order disapproving  
21                           the application, specify in such order the sci-  
22                           entific rationale for such disapproval.

23                   “(d) PREMARKET APPROVAL OF MODERATE-RISK  
24          TESTS.—

1           “(1) IN GENERAL.—The Secretary shall ap-  
2           prove a moderate-risk in vitro clinical test (other  
3           than an in vitro clinical test submitted for approval  
4           under subsection (f)) if, upon the submission to the  
5           Secretary of an application by the developer of the  
6           test, the Secretary determines that the application  
7           demonstrates a reasonable assurance that the in  
8           vitro clinical test is analytically valid and clinically  
9           valid for its intended use.

10           “(2) APPLICATION CONTENTS.—An application  
11           submitted under paragraph (1) with respect to a  
12           moderate-risk in vitro clinical test shall include—

13                   “(A) the name, address, and establishment  
14                   registration number of the developer of the test;

15                   “(B) in the case of an application sub-  
16                   mitted by a person other than the developer,  
17                   the name, address, and establishment registra-  
18                   tion number, if applicable, of the applicant;

19                   “(C) the name of the in vitro clinical test;

20                   “(D) the intended use of the in vitro clin-  
21                   ical test;

22                   “(E) a summary description of the in vitro  
23                   clinical test, including as applicable—

24                           “(i) the analyte, biomarker, substance,  
25                           or other target sought to be identified,

1 measured, calculated, or analyzed by the  
2 test;  
3 “(ii) the specifications of the test;  
4 “(iii) specimen types to be analyzed  
5 by the test;  
6 “(iv) the indications for use of the  
7 test;  
8 “(v) the intended users of, and user  
9 environments for, the test;  
10 “(vi) brief descriptions of components  
11 of the test;  
12 “(vii) principles of properties of the  
13 test or the principles of operation of the  
14 test;  
15 “(viii) the software necessary for ap-  
16 plication of the test, including risk mitiga-  
17 tion for cybersecurity;  
18 “(ix) any quality controls applicable to  
19 the use of the test; and  
20 “(x) the method of specimen collection  
21 and transport to be used with the test;  
22 “(F) applicable performance standards,  
23 voluntary standards, or mitigating measures re-  
24 lied upon by the developer in determining the  
25 analytical and clinical validity of the test;

1           “(G) a declaration of the developer’s con-  
2           formity to design controls;

3           “(H) proposed labeling for the test that ac-  
4           counts for the differences between an in vitro  
5           clinical test that is a laboratory test protocol  
6           and an in vitro clinical test that is a finished  
7           product, as appropriate;

8           “(I) a summary of the risk assessment for  
9           the test;

10          “(J) a statement attesting to the truthful-  
11          ness and accuracy of the submission;

12          “(K)(i) a summary of the valid scientific  
13          evidence that demonstrates a reasonable assur-  
14          ance of analytical validity and clinical validity  
15          for the intended use of the in vitro clinical test;  
16          and

17          “(ii) a summary of the protocol and sum-  
18          mary of results and conclusions from any stud-  
19          ies performed with respect to such test.

20          “(3) APPROVAL PROCESS.—

21          “(A) IN GENERAL.—Not later than 75 cal-  
22          endar days after the date on which an applica-  
23          tion is submitted under paragraph (1), the Sec-  
24          retary shall—

1 “(i) issue an order approving or dis-  
2 approving the application; and

3 “(ii) in the case of an order dis-  
4 approving the application, specify in such  
5 order the scientific rationale for such dis-  
6 approval.

7 “(B) DEEMED APPROVAL.—If the Sec-  
8 retary fails to issue an order under subpara-  
9 graph (A) within the 75-calendar-day period  
10 specified in such subparagraph with respect to  
11 an in vitro clinical test, the in vitro clinical test  
12 is deemed to be approved.

13 “(4) THIRD-PARTY REVIEW AND APPROVAL  
14 PROCESS.—For purposes of reviewing and approving  
15 applications submitted under paragraph (1), the  
16 Secretary shall establish by regulation a process  
17 under which third parties may conduct such review  
18 and approval.

19 “(e) LISTING OF LOW-RISK TESTS.—A low-risk in  
20 vitro clinical test is deemed to be approved so long as the  
21 developer of the test submits a notification regarding the  
22 test to the Secretary in accordance with subsection (n).

23 “(f) SPECIAL PATHWAY FOR CERTAIN TESTS.—

1           “(1) STANDARD.—In lieu of approving a high-  
2 or moderate-risk in vitro clinical test under sub-  
3 section (c) or (d), the Secretary shall—

4           “(A) approve such an in vitro clinical test  
5 under this subsection without confirmatory  
6 postmarket obligations if the developer of the  
7 test submits an application demonstrating a  
8 reasonable assurance of analytical validity and  
9 clinical validity for its intended use;

10           “(B) approve such an in vitro clinical test  
11 under this subsection subject to confirmatory  
12 postmarket obligations under paragraph (5) if  
13 the developer of the test submits an application  
14 demonstrating—

15           “(i) a reasonable assurance of analyt-  
16 ical validity for its intended use and

17           “(ii) probable clinical validity for its  
18 intended use; and

19           “(C) continue an approval under subpara-  
20 graph (B) in effect without confirmatory  
21 postmarket obligations under such subpara-  
22 graph if the developer of the test submits a sup-  
23 plemental application under paragraph (7) with  
24 respect to the test and the Secretary—

1 “(i) finds that such application dem-  
2 onstrates a reasonable assurance of clinical  
3 validity for the intended use of the test; or

4 “(ii) does not disapprove the supple-  
5 mental application under paragraph (8) by  
6 the deadline applicable under such para-  
7 graph.

8 “(2) ELIGIBILITY.—

9 “(A) IN GENERAL.—The in vitro clinical  
10 tests eligible for approval under this subsection  
11 consist of the following:

12 “(i) Unmet need in vitro clinical tests.

13 “(ii) Rare disease in vitro clinical  
14 tests.

15 “(iii) Moderate-risk in vitro clinical  
16 tests that offer a clinically significant ad-  
17 vantage over in vitro clinical tests pre-  
18 viously approved by the Secretary.

19 “(B) EXCEPTIONS.—An in vitro clinical  
20 test described in subparagraph (A) shall not be  
21 eligible for approval or continuation of approval  
22 under this subsection if—

23 “(i) a supplemental application sub-  
24 mitted by the developer or its affiliate for

1 the in vitro clinical test was denied under  
2 paragraph (8); or

3 “(ii) an approval with confirmatory  
4 postmarket obligations under this sub-  
5 section was granted to the developer or its  
6 affiliate for the in vitro clinical test and  
7 was withdrawn under paragraph (11).

8 “(C) ALTERNATIVE PATHWAYS.—If an in  
9 vitro clinical test meets the definition or criteria  
10 for more than one of the categories of rare dis-  
11 ease in vitro clinical test, unmet need in vitro  
12 clinical test, and emergency use in vitro clinical  
13 test under section 564, the developer may elect  
14 to submit the in vitro clinical test under the  
15 pathway for any such category or categories.

16 “(3) APPLICATION CONTENTS.—The developer  
17 of an in vitro test seeking approval of the test under  
18 this subsection shall submit an application to the  
19 Secretary including—

20 “(A) except as inconsistent with the ap-  
21 proval standard specified in paragraph (1), the  
22 information described in subsection (d)(2); and

23 “(B) if such application seeks to dem-  
24 onstrate probable clinical validity under para-

1 graph (1)(A)(ii), a proposed plan for collection  
2 of confirmatory postmarket evidence.

3 “(4) APPROVAL PROCESS.—

4 “(A) IN GENERAL.—The Secretary shall—

5 “(i) issue an order approving or dis-  
6 approving an application submitted under  
7 paragraph (3)—

8 “(I) in the case of an unmet need  
9 in vitro clinical test or rare disease in  
10 vitro clinical test, not later than 30  
11 calendar days after the date on which  
12 such application is submitted; and

13 “(II) in the case of an in vitro  
14 clinical test described in paragraph  
15 (2)(A)(iii), not later than 75 calendar  
16 days after the date on which such ap-  
17 plication is submitted; and

18 “(ii) in any order disapproving an ap-  
19 plication, specify the scientific rationale for  
20 the disapproval.

21 “(B) FAILURE TO APPROVE OR DIS-  
22 APPROVE.—If the Secretary fails to issue an  
23 order approving or disapproving an application  
24 submitted under paragraph (3) within a time

1 period applicable under subparagraph (A), the  
2 application is deemed to be approved.

3 “(5) CONFIRMATORY POSTMARKET OBLIGA-  
4 TIONS.—

5 “(A) AGREED UPON OBLIGATIONS.—If,  
6 pursuant to paragraph (1)(A), the Secretary  
7 approves an application submitted under para-  
8 graph (2) that demonstrates a reasonable as-  
9 surance that the in vitro clinical test is analyt-  
10 ically valid for its intended use and dem-  
11 onstrates probable clinical validity for its in-  
12 tended use without demonstrating a reasonable  
13 assurance of clinical validity for its intended  
14 use—

15 “(i) the Secretary shall specify in the  
16 order granting such approval the confirm-  
17 atory postmarket obligations agreed to by  
18 the Secretary and the developer of the test;  
19 and

20 “(ii) such confirmatory postmarket  
21 obligations—

22 “(I) shall facilitate the devel-  
23 oper’s collection of additional valid  
24 scientific evidence as necessary to  
25 demonstrate a reasonable assurance

1                   that the test is clinically valid for its  
2                   intended use; and

3                   “(II) may include reporting re-  
4                   quirements related to such obliga-  
5                   tions.

6                   “(B) MODIFICATIONS TO OBLIGATIONS.—  
7                   The confirmatory postmarket obligations agreed  
8                   to under subparagraph (A) may be modified at  
9                   any time by the mutual agreement of the Sec-  
10                  retary and the developer.

11                  “(C) LABEL REQUIREMENT.—An order ap-  
12                  proving an in vitro clinical test under para-  
13                  graph (1)(A) shall require the labeling of the  
14                  test to state the following: ‘Approved with con-  
15                  firmatory postmarket obligations’.

16                  “(6) LAPSE OF APPROVAL.—

17                  “(A) IN GENERAL.—An approval with con-  
18                  firmatory postmarket obligations under this  
19                  subsection is deemed to lapse—

20                  “(i) on the date that is three years  
21                  after such approval unless the developer of  
22                  the in vitro clinical test submits a supple-  
23                  mental application pursuant to paragraph  
24                  (7) at least three months prior to such  
25                  date; or

1                   “(ii) on the date specified in an exten-  
2                   sion mutually agreed upon by the Sec-  
3                   retary and the developer of the in vitro  
4                   clinical test unless the developer submits a  
5                   supplemental application pursuant to para-  
6                   graph (7) at least three months prior to  
7                   the agreed upon extension date.

8                   “(B) DURATION OF EXTENSION.—The  
9                   term of any extension described in subpara-  
10                  graph (A)(ii) shall not extend beyond the date  
11                  that is four years after the date of approval  
12                  with confirmatory postmarket obligations for  
13                  the in vitro clinical test.

14                  “(7) SUPPLEMENTAL APPLICATION.—The de-  
15                  veloper of an in vitro clinical test approved under  
16                  this subsection subject to confirmatory postmarket  
17                  obligations may submit a supplemental application  
18                  to demonstrate a reasonable assurance of clinical va-  
19                  lidity for the intended use at any time prior to the  
20                  deadline for submission under paragraph (6).

21                  “(8) DENIAL OF SUPPLEMENTAL APPLICA-  
22                  TION.—

23                  “(A) IN GENERAL.—If the Secretary deter-  
24                  mines that a supplemental application sub-  
25                  mitted under paragraph (7) does not dem-

1           onstrate a reasonable assurance of clinical va-  
2           lidity for the intended use of the in vitro clinical  
3           test—

4                   “(i) the Secretary shall, within 60 cal-  
5                   endar days after submission of such appli-  
6                   cation, issue an order disapproving the  
7                   supplemental application;

8                   “(ii) such order shall specify the sci-  
9                   entific rationale for such decision;

10                   “(iii) subject to clause (iv), such deci-  
11                   sion shall be deemed a withdrawal of the  
12                   approval under this subsection for the in  
13                   vitro clinical test; and

14                   “(iv) such decision shall set forth a  
15                   reasonable timeframe, not to exceed 30 cal-  
16                   endar days, after which the developer of  
17                   the in vitro clinical test shall cease to offer  
18                   such test

19                   “(B) STAY OF DEADLINES.—A deadline  
20                   set forth pursuant to subparagraph (A)(iv) shall  
21                   be stayed during the pendency of an appeal  
22                   under paragraph (9).

23                   “(9) APPEAL OF DENIAL.—

24                   “(A) IN GENERAL.—Not later than 30 cal-  
25                   endar days after the date on which an initial

1 decision is issued under paragraph (8) denying  
2 a supplemental application with respect to an in  
3 vitro clinical test, the developer of the test may  
4 appeal the denial directly to the Director of the  
5 Center for In Vitro Clinical Tests.

6 “(B) DETERMINATION OF DIRECTOR.—  
7 The Director of the Center for In Vitro Clinical  
8 Tests shall determine whether to uphold the de-  
9 nial that is the subject of the appeal—

10 “(i) not later than 45 calendar days  
11 after submission of the appeal; or

12 “(ii) if the developer requests in the  
13 appeal an in-person meeting or teleconfer-  
14 ence with the Director, not later than 30  
15 calendar days after the date of such meet-  
16 ing or teleconference.

17 “(C) EFFECT OF DETERMINATION UP-  
18 HOLDING DENIAL.—If the Director of the Cen-  
19 ter for In Vitro Clinical Tests upholds a denial  
20 of a supplemental application under paragraph  
21 (8), such denial shall—

22 “(i) be deemed to be a withdrawal of  
23 the approval for the in vitro clinical test  
24 that is the subject of such supplemental  
25 application and shall set forth a reasonable

1           timeframe within which the developer must  
2           remove the in vitro clinical test from the  
3           market; and

4                   “(ii) shall constitute final action by  
5           the Secretary and may not be appealed.

6                   “(10) TERMINATION OF POSTMARKET OBLIGA-  
7           TIONS.—The approval of an in vitro clinical test  
8           under paragraph (1)(B) shall continue in effect as  
9           described in paragraph (1)(C), and any confirmatory  
10          postmarket obligations imposed under this sub-  
11          section with respect to an in vitro clinical test, in-  
12          cluding pursuant to the labeling requirement in  
13          paragraph (5)(C), shall terminate, if the Secretary—

14                   “(A) determines a supplemental applica-  
15          tion submitted under paragraph (7) with re-  
16          spect to the test demonstrates a reasonable as-  
17          surance of clinical validity for the intended use  
18          of the test; or

19                   “(B) does not disapprove the supplemental  
20          application under paragraph (8) by the deadline  
21          applicable under such paragraph.

22                   “(11) WITHDRAWAL OF APPROVAL WITH CON-  
23          FIRMATORY POSTMARKET OBLIGATIONS.—The Sec-  
24          retary may, after providing notice to the developer  
25          of the test and an opportunity for an informal hear-

1       ing, withdraw an approval of an in vitro clinical test  
2       made subject to confirmatory postmarket obligations  
3       under this subsection at any time before such ap-  
4       proval would otherwise lapse or be withdrawn under  
5       this subsection if the Secretary determines, based on  
6       new valid scientific evidence, that—

7               “(A) the developer of the test can no  
8               longer demonstrate a reasonable assurance of  
9               the analytical validity, and probable clinical va-  
10              lidity, of the test for its intended use; or

11              “(B) the test presents an unreasonable  
12              risk to human health.

13              “(12) PUBLIC DATABASE.—The Secretary may  
14              establish a public database that—

15              “(A) lists each in vitro clinical test ap-  
16              proved subject to confirmatory postmarket obli-  
17              gations under this subsection;

18              “(B) may include, with respect to each  
19              such test, the end date and status of such con-  
20              firmatory postmarket obligations; and

21              “(C) is updated to reflect any change in  
22              the status of such a test within 10 calendar  
23              days of that change in status.

24              “(13) DEFINITIONS.—In this subsection:

1           “(A) CLINICALLY SIGNIFICANT ADVAN-  
2           TAGE.—The term ‘clinically significant advan-  
3           tage’ means a reasonable potential to improve  
4           the ability to identify, measure, predict, mon-  
5           itor, or assist in selecting treatment for a dis-  
6           ease or other condition, including by providing  
7           for—

8                   “(i) increased patient access;

9                   “(ii) reduced sample size;

10                  “(iii) expanded sample types;

11                  “(iv) faster diagnosis;

12                  “(v) improved accuracy;

13                  “(vi) less intrusive methods; or

14                  “(vi) other improvements or benefit to  
15                  patients or public health.

16           “(B) RARE DISEASE IN VITRO CLINICAL  
17           TEST.—The term ‘rare disease in vitro clinical  
18           test’—

19                   “(i) means an in vitro clinical test in-  
20                   tended to identify, measure, predict, mon-  
21                   itor, or assist in selecting treatment for a  
22                   disease or condition with an incidence of  
23                   8,000 or fewer per year or a prevalence of  
24                   50,000 or fewer in the United States; and

1 “(ii) excludes an in vitro clinical test  
2 intended for the screening of asymptomatic  
3 patients or predicting the occurrence of a  
4 future disease or condition in asymp-  
5 tomatic patients.

6 “(C) UNMET NEED IN VITRO CLINICAL  
7 TEST.—The term ‘unmet need in vitro clinical  
8 test’ means an in vitro clinical test intended to  
9 be used to identify, measure, predict, monitor,  
10 or assist in selecting treatment for, a serious or  
11 life-threatening disease or condition for which—

12 “(i) there is no existing in vitro clin-  
13 ical test with the same intended use; and

14 “(ii) the test could lead to a meaning-  
15 ful improvement in treatment or therapy.

16 “(g) FALSE STATEMENTS; INCOMPLETE INFORMA-  
17 TION.—The Secretary may—

18 “(1) disapprove an in vitro clinical test applica-  
19 tion, or withdraw approval for an in vitro clinical  
20 test, if the Secretary finds that—

21 “(A) the application or listing for such in  
22 vitro clinical test under subsection (c), (d), (e),  
23 or (f) contains one or more material false state-  
24 ments; and

1           “(B) after being given an opportunity to  
2           correct such statements within a reasonable  
3           time, the applicant fails to do so; or

4           “(2) disapprove an in vitro clinical test applica-  
5           tion if the Secretary finds that—

6           “(A) the application for such in vitro clin-  
7           ical test under subsection (c), (d), or (f) fails to  
8           include material information that is required to  
9           be part of the application; and

10           “(B) after being given an opportunity to  
11           correct such failure within a reasonable time,  
12           the applicant fails to do so.

13           “(h) **PREMARKET INSPECTIONS NOT REQUIRED.**—  
14           The Secretary may not condition the approval of an appli-  
15           cation under this subchapter on the occurrence of a pre-  
16           market inspection or manufacturing review related to the  
17           application. Nothing in the preceding sentence shall be  
18           construed as limiting the authority of the Secretary to  
19           conduct quality system inspections under section 704 or  
20           other applicable provisions of this Act.

21           “(i) **LABORATORY TEST PROTOCOL TRANSFER OR**  
22           **SALE.**—

23           “(1) **LISTING REQUIRED.**—An in vitro clinical  
24           test that is a laboratory test protocol and approved  
25           under subsection (c), (d), (e), or (f) may be trans-

1       ferred, licensed, or sold to a third party for use pur-  
2       suant to such approval, so long as, prior to the  
3       transfer, licensure, or sale, the party transferring, li-  
4       censing, or selling the laboratory test protocol sub-  
5       mits a supplement to its listing of such laboratory  
6       test protocol under subsection (n).

7               “(2) SHARING AMONG CORPORATE ENTITIES.—  
8       The supplemental listing requirement under para-  
9       graph (1) does not apply in the case of a transfer,  
10      licensure, or sale from an entity to another entity  
11      if—

12               “(A) the first entity controls or has the  
13      power to control the other entity;

14               “(B) the other entity controls or has the  
15      power to control the first entity; or

16               “(C) the two entities are under common  
17      ownership or control of a third entity.

18               “(3) EFFECT OF LABORATORY TEST PROTOCOL  
19      TRANSFER.—The transfer, license, or sale of less  
20      than the full right, title, and interest in a laboratory  
21      test protocol, without transfer or sale of the ap-  
22      proval, does not transfer the regulatory obligations  
23      of the developer under this subchapter to the trans-  
24      feree, licensee, or purchaser.

25               “(j) TRANSFER OR SALE OF APPROVAL.—

1           “(1) NOTICE REQUIRED.—If a developer of an  
2           in vitro clinical test transfers or sells the approval  
3           of the test issued under subsection (c), (d), (e), or  
4           (f), the transferor or seller shall submit a notice of  
5           the transfer or sale to the Secretary.

6           “(2) EFFECT OF APPROVAL TRANSFER.—Upon  
7           completion of a transfer or sale described in para-  
8           graph (1), the transferee or purchaser shall have the  
9           regulatory obligations of the developer of the in vitro  
10          clinical test under this subchapter.

11          “(k) JUSTIFICATION FOR REQUIREMENT TO PRO-  
12          VIDE EVIDENCE FROM CLINICAL TRIALS.—

13           “(1) WRITTEN JUSTIFICATION FOR MANDATORY  
14          CLINICAL TRIAL.—The Secretary shall not require  
15          the developer of an in vitro clinical test to submit  
16          evidence from a clinical trial as part of any applica-  
17          tion under this subchapter, unless such application  
18          is for approval of a high-risk in vitro clinical test  
19          and the Secretary submits to the developer written  
20          notice that—

21           “(A) provides a justification for such re-  
22          quirement, including an explanation of why the  
23          Secretary determines that, based on scientific  
24          criteria, other evidence is insufficient; and

1           “(B) is signed by the chief scientific officer  
2           of the center for in vitro clinical tests or an-  
3           other member of the senior management of  
4           such center.

5           “(2) WRITTEN JUSTIFICATION FOR OTHER  
6           CLINICAL STUDIES.—The Secretary shall not require  
7           the developer of an in vitro clinical test to submit  
8           evidence from a clinical study other than a clinical  
9           trial as part of any application under this sub-  
10          chapter, unless the Secretary submits to the devel-  
11          oper written notice that—

12                  “(A) provides a justification for such re-  
13                  quirement, including an explanation of why th  
14                  e Secretary determines that, based on scientific  
15                  criteria, other evidence is insufficient; and

16                  “(B) is signed by the chief scientific officer  
17                  of the Center for In Vitro Clinical Tests or an-  
18                  other member of the senior management of  
19                  such center.

20           “(3) WRITTEN JUSTIFICATION FOR OTHER  
21           CLINICAL STUDIES.—The Secretary shall limit the  
22           size, scope, and nature of any clinical trial or other  
23           clinical study required pursuant to paragraph (1) or  
24           (2) to the size, scope, and nature necessary to estab-  
25           lish the sufficient evidence not otherwise available,

1 taking into consideration the feasibility of such clin-  
2 ical trial or other clinical study.

3 “(4) DEFINITION.—For purposes of this sub-  
4 section, the term ‘clinical trial’ means a prospective  
5 clinical study comprised of human subjects that is  
6 performed to demonstrate clinical validity of the in  
7 vitro clinical test versus an established clinical truth,  
8 other than the methodologies specified in any of  
9 clauses (i) through (ix) of section 590(d)(10)(B).

10 “(l) GRANDFATHERED TESTS.—

11 “(1) IN GENERAL.—An in vitro clinical test  
12 first offered on a date that occurs before the date  
13 that is 90 calendar days prior to the date of enact-  
14 ment of the \_\_\_\_\_ Act of 2015, and with respect  
15 to which the Secretary did not require an approval  
16 under section 515, a clearance under section 510(k),  
17 or a notification under section 510(j), or otherwise  
18 asserted enforcement discretion with regard to such  
19 sections and implementing regulations thereunder, is  
20 deemed to be approved under this section if the de-  
21 veloper—

22 “(A) lists such in vitro clinical test in ac-  
23 cordance with subsection (n)(3)(B); and

24 “(B) with respect to a non-reviewed, high-  
25 risk test, submits to the Secretary, not later

1           than 4 years after the date of enactment of the  
2           \_\_\_\_\_ Act of 2015, a summary of available  
3           analytical validity and clinical validity evidence.

4           “(2) CONTENTS OF SUMMARY.—A summary re-  
5           quired by paragraph (1)(B)—

6                     “(A) need not contain any evidence other  
7           than evidence readily available to the developer  
8           and shall be provided in summary form; and

9                     “(B) shall not be subject to a user fee  
10           under [section \_\_\_\_\_].

11           “(3) NO ADDITIONAL APPLICATION RE-  
12           QUIRED.—The developer of an in vitro clinical test  
13           that is described in paragraph (1) and listed in ac-  
14           cordance with subsection (n) need not submit any  
15           application for premarket approval of such test  
16           under subsection (c), (d), or (f).

17           “(4) SUBMISSION OF CERTAIN TESTS.—

18                     “(A) IN GENERAL.—The Secretary shall  
19           provide written notification to the developer of  
20           an in vitro clinical test described in paragraph  
21           (1) if, after conducting a literature review and  
22           creating a related administrative file, the Sec-  
23           retary determines, based on all available evi-  
24           dence, that such in vitro clinical test—

1 “(i) presents an unreasonable risk of  
2 illness or injury when used as intended by  
3 its developer; or

4 “(ii) is being offered by its developer  
5 with materially deceptive or fraudulent an-  
6 alytical or clinical claims.

7 “(B) MISBRANDING.—Upon receipt of a  
8 written notification under subparagraph (A)—

9 “(i) the developer of an in vitro clin-  
10 ical test may avoid a finding of mis-  
11 branding by, not later than 120 calendar  
12 days after the date on which the developer  
13 receives such notification or such later  
14 time as agreed to by the developer and the  
15 Secretary—

16 “(I) ceasing to offer such test; or

17 “(II) submitting a premarket ap-  
18 plication for such test under sub-  
19 section (c), (d), or (f) (as applicable);  
20 or

21 “(ii) if the developer fails (by the  
22 deadline applicable under clause (i)) to  
23 cease offering such test or to submit an  
24 application, as described in such clause, or  
25 if the Secretary disapproves any applica-

1                   tion so submitted, the test is deemed to be  
2                   misbranded under section 502.

3                   “(C) APPLICATION CONSIDERATIONS.—In  
4                   reviewing an application submitted under sub-  
5                   paragraph (B)(i)(II), the Secretary shall con-  
6                   sider—

7                   “(i) previously unpublished evidence  
8                   provided by the developer submitting such  
9                   application; and

10                  “(ii) the developer’s description of the  
11                  past experience with the in vitro clinical  
12                  test.

13                  “(D) TEMPORARY SALES PERIOD.—During  
14                  the period of the review of an application sub-  
15                  mitted under subparagraph (B)(i)(II), the de-  
16                  veloper submitting such application with respect  
17                  to an in vitro clinical test may continue to offer  
18                  the test, without limitation, during the pend-  
19                  ency of such submission and if such submission  
20                  is disapproved, until the date specified by the  
21                  Secretary.

22                  “(6) DEFINITION.—As used in this subsection,  
23                  the term ‘non-reviewed, high-risk test’ means an in  
24                  vitro clinical test—

1           “(A) first offered on a date that occurs be-  
2           fore the date that is 90 calendar days prior to  
3           the date of enactment of the \_\_\_\_\_ Act of  
4           2015, and with respect to which the Secretary  
5           did not require an approval under section 515,  
6           a clearance under section 510(k), or a notifica-  
7           tion under section 510(j) or otherwise asserted  
8           enforcement discretion with regard to such sec-  
9           tions and implementing regulations thereunder;

10           “(B) for which the developer does not hold  
11           an approval under section 515 or a clearance  
12           under section 510(k);

13           “(C) which has not been approved by a  
14           State pursuant to section 353 of the Public  
15           Health Service Act, including the New York  
16           State approval process established pursuant to  
17           part 58 of title 10 (relating to health) of the  
18           Official Compilation of Codes, Rules, and Regu-  
19           lations of the State of New York; and

20           “(D) which is classified as high-risk pursu-  
21           ant to section 590A(e).

22           “(m) PREMARKET REQUIREMENTS FOR MODIFICA-  
23           TIONS.—

24           “(1) IN GENERAL.—A modification to an in  
25           vitro clinical test is subject to approval or listing

1 under subsection (c), (d), (e), or (f) in accordance  
2 with the following:

3 “(A) In the case of a modification made  
4 with respect to a low-risk in vitro clinical test,  
5 the modification is subject to such process only  
6 if the modification—

7 “(i) changes the intended use or adds  
8 a new intended use such that the low-risk  
9 in vitro clinical test would be classified as  
10 moderate-risk or high-risk; or

11 “(ii) results in a meaningful clinical  
12 impact such that the test would be classi-  
13 fied as a moderate-risk or high-risk test.

14 “(B) In the case of a modification made  
15 with respect to a moderate-risk in vitro clinical  
16 test, the modification is subject to such process  
17 only if the modification—

18 “(i) changes the intended use or adds  
19 a new intended use that is high-risk or  
20 moderate-risk; or

21 “(ii) results in a meaningful clinical  
22 impact.

23 “(C) In the case of a modification made  
24 with respect to a high-risk in vitro clinical test,

1 the modification is subject to such process only  
2 if the modification—

3 “(i) changes the intended use or adds  
4 a new intended use of the test that is high-  
5 risk or moderate-risk; or

6 “(ii) results in a meaningful clinical  
7 impact.

8 “(2) TREATMENT OF MODIFIED CLASSIFICA-  
9 TION.—In the case of a modification described in  
10 paragraph (1), the applicable process for approval or  
11 listing of the in vitro clinical test with respect to  
12 which the modification is made shall be determined  
13 in accordance with the risk classification of the test  
14 as so modified, unless validation and verification  
15 demonstrate that there is not a meaningful increase  
16 in risk to the patient or user for the intended uses  
17 compared to the risk assessment for the test as pre-  
18 viously approved

19 “(3) NOTIFICATION.—If the risk assessment for  
20 the modification, prior to consideration of  
21 verification and validation and considering relevant  
22 existing mitigating measures, demonstrates that  
23 there is a meaningful and not remote increase in  
24 risk to the patient or user for the intended uses  
25 compared to the risk assessment for the in vitro clin-

1 ical test as previously approved, but validation and  
2 verification demonstrate that there is not a meaning-  
3 ful increase in risk to the patient or user for the in-  
4 tended uses compared to the risk assessment for the  
5 in vitro clinical test as previously approved, the de-  
6 veloper of the test shall, not later than the date on  
7 which such test is first offered as so modified, sub-  
8 mit to the Secretary a notification of such modifica-  
9 tion. Such notification shall include—

10 “(A) the name of the in vitro clinical test;

11 “(B) a brief description of the modifica-  
12 tion;

13 “(C) a brief summary of the meaningful  
14 and not remote risks identified by the risk as-  
15 sessment described in such paragraph; and

16 “(D) a brief summary of the validation  
17 and verification methodologies or the mitigating  
18 measures used with respect to the test, includ-  
19 ing a brief summary of the results of validation  
20 and verifications studies performed with respect  
21 to the test.

22 “(4) EXCEPTION FOR MODIFICATIONS SATIS-  
23 FYING RECOGNIZED STANDARDS.—

24 “(A) IN GENERAL.—Notwithstanding para-  
25 graph (1), a premarket application shall not be

1 required to be submitted under subsection (c),  
2 (d), (e), or (f) with respect to a modification to  
3 a moderate-risk or high-risk in vitro clinical test  
4 if the developer of such test—

5 “(i) maintains records documenting  
6 that the modification satisfies a standard  
7 applicable to the modification that is recog-  
8 nized, or contained in guidance issued by,  
9 the Secretary and maintains evidence re-  
10 quired by the standard; and

11 “(ii) submits to the Secretary on an  
12 annual basis a report summarizing each  
13 such modification.

14 “(B) SPECIMEN-RELATED MODIFICA-  
15 TIONS.—Notwithstanding paragraph (1), a pre-  
16 market application shall not be required to be  
17 submitted under subsection (c), (d), (e), or (f)  
18 with respect to a modification to a moderate-  
19 risk or high-risk in vitro clinical test if the  
20 modification is a specimen-related modification  
21 made pursuant to methods and criteria ap-  
22 proved or included in a premarket submission  
23 for the in vitro clinical test.

24 “(5) NEW PLATFORMS AND IN VITRO CLINICAL  
25 TEST REPLACEMENTS.—

1           “(A) IN GENERAL.—When an in vitro clin-  
2           ical test has been approved or deemed approved  
3           under this section for use on a specific platform  
4           that has been approved or deemed approved  
5           under this section within a platform family, a  
6           submission under subsection (c), (d), or (f)  
7           shall not be required for application of that in  
8           vitro clinical test to a new platform within that  
9           platform family.

10           “(B) PLATFORM FAMILIES.—A platform is  
11           in a platform family if the developer dem-  
12           onstrates and documents internally that the  
13           platform and platform family—

14                   “(i) have the same basic design and  
15                   performance characteristics;

16                   “(ii) have the same intended use and  
17                   function;

18                   “(iii) share the same measurement  
19                   principle; and

20                   “(iv) produce a similar analytical re-  
21                   sult from samples of the same specimen  
22                   type.

23           “(6) DETERMINATION ON WHETHER TO MAKE  
24           SUBMISSION.—The entity that modifies an in vitro  
25           clinical test is the entity responsible for submitting

1 such modification for any approval or listing re-  
2 quired by paragraph (1) and for any related quality  
3 system requirements under section 590E.

4 “(7) SCOPE OF REVIEW.—In reviewing a modi-  
5 fication to an in vitro clinical test pursuant to this  
6 subsection, the Secretary shall limit the scope of the  
7 review to the modification and shall not conduct a  
8 de novo review of the overall test.

9 “(8) DEFINITION OF MEANINGFUL CLINICAL  
10 IMPACT.—In this subsection, the term ‘meaningful  
11 clinical impact’ means, with respect to a modifica-  
12 tion of an in vitro clinical test—

13 “(A) a modification that changes the diag-  
14 nosis or therapy delivered to the patient;

15 “(B) a modification of, or an addition to,  
16 the indications for use of the test that—

17 “(i) introduce new risks not typically  
18 associated with the previous indications for  
19 use;

20 “(ii) impact public health to a signifi-  
21 cantly greater degree than the previous in-  
22 dications for use;

23 “(iii) are not supported by a body of  
24 evidence that reflects an understanding  
25 within the medical community that the

1 changed or additional indications for use  
2 are a subset of previous indications for  
3 use; or

4 “(iv) are such that performance char-  
5 acteristics or clinical endpoints established  
6 to evaluate the previous indications for use  
7 cannot be applied to the changed or addi-  
8 tional indications for use;

9 “(C) a modification that causes a low-risk  
10 in vitro clinical test to no longer meet required  
11 mitigating measures established for such test,  
12 such that the test is classified as a moderate-  
13 risk or high-risk test;

14 “(D) a modification to a moderate-risk or  
15 high-risk in vitro clinical test if the risk assess-  
16 ment for the modification, prior to consider-  
17 ation of verification and validation and consid-  
18 ering relevant existing mitigating measures,  
19 demonstrates that there is a meaningful and  
20 not remote increase in risk to the patient or  
21 user for the intended uses, unless validation  
22 and verification demonstrate that there is not a  
23 meaningful increase in risk to the patient or  
24 user for the intended uses compared to the risk

1 assessment for the test as previously approved;  
2 or

3 “(E) in the case of a modification to a  
4 moderate-risk or high-risk in vitro clinical test,  
5 a modification that, if, following verification  
6 and validation of the test, the in vitro clinical  
7 test no longer meets the analytical or clinical  
8 performance standards for the intended uses for  
9 which the test is approved.

10 “(n) LISTING REQUIREMENT.—

11 “(1) IN GENERAL.—The Secretary shall estab-  
12 lish and maintain a list of all in vitro clinical tests  
13 approved or otherwise required to be listed under  
14 this subchapter.

15 “(2) PROCESS AND CONTENT OF LISTING.—  
16 The list under paragraph (1) shall, with respect to  
17 each in vitro clinical test, include—

18 “(A) the name of the in vitro clinical test;

19 “(B) the name and contact information of  
20 the developer;

21 “(C) with respect to a laboratory test pro-  
22 tocol transferred, licensed, or purchased under  
23 subsection (i), the name and contact informa-  
24 tion of any transferee, licensee, or purchaser

1 and the completion date of such transfer, li-  
2 cense, or purchase;

3 “(D) the intended use of the in vitro clin-  
4 ical test; and

5 “(E) a summary explanation of the in vitro  
6 clinical test.

7 “(3) PROCESS AND TIMING OF LISTING.—The  
8 developer of an in vitro clinical test that is approved  
9 or otherwise required to be listed under this sub-  
10 chapter shall submit a notification to the Secretary  
11 containing the information described in paragraph  
12 (2)—

13 “(A) in the case of an in vitro clinical test  
14 first offered on or after the date that is 180  
15 calendar days after enactment of the  
16 \_\_\_\_\_ Act of 2015, not later than 10 cal-  
17 endar days after the date on which such in vitro  
18 clinical test is first offered;

19 “(B) in the case of an in vitro clinical test  
20 that has been first offered before the date that  
21 is 180 calendar days after of enactment of the  
22 \_\_\_\_\_ Act of 2015, and which continues  
23 to be so offered, not later than 180 calendar  
24 days after the date of the enactment of such  
25 Act;

1           “(C) in the case of a laboratory test pro-  
2           tocol that is transferred, licensed, or sold under  
3           subsection (i), the later of—

4                   “(i) 180 calendar days after enact-  
5                   ment of the \_\_\_\_\_ Act of 2015; or

6                   “(ii) 10 calendar days after the date  
7                   of such transfer, license, or sale.

8           “(4) UPDATED LISTING.—The developer of an  
9           in vitro clinical test shall submit an updated notifi-  
10          cation under paragraph (3) on an annual basis.

11          “(o) REGISTRATION.—

12                   “(1) INITIAL REGISTRATION.—Before the ear-  
13                   lier of offering an in vitro clinical test or submitting  
14                   an application or notification for approval of such a  
15                   test under this section, the developer of the test shall  
16                   register with the Secretary and include in such reg-  
17                   istration—

18                           “(A) the developer’s name;

19                           “(B) the developer’s place of business; and

20                           “(C) a list of the establishments at which  
21                   the developer is engaged in the design, develop-  
22                   ment, validation, production, manufacture,  
23                   preparation, propagation, assembly, or proc-  
24                   essing of an in vitro clinical test.

1           “(2) ESTABLISHMENTS WITH GRANDFATHERED  
2           IN VITRO CLINICAL TESTS.—Notwithstanding para-  
3           graph (1), the developer of an in vitro clinical test  
4           described in subsection (1)(1) shall register with Sec-  
5           retary and include in such registration the informa-  
6           tion listed in paragraph (1) not later than 180 cal-  
7           endar days after the date of enactment of the  
8           \_\_\_\_\_ Act of 2015.

9           “(3) ADDITIONAL ESTABLISHMENTS.—Every  
10          developer of an in vitro clinical test required to be  
11          registered under paragraph (1) or (2) shall register  
12          with the Secretary any additional establishment at  
13          which the developer begins the design, development,  
14          validation, production, manufacture, preparation,  
15          propagation, assembly, or processing of an in vitro  
16          clinical test not later than 30 calendar days after  
17          first engaging in such activity.

18          “(4) ANNUAL UPDATES.—On or before Decem-  
19          ber 31 of each year, every developer of an in vitro  
20          clinical test shall submit an updated registration  
21          under paragraph (1) or (2), as applicable.

22          “(5) INFORMATION CHANGES.—The developer  
23          of an in vitro clinical test shall notify the Secretary  
24          of any change to the registration information pro-

1 vided under this subsection not later than 30 cal-  
2 endar days after such change.

3 “(6) AFFILIATE REGISTRATION.—Registration  
4 information required to be submitted by a developer  
5 of an in vitro clinical test under this subsection may  
6 be submitted by a parent, subsidiary, or affiliate  
7 company with respect to any establishment under  
8 the joint ownership or control of the submitter and  
9 the developer.

10 “(7) REGULATIONS.—The Secretary shall, to  
11 the extent possible, harmonize regulations for car-  
12 rying out this subsection with the corresponding reg-  
13 ulations for registration with respect to devices.

14 “(p) LABELING.—Notwithstanding any provision of  
15 this Act—

16 “(1) an in vitro clinical test may be labeled by  
17 electronic means (including by directing health care  
18 practitioners and other users to information posted  
19 on the Internet) instead of physically affixing the in-  
20 formation to the in vitro clinical test;

21 “(2) an in vitro clinical test need not be labeled  
22 for purposes of transferring the test between entities  
23 if—

24 “(A) the first entity controls or has the  
25 power to control the other entity;

1           “(B) the other entity controls or has the  
2           power to control the first entity; or

3           “(C) the two entities are under common  
4           ownership or control of a third entity;

5           “(3) patient test results from the use of an in  
6           vitro clinical test or an interpretation of such patient  
7           tests results shall not constitute labeling;

8           “(4) scientific or medical exchanges or discus-  
9           sion regarding one or more in vitro clinical tests  
10          shall not constitute labeling;

11          “(5) communications with actual or potential  
12          investors or business partners regarding an unap-  
13          proved in vitro clinical test or an unapproved in-  
14          tended use of an in vitro clinical test shall not con-  
15          stitute labeling; and

16          “(6) the developer of a platform shall not make  
17          any claims of clinical validity of the platform alone  
18          unless such claim is approved by the Secretary.

19   **“SEC. 590C. INVESTIGATIONAL AND RESEARCH USE IN**  
20                   **VITRO CLINICAL TESTS.**

21          “(a) IN GENERAL.—Except as provided in subsection  
22   (b), an in vitro clinical test for investigational use shall  
23   be exempt from the requirements of this subchapter other  
24   than sections 590F, 590G, and 590H. Sections 502 and

1 721, made applicable to in vitro clinical tests by section  
2 590H, shall not apply to such tests.

3 “(b) APPLICATION FOR AN EXEMPTION.—

4 “(1) IN GENERAL.—The Secretary shall estab-  
5 lish a process under which—

6 “(A) the Secretary shall require that in the  
7 case of an in vitro clinical test the investiga-  
8 tional use of which the Secretary determines  
9 poses a significant risk to the public health  
10 (other than with respect to an investigation for  
11 the collection of clinical data through processes  
12 other than a prospective clinical trial), a spon-  
13 sor of an investigation of such a test seeking an  
14 exemption under subsection (a) submits to the  
15 Secretary an investigational use application  
16 with respect to the test in accordance with  
17 paragraphs (2) and (3); and

18 “(B) in the case of an in vitro clinical test,  
19 the investigational use of which the Secretary  
20 does not determine poses such a risk,—

21 “(i) the Secretary shall require that  
22 the sponsor of such investigation complies  
23 with—

1                   “(I) the requirements specified in  
2                   paragraphs (3)(A), (3)(B), and  
3                   (5)(A)(iii); and

4                   “(II) such other requirements as  
5                   the Secretary may reasonably deter-  
6                   mine to be necessary for the protec-  
7                   tion of the public health and safety,  
8                   including the monitoring of investiga-  
9                   tions conducted with such test, the es-  
10                  tablishment and maintenance of  
11                  records, and the submission to the  
12                  Secretary of reports of data obtained  
13                  as a result of the investigational use  
14                  of the in vitro clinical test during the  
15                  period covered by the exemption; and

16                  “(ii) the exemptions specified in para-  
17                  graph (5)(B) and subsection (g) are avail-  
18                  able with respect to such test.

19                  “(2) APPLICATION CONTENTS.—An investiga-  
20                  tional use application shall be submitted in such  
21                  time and manner and contain such information as  
22                  the Secretary may require, including assurances to  
23                  the satisfaction of the Secretary that the sponsor in-  
24                  volved shall, with respect to the in vitro clinical test  
25                  that is the subject of the application—

1           “(A) establish and maintain any records  
2 relevant to such in vitro clinical test; and

3           “(B) submit to the Secretary reports of  
4 data obtained as a result of the investigational  
5 use of the in vitro clinical test during the period  
6 covered by the exemption that the Secretary  
7 reasonably determines will enable the Sec-  
8 retary—

9           “(C) to ensure compliance with the condi-  
10 tions for approval specified in paragraph (3);

11           “(D) to review the progress of the inves-  
12 tigation involved; and

13           “(E) to evaluate the analytical validity and  
14 clinical validity of such test; and

15           “(3) CONDITIONS ON APPROVAL.—An investiga-  
16 tional use application shall only be approved, if—

17           “(A) the proposed labeling for the in vitro  
18 clinical test involved clearly and conspicuously  
19 states ‘For investigational use’;

20           “(B) in the case of an application sub-  
21 mitted with respect to an in vitro clinical test  
22 the clinical testing of which involves human  
23 subjects, the sponsor of the investigation—

24           “(i) if the Secretary has established  
25 an institutional review committee estab-

1                   lished by the Secretary to supervise clinical  
2                   testing of such in vitro clinical tests, sub-  
3                   mits—

4                               “(I) to such committee a plan  
5                               that meets the requirements specified  
6                               in paragraph (5) for any proposed  
7                               clinical testing of the in vitro clinical  
8                               test and a report of prior investiga-  
9                               tions of the test adequate to justify  
10                              the proposed clinical testing; and

11                             “(II) to the Secretary a summary  
12                             of such plan and a report of prior in-  
13                             vestigations; or

14                            “(ii) if no such committee has been so  
15                            established or the Secretary finds that the  
16                            process of review by such a committee is  
17                            inadequate (whether or not the plan for  
18                            such testing has been approved by such  
19                            committee), for purposes of beginning clin-  
20                            ical testing of the test, submits to the Sec-  
21                            retary a plan that meets the requirements  
22                            specified in paragraph (5) for any pro-  
23                            posed clinical testing of the in vitro clinical  
24                            test and a report of prior investigations of

1           the test adequate to justify the proposed  
2           clinical testing; and

3           “(C) the sponsor submitting such applica-  
4           tion provides assurances to the Secretary that  
5           the sponsor will comply with such other require-  
6           ments as the Secretary may reasonably deter-  
7           mine to be necessary for the protection of the  
8           public health and safety.

9           “(4) COORDINATION WITH INVESTIGATIONAL  
10          NEW DRUG APPLICATIONS.—Any requirement for  
11          the submission of a report to the Secretary pursuant  
12          to an investigational new drug application involving  
13          an in vitro clinical test shall supersede the reporting  
14          requirement in paragraph (2)(A)(ii), but only to the  
15          extent the requirement with respect to the investiga-  
16          tional new drug application is duplicative of the re-  
17          porting requirement under paragraph (2)(A)(ii).

18          “(5) INVESTIGATION PLAN REQUIREMENTS.—

19                 “(A) IN GENERAL.—With respect to a plan  
20                 submitted under paragraph (3)(B), the sponsor  
21                 submitting such plan shall—

22                         “(i) in the case of such a plan sub-  
23                         mitted to an institutional review com-  
24                         mittee, promptly notify the Secretary,  
25                         under such circumstances and in such

1 manner as the Secretary may prescribe, of  
2 the approval or the suspension or termi-  
3 nation of the approval of such plan by an  
4 institutional review committee;

5 “(ii) in the case of an in vitro clinical  
6 test to be distributed or otherwise made  
7 available to investigators for clinical test-  
8 ing, obtain, and submit to the Secretary,  
9 signed agreements from each of the indi-  
10 viduals carrying out the investigation that  
11 is the subject of such plan that—

12 “(I) any testing under such plan  
13 involving human subjects will be  
14 under the supervision of such indi-  
15 vidual; and

16 “(II) the individual will ensure  
17 that informed consent is obtained  
18 from each such human subject; and

19 “(iii) submit an assurance to the Sec-  
20 retary that informed consent will be ob-  
21 tained from each human subject (or the  
22 representative of such subject) of proposed  
23 clinical testing involving such in vitro clin-  
24 ical test, except in cases in which, subject

1 to such other conditions as the Secretary  
2 may prescribe—

3 “(I) the proposed clinical testing  
4 poses no more than minimal risk to  
5 the human subject and includes ap-  
6 propriate safeguards to protect the  
7 rights, safety, and welfare of the  
8 human subject; or

9 “(II) the investigator conducting  
10 or supervising the proposed clinical  
11 testing determines (subject to sub-  
12 paragraph (B)(ii), with the concu-  
13 rence of a licensed physician who is  
14 not involved in the testing of the  
15 human subject) in writing that—

16 “(aa) there exists a life  
17 threatening situation involving  
18 the human subject of such test-  
19 ing which necessitates the use of  
20 such in vitro clinical test;

21 “(bb) it is not feasible to ob-  
22 tain informed consent from the  
23 subject; and

1                   “(cc) there is not sufficient  
2                   time to obtain such consent from  
3                   his representative.

4                   “(B) EXCEPTIONS.—

5                   “(i) SIGNED AGREEMENTS NOT RE-  
6                   QUIRED FOR AFFILIATES.—Subparagraph  
7                   (A)(iii) shall not apply to the distribution  
8                   of or other arrangements by a sponsor to  
9                   make available an in vitro clinical test to  
10                  an investigator that is employed by or af-  
11                  filiated with the sponsor.

12                  “(ii) CONCURRENCE OF PHYSICIAN  
13                  NOT REQUIRED.—The requirement to ob-  
14                  tain the concurrence of a licensed physi-  
15                  cian with respect to a determination under  
16                  subparagraph (A)(iii) shall not apply if—

17                  “(I) immediate use of the in vitro  
18                  clinical test in the investigation in-  
19                  volved is required to save the life of  
20                  the human subject; and

21                  “(II) there is not sufficient time  
22                  to obtain such concurrence.

23                  “(iii) INFORMED CONSENT NOT RE-  
24                  QUIRED WITH RESPECT TO CERTAIN  
25                  SPECIMENS.—Notwithstanding subpara-

1 graph (A)(iii), the informed consent of  
2 human subjects shall not be required to be  
3 obtained with respect to clinical testing  
4 conducted as part of an investigation, if—

5 “(I) the clinical testing uses rem-  
6 nants of specimens collected for rou-  
7 tine clinical care or analysis that  
8 would have been discarded, leftover  
9 specimens that were previously col-  
10 lected for other research purposes, or  
11 specimens obtained from specimen re-  
12 positories;

13 “(II) the identity of the subject  
14 of the specimen is not known to, and  
15 may not readily be ascertained by, the  
16 investigator or any other individual  
17 associated with the investigation, in-  
18 cluding the sponsor;

19 “(III) any clinical information  
20 that accompanies the specimens does  
21 not make the specimen source identifi-  
22 able to the investigator or any other  
23 individual associated with the inves-  
24 tigation, including the sponsor;

1                   “(IV) the individuals caring for  
2                   the human subjects as patients are  
3                   different from, and do not share infor-  
4                   mation about the patient with, the in-  
5                   dividuals conducting the investigation;  
6                   and

7                   “(V) the specimens are provided  
8                   to the investigators without personally  
9                   identifiable information and the sup-  
10                  plier of the specimens has established  
11                  policies and procedures to prevent the  
12                  release of personally identifiable infor-  
13                  mation.

14                  “(6) CLASSIFICATION.—If a developer seeks  
15                  classification of an in vitro clinical test during its in-  
16                  vestigational use, the Secretary shall use processes  
17                  and classifications that are consistent with the proc-  
18                  esses and classifications under section 590A.

19                  “(7) VARIATION OF REQUIREMENTS AL-  
20                  LOWED.—The requirements of this subsection with  
21                  respect to an investigational use application may  
22                  vary based on—

23                         “(A) the scope and duration of clinical  
24                         testing to be conducted under investigation that  
25                         is the subject of such application;

1           “(B) the number of human subjects that  
2           are to be involved in such testing;

3           “(C) the need to permit changes to be  
4           made in the in vitro clinical test involved during  
5           testing conducted in accordance with a plan re-  
6           quired under paragraph (3)(B); or

7           “(D) whether the clinical testing of such in  
8           vitro clinical test is for the purpose of devel-  
9           oping data to obtain approval to offer such test.

10          “(c) REVIEW OF APPLICATIONS.—

11           “(1) DEEMED APPROVED.—Unless the Sec-  
12           retary, not later than the date that is 30 calendar  
13           days after the date of the submission of an inves-  
14           tigational use application that meets the require-  
15           ments of subsection (b)(2), issues an order dis-  
16           approving the application and notifies the sponsor  
17           submitting the application of such disapproval, the  
18           application shall be deemed approved as of such  
19           date.

20           “(2) DISAPPROVAL.—The Secretary may dis-  
21           approve an investigational use application submitted  
22           under this subsection only if the Secretary deter-  
23           mines that the investigation with respect to which  
24           the application is submitted does not conform to the  
25           requirements of subsection (b)(2). A notification of

1 such disapproval submitted to the sponsor with re-  
2 spect to such an application shall—

3 “(A) contain the order of disapproval and  
4 a complete statement of the reasons for the  
5 Secretary’s disapproval of the application; and

6 “(B) provide the sponsor with an oppor-  
7 tunity for an informal hearing on the dis-  
8 approval.

9 “(d) WITHDRAWAL OF APPROVAL.—

10 “(1) IN GENERAL.—The Secretary may, by ad-  
11 ministrative order, withdraw the approval of an ex-  
12 emption granted under this subsection with respect  
13 to an in vitro clinical test if the Secretary deter-  
14 mines that the test does not meet the applicable con-  
15 ditions under paragraph (3) for such approval.

16 “(2) OPPORTUNITY TO BE HEARD.—

17 “(A) IN GENERAL.—Subject to subpara-  
18 graph (B), an order withdrawing the approval  
19 of an exemption granted under this subsection  
20 may be issued after the Secretary provides the  
21 sponsor of the test with an opportunity for an  
22 informal hearing.

23 “(B) EXCEPTION.—An order referred to in  
24 subparagraph (A) with respect to an exemption  
25 granted under this subsection may be issued be-

1           fore the provision of an opportunity for an in-  
2           formal hearing if the Secretary determines that  
3           the continuation of testing under the exemption  
4           will result in an unreasonable risk to the public  
5           health.

6           “(e) CHANGES OR MODIFICATIONS.—

7                 “(1) IN GENERAL.—The Secretary shall by reg-  
8           ulation establish, with respect to an in vitro clinical  
9           test for which an exemption under this subsection is  
10          in effect, procedures and conditions under which the  
11          changes or modifications to the test are allowed  
12          without the additional approval of an application for  
13          an exemption or the approval of a supplement to  
14          such an application. Such regulations shall provide  
15          that such a change or modification may be made  
16          if—

17                 “(A) the sponsor of the investigation deter-  
18           mines, on the basis of credible information (as  
19           defined by the Secretary) that the change or  
20           modification meets the conditions specified in  
21           paragraph (2); and

22                 “(B) the sponsor submits to the Secretary,  
23           not later than 5 calendar days after making the  
24           change or modification, a notice of the change  
25           or modification.

1           “(2) CONDITIONS.—The conditions specified in  
2           this paragraph are that—

3                   “(A) in the case of developmental changes  
4                   to an in vitro clinical test (including manufac-  
5                   turing changes), the changes—

6                           “(i) do not constitute a significant  
7                           change in design or in basic principles of  
8                           operation; or

9                           “(ii)(I) do not constitute a significant  
10                          increase in risk to patients; and

11                          “(II) are made in response to infor-  
12                          mation gathered during the course of an  
13                          investigation; and

14                          “(B) in the case of changes or modifica-  
15                          tions to clinical protocols applicable to the test,  
16                          the changes or modifications do not affect—

17                                  “(i) the validity of data or information  
18                                  resulting from the completion of an ap-  
19                                  proved clinical protocol, or the relationship  
20                                  of likely patient risk-to-benefit relied upon  
21                                  to approve a clinical protocol;

22                                  “(ii) the scientific soundness of a plan  
23                                  submitted under subsection (b)(3)(B); or

1                   “(iii) the rights, safety, or welfare of  
2                   the human subjects (if any) involved in the  
3                   investigation.

4                   “(f) PRE-SUBMISSION MEETING.—

5                   “(1) IN GENERAL.—In the case of a person in-  
6                   tending to investigate the clinical validity of a high-  
7                   or moderate-risk in vitro clinical test, the Secretary  
8                   shall ensure that the person has an opportunity,  
9                   prior to submitting an application to the Secretary  
10                  under subsection (b)(1), to submit to the Secretary  
11                  for review an investigational plan (including a clin-  
12                  ical protocol).

13                  “(2) REQUEST FOR MEETING.—If the person  
14                  described in paragraph (1) submits a written request  
15                  for a meeting with the Secretary regarding the re-  
16                  view of an investigational plan described in such  
17                  paragraph, the Secretary shall, not later than 30  
18                  calendar days after receiving the request, meet with  
19                  the applicant for the purpose of reaching agreement  
20                  regarding the investigational plan. The written re-  
21                  quest shall include—

22                         “(A) a detailed description of the in vitro  
23                         clinical test involved;

24                         “(B) a detailed description of the proposed  
25                         conditions of use of such test;

1           “(C) a proposed plan (including a clinical  
2           protocol) for determining whether there is a  
3           reasonable assurance of clinical validity or prob-  
4           able clinical validity (as applicable) of, and, if  
5           available, information regarding the expected  
6           performance from, such test.

7           “(3) AGREEMENT.—

8           “(A) REDUCED TO WRITING.—Any agree-  
9           ment under this subsection between the Sec-  
10          retary and a person described in paragraph (1)  
11          shall be in writing and part of the administra-  
12          tive record.

13          “(B) NO AMENDMENTS.— An agreement  
14          described in paragraph (1) shall not be  
15          changed, except—

16                 “(i) with the written agreement of the  
17                 person described in such paragraph; or

18                 “(ii) pursuant to a decision, made in  
19                 accordance with subparagraph (C) by the  
20                 director of the center involved in the re-  
21                 view, that a substantial scientific issue es-  
22                 sential to determining the clinical validity  
23                 of the in vitro clinical test involved has  
24                 been identified.

1           “(C) DECISION BY DIRECTOR.—A decision  
2           referred to in subparagraph (B)(ii) shall be in  
3           writing, and may be made only after the Sec-  
4           retary has provided to the person described in  
5           paragraph (1) an opportunity for a meeting at  
6           which the director and such person are present  
7           and at which the director documents the sci-  
8           entific issue involved.

9           “(g) EXEMPTION FROM HUMAN SUBJECT REGULA-  
10          TIONS.—An investigation conducted under an exemption  
11          under this section with respect to an in vitro clinical test  
12          that involves the collection or study of existing data, docu-  
13          ments, records, pathological specimens, or diagnostic  
14          specimens, is exempt from the rules in part 50 of title  
15          21, Code of Federal Regulations (or any successor regula-  
16          tions), if the information obtained during such investiga-  
17          tion is recorded by the investigator in such a manner that  
18          the subjects cannot be identified, directly or through per-  
19          sonally identifiable information linked to the subjects.

20          “(h) CLINICAL HOLD.—

21                 “(1) IN GENERAL.—At any time, the Secretary  
22                 may impose a clinical hold with respect to an inves-  
23                 tigation of an in vitro clinical test if the Secretary  
24                 makes a determination described in subparagraph  
25                 (B). The Secretary shall, in imposing such clinical

1 hold, specify the basis for the clinical hold, including  
2 the specific information available to the Secretary  
3 which served as the basis for such clinical hold, and  
4 confirm such determination in writing. The sponsor  
5 may immediately appeal any such determination  
6 pursuant to section 590F.

7 “(2) DETERMINATION.—For purposes of sub-  
8 paragraph (A), a determination described in this  
9 subparagraph with respect to a clinical hold is a de-  
10 termination that—

11 “(A) based on substantial credible evi-  
12 dence, the in vitro clinical test involved presents  
13 an unreasonable risk to the safety of the per-  
14 sons who are the subjects of the investigation,  
15 taking into account the qualifications of the in-  
16 vestigators, information about the in vitro clin-  
17 ical test, the design of the investigation, the  
18 condition for which the in vitro clinical test is  
19 to be investigated, and the health status of the  
20 subjects involved; or

21 “(B) based on substantial credible evi-  
22 dence, investigator misconduct or sponsor non-  
23 compliance with the requirements of this section  
24 present an unreasonable risk to the safety of

1           the persons who are the subjects of the clinical  
2           investigation.

3           “(3) APPEAL.—A sponsor of an investigation  
4           may submit to the Secretary a written request that  
5           a clinical hold imposed under this subsection be re-  
6           moved. Any such request shall include sufficient in-  
7           formation to support the removal of such clinical  
8           hold. Not later than 30 calendar days after receipt  
9           of such request, the Secretary shall respond to such  
10          a request, in writing and, if denying such request,  
11          specifying the reasons for such denial.

12          “(i) DEFINITIONS.—In this section:

13                 “(1) The term ‘affiliated’ means, with respect  
14                 to a sponsor, owning the sponsor, owned by the  
15                 sponsor, under common ownership with the sponsor,  
16                 or in a joint venture with the sponsor.

17                 “(2) The term ‘clinical hold’ means an action  
18                 taken by the Secretary prohibiting the sponsor of an  
19                 investigation of an in vitro clinical test from con-  
20                 ducting the investigation.

21                 “(3) The term ‘investigational use application’  
22                 means, with respect to an in vitro clinical test, an  
23                 application submitted under subsection (b)(1)(A) for  
24                 the use of the test by experts qualified by scientific

1 training and experience to investigate the analytical  
2 and clinical validity of the test.

3 “(4) The term ‘serious or life-threatening dis-  
4 ease or condition’ means a disease or condition—

5 “(A) for which the likelihood of death  
6 within one year is high unless the course of the  
7 disease or condition is interrupted;

8 “(B) that results in permanent impairment  
9 of a bodily function or permanent damage to a  
10 bodily structure within one year unless the  
11 course of the disease or condition is inter-  
12 rupted; or

13 “(C) that necessitates medical or surgical  
14 intervention within one year to preclude perma-  
15 nent impairment of a bodily function or perma-  
16 nent damage to a bodily structure.

17 “(5) The term ‘significant risk’ means, with re-  
18 spect to an in vitro clinical test that is the subject  
19 of an investigational use application, that the inves-  
20 tigational use of the test—

21 “(A) is a use of substantial importance in  
22 identifying, measuring, predicting, monitoring,  
23 or assisting in selecting treatment for, a serious  
24 or life-threatening disease or condition without

1 confirmation of the diagnosis by a medically es-  
2 tablished diagnostic product or procedure;

3 “(B) requires an invasive sampling proce-  
4 dure;

5 “(C) by design or intention, introduces en-  
6 ergy into the human subject;

7 “(D) otherwise presents a reasonably fore-  
8 seeable serious risk to the health of a human  
9 subject.

10 “(j) EXCEPTION FOR TESTS USED ONLY IN RE-  
11 SEARCH.—

12 “(1) RESEARCH-USE-ONLY TESTS.—

13 “(A) IN GENERAL.—Except as provided in  
14 subparagraph (B), research-use-only in vitro  
15 clinical tests shall not be subject to the require-  
16 ments of this Act.

17 “(B) LABELING.—The Secretary shall re-  
18 quire that any research-use-only in vitro clinical  
19 test be labeled for research use only.

20 “(2) BASIC RESEARCH TESTS.—Basic research  
21 tests shall not be subject to regulation under this  
22 Act.

23 “(3) DEFINITIONS.—In this subsection:

24 “(A) RESEARCH USE ONLY IN VITRO CLIN-  
25 ICAL TEST.—The term ‘research use only in

1           vitro clinical test’ means an in vitro clinical test  
2           that is in the laboratory phase of development.

3           “(B) BASIC RESEARCH TEST.—The term  
4           ‘basic research test’ means a test that—

5                   “(i) is intended solely for use in the  
6                   conduct of non-clinical laboratory research,  
7                   and not for the development of an in vitro  
8                   clinical test; and

9                   “(ii) is not an in vitro clinical test.

10 **“SEC. 590D. QUALITY REQUIREMENTS; UNIQUE IDENTIFI-**  
11 **FIERS.**

12           “(a) IN GENERAL.—The Secretary shall establish, by  
13 regulation, quality requirements for the development and  
14 production of in vitro clinical tests (as defined in section  
15 201(ss)) offered under this subchapter. In establishing  
16 such requirements, the Secretary shall consider whether  
17 to include requirements for each of the following:

18                   “(1) Management responsibility.

19                   “(2) Design controls.

20                   “(3) Document controls.

21                   “(4) Purchasing controls.

22                   “(5) Identification.

23                   “(6) Production and process controls.

24                   “(7) Acceptance activities.

25                   “(8) Nonconforming products.

1 “(9) Corrective and preventive action.

2 “(10) Labeling and package controls.

3 “(11) Handling, storage, distribution, and in-  
4 stallation.

5 “(12) Records.

6 “(13) Servicing.

7 “(14) Statistical techniques.

8 “(b) SCOPE.—The quality requirements under this  
9 section shall—

10 “(1) apply only with respect to the design, de-  
11 velopment, validation, production, manufacture,  
12 preparation, propagation, assembly, or processing of  
13 an in vitro clinical test (as defined in section  
14 201(ss)), offered under this subchapter;

15 “(2) account for differences between in vitro  
16 clinical tests that are finished products and in vitro  
17 clinical tests that are laboratory test protocols (as  
18 such terms are defined in section 201(ss));

19 “(3) not apply with respect to laboratory oper-  
20 ations; and

21 “(4) not apply to components or parts of an in  
22 vitro clinical test or raw materials used in an in  
23 vitro clinical test.

24 “(c) UNIQUE IDENTIFIERS.—

1           “(1) IN GENERAL.—The Secretary shall pro-  
2           mulgate regulations establishing a unique identifica-  
3           tion system for finished products (as defined in sec-  
4           tion 201(ss)(3)) requiring the label of finished prod-  
5           ucts to bear a unique identifier, unless the Secretary  
6           requires an alternative placement or provides an ex-  
7           ception for a particular finished product.

8           “(2) REQUIREMENTS.—The unique identifier  
9           shall adequately identify the finished product  
10          through distribution and use, and may include infor-  
11          mation on the lot or serial number of the product.  
12          The Secretary shall, to the extent possible, har-  
13          monize the unique identification system for finished  
14          products with, and use tools developed by the Sec-  
15          retary for, the unique device identification system  
16          established by the Secretary pursuant to section  
17          519(f). A unique identifier shall not be required for  
18          a laboratory test protocol (as defined in section  
19          201(ss)(2)).

20       **“SEC. 590E. POSTMARKET REQUIREMENTS.**

21           “(a) ADVERSE EVENT REPORTING.—

22           “(1) IN GENERAL.—The developer of any in  
23          vitro clinical test approved or listed under section  
24          590B shall—

1           “(A) maintain records of any adverse event  
2           that is associated with the test and is known by  
3           the developer;

4           “(B) include in such records any informa-  
5           tion, or references to such information, that is  
6           in the developer’s possession and relates to the  
7           adverse event, including documentation of the  
8           developer’s deliberations used to determine  
9           whether an in vitro clinical test error is re-  
10          quired to be reported under subparagraph (C)  
11          or (F);

12          “(C) submit to the Secretary a report on  
13          an adverse event—

14                 “(i) not later than 5 calendar days  
15                 after the adverse event becomes known to  
16                 the developer, if the adverse event involves  
17                 a patient death; or

18                 “(ii) not later than 15 calendar days  
19                 after the adverse event becomes known to  
20                 the developer, if the adverse event presents  
21                 an imminent threat to public health;

22          “(D) include in any report under clause (i)  
23          or (ii) of subparagraph (C), as applicable, infor-  
24          mation regarding—

25                 “(i) the patient;

- 1 “(ii) the test;
- 2 “(iii) the adverse event;
- 3 “(iv) the person who reported the ad-
- 4 verse event to the developer;
- 5 “(v) the developer; and
- 6 “(vi) the laboratory;
- 7 “(E) submit to the Secretary a report on
- 8 all adverse events that are associated with the
- 9 test and become known to the developer during
- 10 the preceding quarter of the year, if any; and
- 11 “(F) include in any report under subpara-
- 12 graph (E)—
- 13 “(i) the number and type of such ad-
- 14 verse events which became known to the
- 15 developer during the quarter covered by
- 16 the report;
- 17 “(ii) trend information regarding ad-
- 18 verse events that are associated with the
- 19 test;
- 20 “(iii) aggregated summary informa-
- 21 tion regarding the medical impact of such
- 22 adverse events on patients, if known; and
- 23 “(iv) any newly identified issues or
- 24 problems relating to the test.

1           “(2) STATEMENT REQUIRED IN LIEU OF INFOR-  
2           MATION IN CERTAIN QUARTERS.—A report under  
3           paragraph (1)(E) for any quarter in which no ad-  
4           verse events occur shall be limited to a statement  
5           that no adverse events occurred in such quarter.

6           “(3) LABORATORY ERRORS.—The developer of  
7           an in vitro clinical test shall not be required to  
8           maintain records or report under this section regard-  
9           ing laboratory errors that are subject to the stand-  
10          ards under section 353(f)(5) of the Public Health  
11          Service Act and corrective and preventive actions to  
12          address such errors.

13          “(4) REPORT NOT AN ADMISSION.—A report or  
14          other information submitted by a developer or other  
15          responsible party under this subsection (and any re-  
16          lease by the Secretary of that report or other infor-  
17          mation) does not constitute an admission by the de-  
18          veloper or other responsible party that the in vitro  
19          clinical test caused or contributed to an adverse  
20          event.

21          “(5) DEFINITIONS.—In this subsection:

22                  “(A) The term ‘adverse event’ means—

23                          “(i) any death or serious injury that  
24                          is reasonably believed to have been caused  
25                          by an in vitro clinical test error; or

1           “(ii) any in vitro clinical test error  
2           which, if the error were to reoccur, would  
3           have a reasonable probability (meaning  
4           more than a remote possibility, taking into  
5           account the probability of recurrence, ex-  
6           isting safeguards, and the probability of  
7           resulting harm) of causing death or serious  
8           injury.

9           “(B) The term ‘caused by an in vitro clin-  
10          ical test error’ means that an in vitro clinical  
11          test error was the primary factor in the death  
12          of, or serious injury to, a specific patient or  
13          user occurring within 1 year of the error.

14          “(C) The term ‘in vitro clinical test error’  
15          means a clinically significant failure of an in  
16          vitro clinical test to meet its performance speci-  
17          fications or otherwise perform as intended, ex-  
18          cept that such term excludes any such event or  
19          error related to laboratory operations.

20          “(D) The term ‘permanent’ means irre-  
21          versible impairment or damage to a body struc-  
22          ture or function, excluding trivial impairment or  
23          damage.

24          “(E) The term ‘serious injury’ means an  
25          injury or illness that—

1 “(i) is life-threatening;

2 “(ii) results in permanent impairment  
3 of a body function or permanent damage  
4 to a body structure; or

5 “(iii) necessitates medical or surgical  
6 intervention to preclude permanent impair-  
7 ment of a body function or permanent  
8 damage to a body structure.

9 “(b) NOTIFICATION.—

10 “(1) IN GENERAL.—Except with respect to an  
11 in vitro clinical test described in section 590B(l)(4),  
12 the Secretary may issue such notifications or orders  
13 as may be necessary to assure that adequate notifi-  
14 cation is provided in an appropriate form, by the  
15 persons and means best suited under the cir-  
16 cumstances involved, to all health care practitioners  
17 who prescribe or use an in vitro clinical test and to  
18 any other person (including manufacturers, import-  
19 ers, distributors, retailers, and users (including  
20 home users)) who should properly receive such noti-  
21 fication, if the Secretary determines that—

22 “(A) the in vitro clinical test has been of-  
23 fered and presents an unreasonable risk of sub-  
24 stantial harm to the public health; and

1           “(B) notification under this subsection is  
2           necessary to eliminate the unreasonable risk of  
3           such harm and no more practicable means is  
4           available under the provisions of this Act (other  
5           than this section) to eliminate such risk,

6           “(2) ORDERS.—An order under this subsection  
7           shall require that the individuals subject to the risk  
8           with respect to which the order is to be issued be in-  
9           cluded in the persons to be notified of the risk un-  
10          less the Secretary determines that notice to such in-  
11          dividuals would present a greater danger to the  
12          health of such individuals than no such notification.  
13          That notification shall describe the risk presented by  
14          the test and any action which may be taken to elimi-  
15          nate or reduce such risk. Before issuing an order  
16          under this subsection, the Secretary shall consult  
17          with the persons who are to give notice under the  
18          order.

19          “(c) VOLUNTARY CORRECTIONS AND REMOVALS.—

20                 “(1) IN GENERAL.—A developer or other re-  
21                 sponsible party may, at any time, initiate a vol-  
22                 untary correction or removal action with respect to  
23                 an in vitro clinical test.

24                 “(2) NOTICE TO SECRETARY.—Not later than 7  
25                 calendar days after the first correction or removal

1       action undertaken by the developer or other respon-  
2       sible party pursuant to paragraph (1), the developer  
3       or other responsible party shall submit to the Sec-  
4       retary, as applicable—

5               “(A) the name, unique identifier, and other  
6       similar information about the in vitro clinical  
7       test;

8               “(B) the name, address, contact informa-  
9       tion, and registration number of the developer  
10      or other responsible party;

11              “(C) a copy of any customer notification  
12      issued by the developer or other responsible  
13      party;

14              “(D) a description of the problem sought  
15      to be addressed by the correction or removal,  
16      including a health hazard evaluation;

17              “(E) a status and summary of the devel-  
18      oper or other responsible party’s internal inves-  
19      tigation;

20              “(F) the number of adverse event reports  
21      related to the problem sought to be addressed  
22      by the correction or removal;

23              “(G) relevant in vitro clinical test labeling,  
24      including instructions for use; and

25              “(H) a list of consignees.

1           “(3) CORRECTION OR REMOVAL IDENTIFIER.—  
2           Not later than 7 calendar days after receipt of a no-  
3           tification under paragraph (2), the Secretary shall  
4           assign a unique correction or removal identifier to  
5           such action and provide such identifier to the devel-  
6           oper or other responsible party. The developer or  
7           other responsible party shall include such unique  
8           identifier on all subsequent correspondence regard-  
9           ing the correction or removal action with the Sec-  
10          retary or any user.

11          “(4) NOTIFICATION TO USERS.—If communica-  
12          tion of a correction or removal action to patients,  
13          health care practitioners, and other users is nec-  
14          essary to protect public health, such communication  
15          shall include, as applicable—

16                 “(A) the unique correction or removal  
17                 identifier, as assigned by the Secretary;

18                 “(B) information sufficient to identify the  
19                 in vitro clinical test subject to the correction or  
20                 removal;

21                 “(C) a description of the problem sought  
22                 to be addressed by the correction or removal,  
23                 including the extent of the problem;

24                 “(D) a description of the potential risks to  
25                 patients or the public due to the problem, in-

1 including whether injuries or deaths have been  
2 associated with the problem;

3 “(E) instructions to the patient, health  
4 care practitioner, or other user, on appropriate  
5 actions to be taken; and

6 “(F) contact information for obtaining ad-  
7 ditional information from the developer or other  
8 responsible party.

9 “(5) CLASSIFICATION OF CORRECTION OR RE-  
10 MOVAL.—The Secretary shall classify a correction or  
11 removal under this subsection (according to the rel-  
12 ative degree of health hazard presented by the in  
13 vitro clinical test being corrected or removed) within  
14 30 calendar days of receiving notice pursuant to  
15 paragraph (2). If the Secretary determines a notifi-  
16 cation of such classification in addition to any notifi-  
17 cation already provided by the developer or other re-  
18 sponsible party pursuant to paragraph (4) is nec-  
19 essary to protect public health, the Secretary may  
20 issue such notice, and shall include in such notice in-  
21 formation clarifying that such notice is intended to  
22 inform patients, health care practitioners, and other  
23 users that the notice is not a second correction or  
24 removal and that the notice is part of an agency

1 process for classifying an existing correction or re-  
2 moval.

3 “(6) REPORT NOT AN ADMISSION.—A report or  
4 other information submitted by a developer or other  
5 responsible party under this subsection (and any re-  
6 lease by the Secretary of that report or other infor-  
7 mation) does not constitute an admission by the de-  
8 veloper or other responsible party that the in vitro  
9 clinical test caused or contributed to an adverse  
10 event..

11 “(7) CLOSING A CORRECTION OR REMOVAL.—  
12 Not later than 45 calendar days after the developer  
13 or other responsible party notifies the Secretary that  
14 it has completed a correction or removal action, the  
15 Secretary shall provide the developer or other re-  
16 sponsible party a written statement closing the cor-  
17 rection or removal or stating the reasons the Sec-  
18 retary cannot close the correction or removal at that  
19 time.

20 “(d) MANDATORY CORRECTIONS AND REMOVALS.—

21 “(1) IN GENERAL.—If the Secretary finds that  
22 there is a reasonable probability that an in vitro  
23 clinical test would cause serious, adverse health con-  
24 sequences or death, the Secretary shall issue an  
25 order requiring the appropriate person—

1           “(A) to immediately cease offering such  
2           test; and

3           “(B) to immediately notify health care  
4           practitioners and other users of the in vitro  
5           clinical test of the order and to instruct such  
6           practitioners and users to cease offering or  
7           using such in vitro clinical test.

8           “(2) INFORMAL HEARING.—An order under  
9           paragraph (1) shall provide the person subject to the  
10          order with an opportunity for an informal hearing,  
11          to be held not later than 10 calendar days after the  
12          date of the issuance of the order, on the actions re-  
13          quired by the order and on whether the order should  
14          be amended to require a correction or removal of  
15          such in vitro clinical test. If, after providing an op-  
16          portunity for such a hearing, the Secretary deter-  
17          mines that inadequate grounds exist to support the  
18          actions required by the order, the Secretary shall va-  
19          cate the order.

20          “(3) AMENDMENT TO REQUIRE CORRECTION OR  
21          REMOVAL.—

22          “(A) AMENDMENT.—If, after providing an  
23          opportunity for an informal hearing under  
24          paragraph (2), the Secretary determines that  
25          an order should be amended to include a correc-

1           tion or removal of the in vitro clinical test with  
2           respect to which the order was issued, the Sec-  
3           retary shall, except as provided in subpara-  
4           graphs (B) and (C), amend the order to require  
5           a correction or removal. The Secretary shall  
6           specify a timetable in which the in vitro clinical  
7           test correction or removal will occur and shall  
8           require periodic reports to the Secretary de-  
9           scribing the progress of the correction or re-  
10          moval.

11                 “(B) CONTENTS.—An amended order  
12          under subparagraph (A)—

13                         “(i) shall—

14                                 “(I) not include correction or re-  
15                                 moval of an in vitro clinical test from  
16                                 individuals; and

17                                 “(II) not include correction or re-  
18                                 moval of an in vitro clinical test from  
19                                 in vitro clinical test user facilities if  
20                                 the Secretary determines that the risk  
21                                 of correcting or removing such in vitro  
22                                 clinical test from the facilities pre-  
23                                 sents a greater health risk than the  
24                                 health risk of not correcting or remov-

1                   ing the in vitro clinical test from use;  
2                   and

3                   “(ii) shall provide for notice to indi-  
4                   viduals subject to the risks associated with  
5                   the use of such in vitro clinical test.

6                   “(C) ASSISTANCE OF HEALTH CARE PRAC-  
7                   TITIONERS.—In providing the notice required  
8                   by subparagraph (B)(ii), the Secretary may use  
9                   the assistance of health care practitioners who  
10                  prescribed, ordered, or used such an in vitro  
11                  clinical test for individuals. If a significant  
12                  number of such individuals cannot be identified,  
13                  the Secretary shall notify such individuals pur-  
14                  suant to section 705(b).

15                  “(4) CLASSIFICATION.—The Secretary shall  
16                  classify a correction or removal under this sub-  
17                  section (according to the relative degree of health  
18                  hazard presented by the in vitro clinical test being  
19                  corrected or removed) within 30 calendar days of or-  
20                  dering the correction or removal.

21                  “(e) INAPPLICABILITY TO CERTAIN MATTERS.—The  
22                  Secretary shall not order a notification under subsection  
23                  (b) or a correction or removal under subsection (d) on the  
24                  basis of any of the following:

1           “(1) Changes or improvements in laboratory  
2 operations.

3           “(2) Corrections or updates to patient-specific  
4 laboratory reports.

5           “(3) Enhancements to an in vitro clinical test.

6           “(f) POSTMARKET SURVEILLANCE.—

7           “(1) IN GENERAL.—The Secretary may by  
8 order require a developer to conduct postmarket sur-  
9 veillance, including postmarket studies, for an ap-  
10 proved high-risk or moderate-risk in vitro clinical  
11 test only if the Secretary determines, based on new  
12 valid scientific evidence, that the failure of such in  
13 vitro clinical test would be reasonably likely to have  
14 serious adverse health consequences.

15           “(2) POSTMARKET CLINICAL TRIALS.—The Sec-  
16 retary may require the developer of an in vitro clin-  
17 ical test to conduct a postmarket clinical trial under  
18 paragraph (1) only for a high-risk in vitro clinical  
19 test and only if the Secretary determines that no  
20 other approach can provide the necessary informa-  
21 tion. The authority to require such a trial shall not  
22 be delegated to any official or employee below the  
23 level of senior management of the Center for in vitro  
24 clinical tests.

1           “(g) MISBRANDED IN VITRO CLINICAL TESTS.—An  
2 in vitro clinical test shall be deemed to be misbranded if  
3 the Secretary finds, based on all available data and infor-  
4 mation, that the in vitro clinical test presents an unreason-  
5 able and substantial risk of illness or injury when used  
6 as intended by its developer.

7           **“SEC. 590F. APPEALS.**

8           “(a) IN GENERAL.—The Secretary shall establish by  
9 regulation an appeals process for the review of classifica-  
10 tion and reclassification determinations under section  
11 590A, premarket determinations under sections 590B and  
12 590C, and other adverse decisions made by the Secretary  
13 under this subchapter. Except as otherwise provided in  
14 this subchapter, the process established by the Secretary  
15 shall be consistent with the guidance entitled ‘Center for  
16 Devices and Radiological Health Appeals Processes’ and  
17 dated May 17, 2013.

18           “(b) FINAL ACTION FOR JUDICIAL REVIEW.—In all  
19 cases, the process established under subsection (a) shall  
20 provide for a decision constituting final action by the agen-  
21 cy not later than 180 calendar days after the date on  
22 which the appeal is first submitted.

23           “(b) ADVISORY PANELS.—The appeal process estab-  
24 lished under subsection (a) shall permit the appellant to  
25 request review by an advisory panel. Any such advisory

1 panel shall include interested persons with knowledge of  
2 in vitro clinical tests, laboratory operations, and the use  
3 of in vitro clinical tests.

4 **“SEC. 590G. PREEMPTION.**

5 “(a) IN GENERAL.—No State, tribal, or local govern-  
6 ment (or political subdivision thereof) may establish or  
7 continue in effect any requirement related to the develop-  
8 ment, manufacture, labeling, distribution, sale, or use of  
9 an in vitro clinical test that is different from, or in addi-  
10 tion to, the requirements of this subchapter.

11 “(b) EXCEPTIONS.—Subsection (a) shall not be con-  
12 strued to affect the authority of a State, tribal, or local  
13 government—

14 “(1) to license health care practitioners or  
15 health care facilities or to regulate any aspect of a  
16 health care practitioner-patient relationship; or

17 “(2) to enforce laws of general applicability,  
18 such as zoning laws, environmental laws, labor laws,  
19 and general business laws.

20 “(c) CLARIFICATION.—This section shall not be con-  
21 strued to shift liability to health care practitioners or other  
22 users.

23 **“SEC. 590H. APPLICABILITY OF CERTAIN PROVISIONS.**

24 “The provisions of sections 301, 303(f)(1), 304, 306,  
25 501, 502, 503(a), 503(g), 506, 509, 517 , 520(c), 561,

1 562, 563, 566(b), 566(e), 702, 703, 705, 721, 756, 770,  
2 801, 802, 803, 1003, 1003a, and 1011 apply with respect  
3 to in vitro clinical tests to the same extent and in the same  
4 manner as such provisions apply with respect to devices,  
5 except as follows:

6           “(1) Such provisions apply with respect to in  
7 vitro clinical tests only to the extent such provisions  
8 are determined by the Secretary to be consistent  
9 with this subchapter.

10           “(2) The following provisions do not apply with  
11 respect to in vitro clinical tests: Section 301(y), sub-  
12 sections (e), (f), (g), (h), and (i) of section 501, sub-  
13 sections (q), (r), (s), (t)(2), and (t)(3) of section  
14 502, and section 510.

15           “(3) In the case of in vitro clinical tests, the  
16 statement required by section 502(v) is ““Reproc-  
17 essed in vitro clinical test for single use. Reprocessed  
18 by \_\_\_\_.””.

19           “(4) In applying section 503(g)(1)(B), if the  
20 Secretary determines that the primary mode of ac-  
21 tion is that of an in vitro clinical test, the agency  
22 center charged with premarket review of in vitro  
23 clinical tests shall have primary jurisdiction.”.

1 (b) CONFORMING AMENDMENT.—Section 517(a) of  
2 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
3 360g(a)) is amended—

4 (1) by striking “or” at the end of paragraph  
5 (8);

6 (2) by inserting “or” at the end of paragraph  
7 (9); and

8 (3) by inserting after paragraph (9) the fol-  
9 lowing:

10 “(10) the issuance of a decision under section  
11 590F,”.

12 (c) EMERGENCY USE OF IN VITRO CLINICAL  
13 TESTS.—Section 564 of the Federal Food, Drug, and Cos-  
14 metic Act (21 U.S.C. 360bbb–3) is amended—

15 (1) in subsections (a)(1) and (a)(4)(C), by in-  
16 serting “in vitro clinical test,” before “or biological  
17 product” each place it appears;

18 (2) in paragraph (2) of subsection (b), by add-  
19 ing at the end the following:

20 “(C) CONTINUED PRODUCT AVAILABILITY  
21 AFTER TERMINATION.—A manufacturer or pro-  
22 vider of an in vitro clinical test with an author-  
23 ization under this section may consult with the  
24 Secretary for, and the Secretary may allow,  
25 continued distribution and use of such test after

1           termination of the authorization if the condi-  
2           tions of subsections (c)(2), (c)(3), and (c)(4)  
3           continue to be satisfied.”;

4           (3) in subsection (c), in the matter before para-  
5           graph (1), by inserting “(and with respect to in vitro  
6           clinical tests local, State, or regional public health  
7           authorities)” after “the Director of the Centers for  
8           Disease Control and Prevention”;

9           (4) in subsection (e)(3)—

10           (A) in subparagraph (A), by inserting “de-  
11           sign (with respect to in vitro clinical tests),” be-  
12           fore “manufacture,”; and

13           (B) in subparagraph (B), by striking  
14           “and” at the end;

15           (C) in subparagraph (C), by striking the  
16           period at the end and inserting “; and”; and

17           (D) by adding at the end the following:

18           “(D) quality system requirements (with re-  
19           spect to laboratories and laboratory operations)  
20           established under section 353 of the Public  
21           Health Service Act.”;

22           (5) in subsection (f)(2), by inserting “or, in the  
23           case of an in vitro clinical test, for diagnosis, prog-  
24           nosis, or monitoring” before “to the extent”; and

25           (6) in subsection (m)—

1 (A) in the subsection heading, by striking  
2 “LABORATORY TESTS ASSOCIATED WITH DE-  
3 VICES” and inserting “IN VITRO CLINICAL  
4 TESTS”; and

5 (B) in paragraph (1)—

6 (i) by striking “a device” and insert-  
7 ing “an in vitro clinical test”; and

8 (ii) by striking “such device” and in-  
9 serting “such in vitro clinical test”.

10 (d) INSPECTIONS.—Section 704 of the Federal Food,  
11 Drug, and Cosmetic Act (21 U.S.C. 374) is amended by  
12 adding at the end the following:

13 “(h) INSPECTIONS BY ACCREDITED PERSONS.—

14 “(1) IN GENERAL.—The Secretary shall estab-  
15 lish by regulation a process to accredit persons for  
16 the purpose of conducting inspections of establish-  
17 ments engaged in the design, development, valida-  
18 tion, production, manufacture, preparation, propaga-  
19 tion, assembly, or processing of an in vitro clinical  
20 test. The process established by the Secretary shall  
21 permit the owner or operator of such an establish-  
22 ment to select, from the list published under para-  
23 graph (4), an accredited person to conduct such in-  
24 spections.

1           “(2) ACCREDITATION CRITERIA.—The Sec-  
2           retary shall publish in the Federal Register criteria  
3           to accredit or deny accreditation to persons who re-  
4           quest to perform the duties specified in paragraph  
5           (1).

6           “(3) DISPOSITION OF REQUESTS FOR ACCREDI-  
7           TATION.—The Secretary shall—

8                   “(A) not later than 60 calendar days after  
9                   the receipt of a request for accreditation under  
10                  this subsection, inform the requesting person  
11                  whether the request is adequate for review; and

12                   “(B) promptly accredit or deny accredita-  
13                  tion to the person.

14           “(4) LIST.—The Secretary shall—

15                   “(A) publish on the Internet site of the  
16                   Food and Drug Administration a list of persons  
17                   who are accredited under this subsection; and

18                   “(B) keep such list updated to ensure that  
19                   the identity of each accredited person, and the  
20                   particular activities for which the person is ac-  
21                   credited, is available to the public.

22           “(i) HYBRID INSPECTIONS.—

23                   “(1) INTERAGENCY AGREEMENT.—The Com-  
24                   missioner of Food and Drugs may enter into an  
25                   agreement with the Administrator of the Centers for

1 Medicare & Medicaid Services to jointly train and  
2 accredit hybrid inspectors authorized to inspect—

3 “(A) establishments engaged in the design,  
4 development, validation, production, manufac-  
5 ture, preparation, propagation, assembly, or  
6 processing of an in vitro clinical test pursuant  
7 to subchapter J of chapter V; and

8 “(B) laboratories operating under section  
9 353 of the Public Health Service Act

10 “(2) REQUIREMENTS.—A hybrid inspector con-  
11 ducting an inspection pursuant to an agreement  
12 under subparagraph (A) shall—

13 “(A) prior to such inspection, state wheth-  
14 er the hybrid inspector intends to conduct an  
15 inspection pursuant to subchapter J of chapter  
16 V, section 353(g)(1) of the Public Health Serv-  
17 ice Act, or both;

18 “(B) conduct any inspection in accordance  
19 with the intent stated under clause (i); and

20 “(C) with respect to an establishment that  
21 is both engaged in the design, development, val-  
22 idation, production, manufacture, preparation,  
23 propagation, assembly, or processing of an in  
24 vitro clinical test and operating as a laboratory,  
25 if the inspector intends to inspect such estab-

1            lishment pursuant to both subchapter J of  
2            chapter V and section 353(g)(1) of the Public  
3            Health Service Act, notify such establishment  
4            or laboratory of such intent and maintain a  
5            clear distinction between the portions of such  
6            inspection conducted pursuant to such sub-  
7            chapter J and the portions of such inspection  
8            conducted pursuant to such section 353(g)(1).

9            “(3) UNEXPECTED ISSUES.—If during the  
10          course of an inspection for which the stated intent  
11          is to conduct an inspection pursuant to subchapter  
12          J of chapter V, a hybrid inspector identifies one or  
13          more issues under section 353 of the Public Health  
14          Service Act, the hybrid inspector shall—

15                “(A) notify the establishment or laboratory  
16                of the issues and, at the discretion of the in-  
17                spector, notify the Centers for Medicare & Med-  
18                icaid of the issues; and

19                “(B) in collaboration with the Centers for  
20                Medicare & Medicaid, determine whether such  
21                notice warrants other action under such section  
22                353.”.

23          (e) REGULATIONS.—

24                (1) PROMULGATION.—Not later than 2 years  
25          after the date of enactment of this Act, the Sec-

1       retary of Health and Human Services, acting  
2       through the Commissioner of Food and Drugs, shall  
3       promulgate final regulations to carry out the amend-  
4       ments made by this section.

5               (2) EFFECTIVE DATE.—

6                       (A) IN GENERAL.—The regulations pro-  
7                       mulgated pursuant to paragraph (1) shall take  
8                       effect on the date that is 2 years after the date  
9                       of such promulgation.

10                      (B) PREMARKET REQUIREMENTS.—Not-  
11                      withstanding subparagraph (A), with respect to  
12                      a manufacturer (as defined in section 7), the  
13                      regulations promulgated pursuant to paragraph  
14                      (1) to carry out sections 590A, 590B, and  
15                      590C of the Federal Food, Drug, and Cosmetic  
16                      Act, as added by subsection (a), shall take ef-  
17                      fect on the date that is 1 year after the date  
18                      of such promulgation.

19                      (3) FINISHED PRODUCTS AND LABORATORY  
20                      TEST PROTOCOLS.—All regulations established pur-  
21                      suant to paragraph (1) shall account for differences  
22                      between finished products and laboratory test proto-  
23                      cols (as such terms are defined in section 201(ss) of  
24                      the Federal Food, Drug, and Cosmetic Act, as  
25                      added by section 2(a)).

1 (f) EDUCATION AND TRAINING OF AGENCY EMPLOY-  
2 EES AND CONTRACTORS.—

3 (1) ESTABLISHMENT OF PLAN.—The Secretary  
4 of Health and Human Services, acting through the  
5 Commissioner of Food and Drugs, shall—

6 (A) publish a proposed plan for education  
7 and training of employees and contractors of  
8 the Food and Drug Administration on imple-  
9 mentation of the amendments made by this sec-  
10 tion;

11 (B) provide an opportunity for public com-  
12 ment on such plan during a period of not less  
13 than 90 calendar days;

14 (C) not later than 2 years after the date  
15 of enactment of this Act, publish a final version  
16 of such plan; and

17 (D) ensure that initial training of employ-  
18 ees and contractors under the plan is completed  
19 within 1 year of the date of publishing such  
20 final version.

21 (2) PLAN CONTENTS.—The plan required by  
22 paragraph (1) shall include—

23 (A) detailed plans for rigorous ongoing and  
24 initial training of employees and contractors of  
25 the Food and Drug Administration on imple-

1           mentation of the amendments made by this sec-  
2           tion, including the standard for review, ap-  
3           proval, and listing of an in vitro clinical test  
4           under section 590B of the Federal Food, Drug,  
5           and Cosmetic Act, as added by subsection (a);

6                   (B) education of such employees and con-  
7           tractors on the operation of clinical laboratories  
8           and the scope of activities within such labora-  
9           tories that are subject to regulation under such  
10          amendments; and

11                   (C) ongoing training of such employees  
12          and contractors on the technology and utiliza-  
13          tion of in vitro clinical tests.

14          (g) ANNUAL REPORT.—Not later than one year after  
15          the date of enactment of this Act, and annually thereafter,  
16          the Secretary of Health and Human Services, acting  
17          through the Commissioner of Food and Drugs, shall sub-  
18          mit a report to the Congress—

19                   (1) describing activities that have been under-  
20          taken by the Food and Drug Administration pursu-  
21          ant to the amendments made by this section and  
22          progress toward relevant statutory deadlines;

23                   (2) explaining the ways in which such activities  
24          account for the unique characteristics of in vitro

1 clinical tests and differ from the regulation of de-  
2 vices; and

3 (3) explaining the ways in which such activities  
4 promote patient access to new in vitro clinical tests.

5 (h) EXECUTIVE PERFORMANCE.—Timely and appro-  
6 priate implementation and execution of this Act shall be  
7 included in the performance evaluations of relevant Food  
8 and Drug Administration executives, including members  
9 of the Senior Executive Service and equivalent positions,  
10 for purposes of determining any performance bonus, sal-  
11 ary increase, or job advancement.

12 **[SEC. 4. FDA FEES.**

13 ***[to be supplied]***

14 **SEC. 5. CERTIFICATION OF LABORATORIES (CLIA).**

15 Section 353 of the Public Health Service Act (42  
16 U.S.C. 263a) is amended to read as follows:

17 **“SEC. 353. CERTIFICATION OF LABORATORIES.**

18 **“(a) SCOPE OF AUTHORITY; DEFINITIONS.—**

19 **“(1) SCOPE OF AUTHORITY.—**Laboratories  
20 shall be regulated by the Secretary under this sec-  
21 tion. Laboratory operations shall be regulated by the  
22 Secretary under this section and shall not be regu-  
23 lated under the Federal Food, Drug, and Cosmetic  
24 Act.

25 **“(2) LIMITATIONS OF AUTHORITY.—**

1           “(A) FDA REGULATION.—The design, de-  
2           velopment, validation, production, manufacture,  
3           preparation, propagation, assembly, and proc-  
4           essing of an in vitro clinical test shall be regu-  
5           lated under subchapter J of chapter V of the  
6           Federal Food, Drug, and Cosmetic Act, and  
7           shall not be regulated by the Secretary under  
8           this section.

9           “(B) OTHER ACTIVITIES.—The Secretary  
10          shall not regulate the practice of medicine  
11          under this section. The authority to so regulate  
12          shall be reserved to the individual States.

13          “(3) DEFINITIONS.—In this section:

14               “(A) The term ‘certificate’ refers, as appli-  
15               cable, to—

16                       “(i) the documentary evidence of au-  
17                       thorization to engage in the activities regu-  
18                       lated in this section required under sub-  
19                       section (b); or

20                       “(ii) a certificate of waiver issued  
21                       under subsection (d)(2).

22               “(B) The term ‘in vitro clinical test’ has  
23               the meaning given to that term in section  
24               201(ss) of the Federal Food, Drug, and Cos-  
25               metic Act.

1           “(C) The term ‘laboratory’ or ‘clinical lab-  
2           oratory’ means a facility for the biological,  
3           microbiological, serological, chemical, immuno-  
4           hematological, hematological, biophysical,  
5           cytological, pathological, or other examination  
6           of materials derived from the human body for  
7           the purpose of providing information for the di-  
8           agnosis, prevention, or treatment of any disease  
9           or impairment of, or the assessment of the  
10          health of, human beings.

11          “(D)(i) The term ‘laboratory operations’  
12          means the conduct of an in vitro clinical test  
13          and associated activities not excluded by para-  
14          graph (a)(1)(B) from the Secretary’s authority  
15          to regulate under this section, within or under  
16          the oversight of a laboratory. Such term in-  
17          cludes the following activities:

18                 “(I) Developing and implementing  
19                 standard operating procedures.

20                 “(II) Verifying laboratory perform-  
21                 ance of an in vitro clinical test.

22                 “(III) Performing pre-analytical proc-  
23                 esses for an in vitro clinical test.

24                 “(IV) Collection, transportation, dis-  
25                 position, and storage of patient specimens.

1           “(V) Preparing reagents or other test  
2 materials which do not meet the definition  
3 of a finished test product under section  
4 201(ss) of the Federal Food, Drug, and  
5 Cosmetic Act.

6           “(VI) Performing an in vitro clinical  
7 test pursuant to the relevant standard op-  
8 erating procedures for such test.

9           “(VII) Reporting the output or results  
10 of an in vitro clinical test.

11           “(VIII) Validating modifications to in  
12 vitro clinical tests if such modifications are  
13 not regulated under subchapter J of the  
14 Federal Food, Drug, and Cosmetic Act.

15           “(ii) Such term includes the preparation  
16 and transfer of individual components, parts,  
17 and raw materials between commonly owned  
18 laboratories within the same State, if—

19           “(I) the Secretary has established by  
20 regulation—

21           “(aa) applicable quality require-  
22 ments that are substantially equiva-  
23 lent to the comparable quality require-  
24 ments under subchapter J of the Fed-  
25 eral Food, Drug and Cosmetic Act;

1                   “(bb) inspection processes that  
2                   are substantially equivalent to the  
3                   comparable inspection processes under  
4                   such subchapter J; and

5                   “(cc) enforcement processes that  
6                   are substantially equivalent to the  
7                   comparable enforcement processes  
8                   under such subchapter J;

9                   “(II) the Secretary reviews the regula-  
10                  tions established pursuant to subclause (I)  
11                  three years after the effective date of such  
12                  regulations to determine whether com-  
13                  parable quality requirements are being im-  
14                  plemented as required by such clause and  
15                  whether the value of such requirements are  
16                  commensurate with the related burden;  
17                  and

18                  “(III) as part of the review conducted  
19                  pursuant to subclause (II), the Secretary—

20                         “(aa) holds at least one public  
21                         meeting;

22                         “(bb) issues a draft determina-  
23                         tion regarding whether to maintain or  
24                         amend the quality requirements estab-  
25                         lished pursuant to subclause (I);

1                   “(cc) provides for a public com-  
2                   ment period of 90 days on the draft  
3                   determination; and

4                   “(dd) issues a final determina-  
5                   tion, with any proposed amended reg-  
6                   ulations, not later than four years  
7                   after the effective date of the regula-  
8                   tions established pursuant to sub-  
9                   clause (I).

10                  “(E) The term ‘standard operating proce-  
11                  dures’ means instructions for implementation of  
12                  one or more in vitro clinical tests, in one or  
13                  more laboratories, that do not materially alter  
14                  the design, development, validation, production,  
15                  manufacture, preparation, propagation, assem-  
16                  bly, or processing of such in vitro clinical tests.

17                  “(b) CERTIFICATE REQUIREMENT.—No person may  
18                  solicit or accept materials derived from the human body  
19                  for laboratory examination or other laboratory procedure  
20                  unless there is in effect for the laboratory a certificate  
21                  issued by the Secretary under this section applicable to  
22                  the category of examinations or procedures which includes  
23                  such examination or procedure.

24                  “(c) ISSUANCE AND RENEWAL OF CERTIFICATES.—

1           “(1) IN GENERAL.—The Secretary may issue or  
2           renew a certificate for a laboratory only if the lab-  
3           oratory meets the requirements of subsection (d).

4           “(2) TERM.—A certificate issued under this  
5           section shall be valid for a period of 2 years or such  
6           shorter period as the Secretary may establish.

7           “(d) REQUIREMENTS FOR CERTIFICATES.—

8           “(1) IN GENERAL.—A laboratory may be issued  
9           a certificate or have its certificate renewed if—

10                   “(A) the laboratory submits (or if the lab-  
11                   oratory is accredited under subsection (e), the  
12                   accreditation body which accredited the labora-  
13                   tory submits), an application—

14                           “(i) in such form and manner as the  
15                           Secretary shall prescribe;

16                           “(ii) that describes the characteristics  
17                           of the laboratory examinations and other  
18                           procedures performed by the laboratory in-  
19                           cluding—

20                                   “(I) the number and types of lab-  
21                                   oratory examinations and other proce-  
22                                   dures performed;

23                                   “(II) the methodologies for lab-  
24                                   oratory examinations and other proce-  
25                                   dures employed; and

1                   “(III) the qualifications (edu-  
2                   cational background, training, and ex-  
3                   perience) of the personnel directing  
4                   and supervising the laboratory and  
5                   performing the laboratory examina-  
6                   tions and other procedures; and

7                   “(iii) that contains such other infor-  
8                   mation as the Secretary may require to de-  
9                   termine compliance with this section; and  
10                  the laboratory agrees to provide to the Sec-  
11                  retary (or if the laboratory is accredited, to the  
12                  accreditation body which accredited it) a de-  
13                  scription of any change in the information sub-  
14                  mitted under clause (ii) not later than 6 months  
15                  after the change was put into effect;

16                  “(B) the laboratory provides the Sec-  
17                  retary—

18                         “(i) with satisfactory assurances that  
19                         the laboratory will be operated in accord-  
20                         ance with standards issued by the Sec-  
21                         retary under subsection (f); or

22                         “(ii) with proof of accreditation under  
23                         subsection (e);

24                         “(C) the laboratory agrees to permit in-  
25                         spections by the Secretary under subsection (g);

1           “(D) the laboratory agrees to make records  
2 available and submit reports to the Secretary as  
3 the Secretary may reasonably require;

4           “(E) the laboratory agrees to treat pro-  
5 ficiency testing samples in the same manner as  
6 it treats materials derived from the human body  
7 referred to it for laboratory examinations or  
8 other procedures in the ordinary course of busi-  
9 ness, except that no proficiency testing sample  
10 shall be intentionally referred to another labora-  
11 tory for analysis as prohibited under subsection  
12 (i)(4); and

13           “(F) the laboratory has in place processes  
14 and policies to review and assess modifications  
15 to in vitro clinical tests, as required by para-  
16 graph (4).

17           “(2) REQUIREMENTS FOR CERTIFICATES OF  
18 WAIVER.—

19           “(A) IN GENERAL.—A laboratory which  
20 only performs laboratory examinations and pro-  
21 cedures described in paragraph (3) shall be  
22 issued a certificate of waiver or have its certifi-  
23 cate of waiver renewed if—

24                   “(i) the laboratory submits an appli-  
25 cation—

1                   “(I) in such form and manner as  
2                   the Secretary shall prescribe;

3                   “(II) that describes the charac-  
4                   teristics of the laboratory examina-  
5                   tions and other procedures performed  
6                   by the laboratory, including the num-  
7                   ber and types of laboratory examina-  
8                   tions and other procedures performed,  
9                   the methodologies for laboratory ex-  
10                  aminations and other procedures em-  
11                  ployed, and the qualifications (edu-  
12                  cational background, training, and ex-  
13                  perience) of the personnel directing  
14                  and supervising the laboratory and  
15                  performing the laboratory examina-  
16                  tions and other procedures; and

17                  “(III) that contains such other  
18                  information as the Secretary may rea-  
19                  sonably require to determine compli-  
20                  ance with this section; and

21                  “(ii) the laboratory agrees to make  
22                  records available and submit reports to the  
23                  Secretary as the Secretary may require.

24                  “(B) CHANGES THAT MAY AFFECT WAIVED  
25                  STATUS.—

1                   “(i) CHANGES TO CERTAIN EXAMINA-  
2                   TIONS AND PROCEDURES.—If a laboratory  
3                   makes changes in the examinations and  
4                   other procedures performed by it only with  
5                   respect to examinations and procedures  
6                   which are described in paragraph (3), the  
7                   laboratory shall report such changes to the  
8                   Secretary not later than 6 months after  
9                   the change has been put into effect.

10                   “(ii) OTHER CHANGES.—If a labora-  
11                   tory proposes to make changes in the ex-  
12                   aminations and procedures performed by it  
13                   such that the laboratory will perform an  
14                   examination or procedure not described in  
15                   paragraph (3), the laboratory shall report  
16                   such change to the Secretary before the  
17                   change takes effect. The laboratory shall  
18                   report any such change to the Secretary  
19                   without regard to whether such change is  
20                   a modification subject to premarket ap-  
21                   proval under section 590B(m) of the Fed-  
22                   eral Food, Drug, and Cosmetic Act. If any  
23                   such change is a modification subject to  
24                   premarket approval under such section  
25                   590B(m), the laboratory shall obtain such

1 approval before putting the modification  
2 into effect.

3 “(iii) HIGH COMPLEXITY.— In the  
4 case of any modification by a laboratory to  
5 an examination or procedure described in  
6 paragraph (3) that causes the examination  
7 or procedure to have high complexity, the  
8 examination or procedure shall be subject  
9 to the requirements under this section for  
10 high complexity examinations and proce-  
11 dures.

12 “(C) EFFECT.—Subsections (g) and (h)  
13 shall not apply to a laboratory to which a cer-  
14 tificate of waiver has been issued.

15 “(3) EXAMINATIONS AND PROCEDURES.—

16 “(A) IN GENERAL.—The examinations and  
17 procedures identified in paragraph (2) are lab-  
18 oratory examinations and procedures that have  
19 been approved by the Food and Drug Adminis-  
20 tration for home use or that, as determined by  
21 the Secretary, are simple laboratory examina-  
22 tions and procedures that have an insignificant  
23 risk of an erroneous result, including those  
24 that—

1           “(i) employ methodologies that are so  
2           simple and accurate as to render the likeli-  
3           hood of erroneous results by the user neg-  
4           ligible; or

5           “(ii) the Secretary has determined  
6           pose no unreasonable risk of harm to the  
7           patient if performed incorrectly.

8           “(B) DEFINITION.—In this paragraph, the  
9           phrase ‘accurate as to render the likelihood of  
10          erroneous results by the user negligible’ means,  
11          with respect to an in vitro clinical test, that the  
12          accuracy achieved by individuals qualified to  
13          perform a laboratory examination or procedure  
14          in a laboratory holding a certificate of waiver  
15          under paragraph (2) is equivalent to the accu-  
16          racy achieved by individuals qualified to per-  
17          form a laboratory examination or procedure in  
18          a laboratory certified under paragraph (1), as  
19          shown by evidence that directly compares such  
20          accuracy or evaluates such agreement of re-  
21          sults.

22          “(e) ACCREDITATION.—

23                 “(1) IN GENERAL.—A laboratory may be ac-  
24                 credited for purposes of obtaining a certificate if the  
25                 laboratory—

1           “(A) meets the standards of an approved  
2 accreditation body; and

3           “(B) authorizes the accreditation body to  
4 submit to the Secretary (or such State agency  
5 as the Secretary may designate) such records or  
6 other information as the Secretary may require.

7           “(2) APPROVAL OF ACCREDITATION BODIES.—

8           “(A) IN GENERAL.—The Secretary may  
9 approve a State’s laboratory licensure program,  
10 or a private nonprofit organization, to be an ac-  
11 creditation body for the accreditation of labora-  
12 tories if—

13           “(i) using inspectors qualified to  
14 evaluate the methodologies used by the lab-  
15 oratories in performing laboratory exami-  
16 nations and other procedures, the accredi-  
17 tation body agrees to inspect a laboratory  
18 for purposes of accreditation with such fre-  
19 quency as may be determined by the Sec-  
20 retary;

21           “(ii) the standards applied by the  
22 body in determining whether or not to ac-  
23 credit a laboratory are the standards  
24 issued by the Secretary under subsection  
25 (f);

1           “(iii) there is adequate provision for  
2           assuring that the standards issued by the  
3           Secretary under subsection (f) continue to  
4           be met by the laboratory;

5           “(iv) in the case of any laboratory ac-  
6           credited by the body which has had its ac-  
7           creditation denied, suspended, withdrawn,  
8           or revoked or which has had any other ac-  
9           tion taken against it by the accrediting  
10          body, the accrediting body agrees to sub-  
11          mit to the Secretary the name of such lab-  
12          oratory within 30 days of the action taken;  
13          and

14          “(vi) if the accreditation body has its  
15          approval withdrawn by the Secretary, the  
16          body agrees to notify each laboratory ac-  
17          credited by the body of the withdrawal  
18          within 10 days of the withdrawal.

19          “(B) CRITERIA AND PROCEDURES.—The  
20          Secretary shall promulgate criteria and proce-  
21          dures for approving an accreditation body and  
22          for withdrawing such approval if the Secretary  
23          determines that the accreditation body does not  
24          meet the requirements of subparagraph (A).

1           “(C) EFFECT OF WITHDRAWAL OF AP-  
2           PROVAL.—If the Secretary withdraws the ap-  
3           proval of an accreditation body under subpara-  
4           graph (B), the certificate of any laboratory ac-  
5           credited by the body shall continue in effect for  
6           60 calendar days after the laboratory receives  
7           notification of the withdrawal of the approval,  
8           except that the Secretary may extend such pe-  
9           riod for a laboratory if the Secretary determines  
10          that the laboratory submitted an application for  
11          accreditation or a certificate in a timely manner  
12          after receipt of the notification of the with-  
13          drawal of approval.

14          “(D) EVALUATIONS.—The Secretary shall  
15          evaluate annually the performance of each ap-  
16          proved accreditation body by—

17                 “(i) inspecting under subsection (g) a  
18                 sufficient number of the laboratories ac-  
19                 credited by such body to allow a reasonable  
20                 estimate of the performance of such body;  
21                 and

22                 “(ii) such other means as the Sec-  
23                 retary determines appropriate.

24          “(3) WITHDRAWAL OR REVOCATION OF LAB-  
25          ORATORY ACCREDITATION.—If an accreditation body

1       withdraws or revokes the accreditation of a labora-  
2       tory, the certificate of the laboratory shall continue  
3       in effect—

4               “(A) for 45 calendar days after the labora-  
5       tory receives notice of the withdrawal or revoca-  
6       tion of the accreditation; or

7               “(B) until the effective date of any action  
8       taken by the Secretary under subsection (j).

9               “(4) UPDATED STANDARDS.—Approved accredi-  
10      tation bodies shall ensure that, beginning no later  
11      than the effective date of the standards under sub-  
12      section (f)(5) and the regulations for carrying out  
13      such standards—

14              “(A) the inspectors of such bodies are  
15      trained with respect to, and the processes of  
16      such bodies are updated in accordance with,  
17      such regulations; and

18              “(B) any inspection or other review of a  
19      laboratory by the approved accreditation body  
20      for purposes of accreditation includes a review  
21      and assessment of—

22              “(i) compliance by the laboratory with  
23      such regulations; and

24              “(ii) whether sufficient processes, poli-  
25      cies, organization, and training systems

1           are in place to demonstrate reasonable as-  
2           surance of future compliance with such  
3           regulations.

4           “(f) STANDARDS.—

5           “(1) IN GENERAL.—The Secretary shall issue  
6           standards to assure consistent performance by lab-  
7           oratories issued a certificate under this section of  
8           valid and reliable laboratory examinations and other  
9           procedures. Such standards shall require each lab-  
10          oratory issued a certificate under this section—

11           “(A) to maintain a quality system for all  
12          phases of the total testing process (consisting of  
13          the pre-analytic, analytic, and post-analytic  
14          processes) and general laboratory systems ade-  
15          quate and appropriate for the validity and reli-  
16          ability of the laboratory examinations and other  
17          procedures of the laboratory and to meet re-  
18          quirements relating to the proper collection,  
19          transportation, and storage of specimens and  
20          the reporting of results;

21           “(B) to maintain records, equipment, and  
22          facilities necessary for the proper and effective  
23          operation of the laboratory;

24           “(C) in performing and carrying out its  
25          laboratory examinations and other procedures,

1 to use only personnel meeting such qualifica-  
2 tions as the Secretary may establish for the di-  
3 rection, supervision, and performance of exami-  
4 nations and procedures within the laboratory,  
5 which qualifications shall take into consider-  
6 ation competency, training, experience, job per-  
7 formance, and education and which qualifica-  
8 tions shall, as appropriate, be different on the  
9 basis of the type of examinations and proce-  
10 dures being performed by the laboratory and  
11 the risks and consequences of erroneous results  
12 associated with such examinations and proce-  
13 dures;

14 “(D) to qualify under a proficiency testing  
15 program meeting the standards established by  
16 the Secretary under paragraph (3);

17 “(E) to have in place change control proce-  
18 dures assessing the impact of changes in lab-  
19 oratory operations, equipment, or material on  
20 the validity and reliability of the examinations  
21 and other procedures of the laboratory;

22 “(G) to have in place quality systems to  
23 assess the ability of incoming materials and  
24 equipment to meet their intended purposes;

1           “(H) to meet such other requirements as  
2           the Secretary reasonably determines necessary  
3           to assure consistent performance by such lab-  
4           oratories of valid and reliable laboratory exami-  
5           nations and procedures; and

6           “(I) to have in place processes and policies  
7           to review and assess modifications to in vitro  
8           clinical tests in accordance with paragraph (7).

9           “(2) CONSIDERATIONS.—In developing the  
10          standards to be issued under paragraph (1), the Sec-  
11          retary shall, within the flexibility provided under  
12          subparagraphs (A) through (H) of paragraph (1),  
13          take into consideration—

14                 “(A) the examinations and procedures per-  
15                 formed and the methodologies employed;

16                 “(B) the degree of independent judgment  
17                 involved;

18                 “(C) the amount of interpretation involved;

19                 “(D) the difficulty of the calculations in-  
20                 volved;

21                 “(E) the calibration and quality control re-  
22                 quirements of the instruments used;

23                 “(F) the type of training required to oper-  
24                 ate the instruments used in the methodology;

1           “(G) the regulations issued by the Sec-  
2           retary to carry out subchapter J of the Federal  
3           Food, Drug, and Cosmetic Act, in order to  
4           avoid duplicative requirements; and

5           “(H) such other factors as the Secretary  
6           considers relevant.

7           “(3) PROFICIENCY TESTING PROGRAM.—

8           “(A) IN GENERAL.—The Secretary shall  
9           establish standards for the proficiency testing  
10          programs for laboratories issued a certificate  
11          under this section which are conducted by the  
12          Secretary, conducted by an organization ap-  
13          proved under subparagraph (C), or conducted  
14          by an approved accrediting body. The standards  
15          shall require that a laboratory issued a certifi-  
16          cate under this section be tested for each exam-  
17          ination and procedure conducted within a cat-  
18          egory of examinations or procedures for which  
19          it has received a certificate, except for examina-  
20          tions and procedures for which the Secretary  
21          has determined that a proficiency test cannot  
22          reasonably be developed. The testing shall be  
23          conducted on a quarterly basis, except where  
24          the Secretary determines for technical and sci-  
25          entific reasons that a particular examination or

1 procedure may be tested less frequently (but  
2 not less often than twice per year). Such stand-  
3 ards shall include standards for proficiency test-  
4 ing programs for the new specialties and sub-  
5 specialties identified under paragraph (5)(iii).

6 “(B) CRITERIA.—The standards estab-  
7 lished under subparagraph (A) shall include  
8 uniform criteria for acceptable performance  
9 under a proficiency testing program, based on  
10 the available technology and the clinical rel-  
11 evance of the laboratory examination or other  
12 procedure subject to such program. The criteria  
13 shall be established for all examinations and  
14 procedures and shall be uniform for each exam-  
15 ination and procedure. The standards shall also  
16 include a system for grading proficiency testing  
17 performance to determine whether a laboratory  
18 has performed acceptably for a particular quar-  
19 ter and acceptably for a particular examination  
20 or procedure or category of examination or pro-  
21 cedure over a period of successive quarters.

22 “(C) APPROVED PROFICIENCY TESTING  
23 PROGRAMS.—For the purpose of administering  
24 proficiency testing programs which meet the  
25 standards established under subparagraph (A),

1 the Secretary shall approve a proficiency testing  
2 program offered by a private nonprofit organi-  
3 zation or a State if the program meets the  
4 standards established under subparagraph (A)  
5 and the organization or State provides technical  
6 assistance to laboratories seeking to qualify  
7 under the program. The Secretary shall evalu-  
8 ate each program approved under this subpara-  
9 graph annually to determine if the program  
10 continues to meet the standards established  
11 under subparagraph (A) and shall withdraw the  
12 approval of any program that no longer meets  
13 such standards.

14 “(D) ONSITE TESTING.—The Secretary  
15 shall perform, or shall direct a program ap-  
16 proved under subparagraph (C) to perform, on-  
17 site proficiency testing to assure compliance  
18 with the standards under this section, in ac-  
19 cordance with paragraph (5). The Secretary  
20 shall perform, on an onsite or other basis, pro-  
21 ficiency testing to evaluate the performance of  
22 a proficiency testing program approved under  
23 subparagraph (C) and to assure quality per-  
24 formance by a laboratory.

1           “(E) TRAINING, TECHNICAL ASSISTANCE,  
2           AND ENHANCED PROFICIENCY TESTING.—The  
3           Secretary may, in lieu of or in addition to ac-  
4           tions authorized under subsection (i), (j), or  
5           (k), require any laboratory which fails to per-  
6           form acceptably on an individual examination  
7           and procedure or a category of examinations  
8           and procedures—

9                   “(i) to undertake training and to ob-  
10                   tain the necessary technical assistance to  
11                   meet the requirements of the proficiency  
12                   testing program;

13                   “(ii) to enroll in a program of en-  
14                   hanced proficiency testing; or

15                   “(iii) to undertake any combination of  
16                   the training, technical assistance, or test-  
17                   ing described in clauses (i) and (ii).

18           “(F) TESTING RESULTS.—The Secretary  
19           shall establish a system to make the results of  
20           the proficiency testing programs subject to the  
21           standards established by the Secretary under  
22           subparagraph (A) available, on a reasonable  
23           basis, upon request of any person. The Sec-  
24           retary shall include with results made available  
25           under this subparagraph such explanatory in-

1           formation as may be appropriate to assist in  
2           the interpretation of such results.

3           “(4) NATIONAL STANDARDS FOR QUALITY AS-  
4           SURANCE IN CYTOLOGY SERVICES.—

5                   “(A) ESTABLISHMENT.—The Secretary  
6           shall establish national standards for quality as-  
7           surance in cytology services designed to assure  
8           consistent performance by laboratories of valid  
9           and reliable cytological services.

10                   “(B) STANDARDS.—The standards estab-  
11           lished under subparagraph (A) shall include—

12                           “(i) the maximum number of cytology  
13           slides that any individual may screen in a  
14           24-hour period;

15                           “(ii) requirements that a clinical lab-  
16           oratory maintain a record of—

17                                   “(I) the number of cytology  
18           slides screened during each 24-hour  
19           period by each individual who exam-  
20           ines cytology slides for the laboratory;  
21           and

22                                   “(II) the number of hours de-  
23           voted during each 24-hour period to  
24           screening cytology slides by such indi-  
25           vidual;

- 1                   “(iii) criteria for requiring rescreening  
2 of cytological preparations, such as—  
3                   “(I) random rescreening of cytology  
4 specimens determined to be in the  
5 benign category;  
6                   “(II) focused rescreening of such  
7 preparations in high risk groups; and  
8                   “(III) for each abnormal  
9 cytological result, rescreening of all  
10 prior cytological specimens for the pa-  
11 tient, if available;  
12                   “(iv) periodic confirmation and eval-  
13 uation of the proficiency of individuals in-  
14 volved in screening or interpreting  
15 cytological preparations, including an-  
16 nounced and unannounced on-site pro-  
17 ficiency testing of such individuals, with  
18 such testing to take place, to the extent  
19 practicable, under normal working condi-  
20 tions;  
21                   “(v) procedures for detecting inad-  
22 equately prepared slides, for assuring that  
23 no cytological diagnosis is rendered on  
24 such slides, and for notifying referring  
25 physicians of such slides;

1 “(vi) requirements that all cytological  
2 screening be done on the premises of a lab-  
3 oratory that is certified under this section;

4 “(vii) requirements for the retention  
5 of cytology slides by laboratories for such  
6 periods of time as the Secretary considers  
7 appropriate; and

8 “(viii) standards requiring periodic in-  
9 spection of cytology services by persons ca-  
10 pable of evaluating the quality of cytology  
11 services.

12 “(5) UNIFORMITY; SPECIALTIES AND SUB-  
13 SPECIALTIES; ERRORS; HARMONIZATION.—

14 “(A) IN GENERAL.—The Secretary shall  
15 ensure that the standards under this sub-  
16 section—

17 “(i) provide nationally uniform stand-  
18 ards for the performance of laboratory op-  
19 erations;

20 “(ii) include—

21 “(I) standards for specialty and  
22 subspecialty testing, including with re-  
23 spect to molecular pathology, molec-  
24 ular microbiology, biochemical genet-  
25 ics, and flow cytometry testing and

1 other specialty and subspecialty test-  
2 ing not specifically included as of the  
3 date of enactment of the \_\_\_\_\_ Act  
4 of 2015 in existing regulations and  
5 standards; and

6 “(II) updated standards for cyto-  
7 genetics, microbiology, and other ap-  
8 propriate specialties and subspecial-  
9 ties;

10 “(iii) include common standards for  
11 the identification, investigation, and as-  
12 sessment of laboratory errors and for the  
13 corrective and preventive actions appro-  
14 priate to address such errors;

15 “(iv) include enhanced quality require-  
16 ments for preparation of reagents for use  
17 not as a finished product but as a compo-  
18 nent, part, or raw material of an in vitro  
19 clinical test performed by the same facility,  
20 and for preparation and transfer of indi-  
21 vidual components, parts, and raw mate-  
22 rials between commonly owned laboratories  
23 within the same State, to ensure consistent  
24 reagent preparation and quality control of  
25 the reagent; and

1           “(v) to the extent possible, be har-  
2           monized, in cooperation with the Food and  
3           Drug Administration and the Centers for  
4           Medicare & Medicaid Services, with other  
5           existing standards and best practices, in-  
6           cluding the accreditation standards of  
7           widely recognized professional organiza-  
8           tions and the terms, definitions, and stand-  
9           ards under section 590E of the Federal  
10          Food, Drug and Cosmetic Act

11          “(B) QUALITY SYSTEM PROCESSES.—The  
12          standards under this subsection shall include  
13          quality assurance processes for—

14                 “(i) management responsibility and  
15                 authority;

16                 “(ii) document controls;

17                 “(iii) purchasing controls;

18                 “(iv) laboratory process and operation  
19                 quality systems and controls;

20                 “(v) corrective and preventive actions;

21                 “(vi) records; and

22                 “(vii) servicing.

23          “(C) MODERNIZED REGULATIONS.—Not  
24          later than the day that is 2 years after the date  
25          of enactment of the \_\_\_\_\_ Act of 2015, the

1 Secretary shall issue final regulations to imple-  
2 ment this paragraph.

3 “(D) EFFECTIVE DATE.—The final regula-  
4 tions required to be issued under subparagraph  
5 (C) shall take effect on the date that is 2 years  
6 after the date of issuance of such final regula-  
7 tions. On and after such effective date—

8 “(i) the Secretary may issue or renew  
9 a certificate for a laboratory under this  
10 section only if the laboratory is in compli-  
11 ance with such regulations and standards;  
12 and

13 “(ii) each laboratory required to be  
14 certified under this section shall comply  
15 with such regulations.

16 “(6) ADVISORY PANEL.—In proposing and fi-  
17 nalizing regulations under paragraph (5), the Sec-  
18 retary shall utilize an advisory panel to provide  
19 input into the development and content of such reg-  
20 ulations. Such advisory panel shall include, at a min-  
21 imum, representatives of laboratories, laboratory op-  
22 erations experts, health care professionals, profes-  
23 sional societies, patient groups, laboratory test devel-  
24 opers, regulatory and quality experts, and public  
25 health experts.

1           “(7) MODIFICATIONS TO IN VITRO CLINICAL  
2 TESTS.—

3           “(A) PROCESSES AND POLICIES.—A lab-  
4 oratory shall have in place processes and poli-  
5 cies to review and assess modifications to in  
6 vitro clinical tests prior to the implementation  
7 of such a modification within laboratory oper-  
8 ations. Such a review and assessment shall be  
9 designed to determine whether the proposed  
10 modification results in a meaningful clinical im-  
11 pact or changes the intended use of the in vitro  
12 clinical test so as to be subject to premarket ap-  
13 proval or listing under section 590B(m) of the  
14 Federal Food, Drug, and Cosmetic Act.

15           “(B) PREMARKET APPROVAL OR LIST-  
16 ING.—If the proposed modification has a mean-  
17 ingful clinical impact or changes the intended  
18 use of the in vitro clinical test so as to be sub-  
19 ject to premarket approval or listing under sec-  
20 tion 590B(m) of the Federal Food, Drug, and  
21 Cosmetic Act, the laboratory—

22           “(i) shall obtain an approval pursuant  
23 to Section 590B of the Federal Food,  
24 Drug, and Cosmetic Act or, if such an ap-  
25 proval is not required, shall list such modi-

1           fication pursuant to section 590B(e) of the  
2           Federal Food, Drug, and Cosmetic Act;  
3           and

4           “(ii) shall not implement such modi-  
5           fication until such approval is obtained or  
6           listing occurs, as applicable.

7           “(C)           EXCLUSIONS.—Amendments,  
8           changes, corrections, or updates to a patient  
9           specific laboratory test report—

10           “(i) shall not be considered a modi-  
11           fication that requires review under section  
12           590B(m) of the Federal Food, Drug, and  
13           Cosmetic Act; and

14           “(ii) shall not be treated—

15           “(I) as labeling under the Fed-  
16           eral Food, Drug, and Cosmetic Act;  
17           or

18           “(II) as establishing an intended  
19           use for purposes of such Act.

20           “(g) INSPECTIONS.—

21           “(1) IN GENERAL.—The Secretary may, on an  
22           announced or unannounced basis, enter and inspect,  
23           during regular hours of operation, laboratories sub-  
24           ject to the requirements of this section. In con-  
25           ducting such inspections the Secretary shall have ac-

1       cess to all facilities, equipment, materials, records,  
2       and information that the Secretary determines have  
3       a bearing on whether the laboratory is being oper-  
4       ated in accordance with this section. As part of such  
5       an inspection the Secretary may copy any such ma-  
6       terial or require to it be submitted to the Secretary.  
7       An inspection under this paragraph may be made  
8       only upon presenting identification to the owner, op-  
9       erator, or agent in charge of the laboratory being in-  
10      spected.

11           “(2) COMPLIANCE WITH REQUIREMENTS AND  
12      STANDARDS.—The Secretary shall conduct inspec-  
13      tions of laboratories under paragraph (1) to deter-  
14      mine their compliance with the requirements of sub-  
15      section (d) and the standards issued under sub-  
16      section (f). Inspections of laboratories not accredited  
17      under subsection (e) shall be conducted on a biennial  
18      basis or with such other frequency as the Secretary  
19      determines to be necessary to assure compliance  
20      with such requirements and standards. Inspections  
21      of laboratories accredited under subsection (e) shall  
22      be conducted on such basis as the Secretary deter-  
23      mines is necessary to assure compliance with such  
24      requirements and standards.

1           “(3) SCOPE OF INSPECTIONS.—Any inspections  
2           conducted pursuant to this section shall be limited  
3           to laboratory operations and related issues and shall  
4           not include any inspection related to activities regu-  
5           lated under subchapter J of the Federal Food,  
6           Drug, and Cosmetic Act, unless the inspector has  
7           been authorized to act on behalf of both the Centers  
8           for Medicare & Medicaid Services and the Food and  
9           Drug Administration as a hybrid inspector pursuant  
10          to paragraph (4).

11          “(4) HYBRID INSPECTIONS.—

12                 “(A) INTERAGENCY AGREEMENT.—The  
13                 Commissioner of Food and Drugs may enter  
14                 into an agreement with the Administrator of  
15                 the Centers for Medicare & Medicaid Services  
16                 to jointly train and accredit hybrid inspectors  
17                 authorized to inspect—

18                         “(i) establishments engaged in the de-  
19                         sign, development, validation, production,  
20                         manufacture, preparation, propagation, as-  
21                         sembly, or processing of an in vitro clinical  
22                         test pursuant to subchapter J of the Fed-  
23                         eral Food, Drug, and Cosmetic Act; and

24                         “(ii) laboratories pursuant to para-  
25                         graph (1).

1           “(B) REQUIREMENTS.—A hybrid inspector  
2           conducting an inspection pursuant to an agree-  
3           ment under subparagraph (A) shall—

4                   “(i) prior to such inspection, state  
5                   whether the hybrid inspector intends to  
6                   conduct an inspection pursuant to sub-  
7                   chapter J of the Federal Food, Drug, and  
8                   Cosmetic Act, paragraph (1), or both;

9                   “(ii) conduct any inspection in accord-  
10                  ance with the intent stated under clause  
11                  (i); and

12                  “(iii) with respect to an establishment  
13                  that is both engaged in the design, devel-  
14                  opment, validation, production, manufac-  
15                  ture, preparation, propagation, assembly,  
16                  or processing of an in vitro clinical test  
17                  and operating as a laboratory, if the in-  
18                  spector intends to inspect such establish-  
19                  ment pursuant to both subchapter J of  
20                  chapter V of the Federal Food, Drug, and  
21                  Cosmetic Act and paragraph (1), notify  
22                  such establishment or laboratory of such  
23                  intent and maintain a clear distinction be-  
24                  tween the portions of such inspection con-  
25                  ducted pursuant to such subchapter J and

1           the portions of such inspection conducted  
2           pursuant to paragraph (1).

3           “(C) UNEXPECTED ISSUES.—If during the  
4           course of an inspection for which the stated in-  
5           tent is to conduct an inspection pursuant to  
6           paragraph (1), a hybrid inspector identifies one  
7           or more issues under subchapter J of the Fed-  
8           eral Food, Drug, and Cosmetic Act, the hybrid  
9           inspector shall—

10                   “(i) notify the establishment or lab-  
11                   oratory of the issues and, at the discretion  
12                   of the inspector, notify the Food and Drug  
13                   Administration of the issues; and

14                   “(ii) in collaboration with the Food  
15                   and Drug Administration, determine  
16                   whether such notice warrants other action  
17                   under such subchapter J.

18           “(h) INTERMEDIATE SANCTIONS.—

19                   “(1) IN GENERAL.—If the Secretary determines  
20                   that a laboratory which has been issued a certificate  
21                   under this section no longer substantially meets the  
22                   requirements for the issuance of a certificate, the  
23                   Secretary may impose intermediate sanctions in lieu  
24                   of the actions authorized by subsection (i).

1           “(2) TYPES OF SANCTIONS.—The intermediate  
2 sanctions which may be imposed under paragraph  
3 (1) shall consist of—

4                   “(A) directed plans of correction;

5                   “(B) civil money penalties in an amount  
6 not to exceed \$10,000 for each violation listed  
7 in subsection (i)(1) or for each day of substan-  
8 tial noncompliance with the requirements;

9                   “(C) payment for the costs of onsite moni-  
10 toring; or

11                   “(D) any combination of the actions de-  
12 scribed in subparagraphs (A), (B), and (C).

13           “(3) PROCEDURES.—The Secretary shall de-  
14 velop and implement procedures with respect to  
15 when and how each of the intermediate sanctions is  
16 to be imposed under paragraph (1). Such procedures  
17 shall provide for notice to the laboratory and a rea-  
18 sonable opportunity to respond to the proposed sanc-  
19 tion and appropriate procedures for appealing deter-  
20 minations relating to the imposition of intermediate  
21 sanctions.

22           “(i) SUSPENSION, REVOCATION, AND LIMITATION.—

23                   “(1) IN GENERAL.—Except as provided in para-  
24 graph (2), the certificate of a laboratory issued  
25 under this section may be suspended, revoked, or

1 limited if the Secretary finds, after reasonable notice  
2 and opportunity for hearing to the owner or operator  
3 of the laboratory, that such owner or operator or  
4 any employee of the laboratory—

5 “(A) has been guilty of misrepresentation  
6 in obtaining the certificate;

7 “(B) has performed or represented the lab-  
8 oratory as entitled to perform a laboratory ex-  
9 amination or other procedure which is not with-  
10 in a category of laboratory examinations or  
11 other procedures authorized in the certificate;

12 “(C) has failed to comply with the require-  
13 ments of subsection (d) or the standards pre-  
14 scribed by the Secretary under subsection (f);

15 “(D) has failed to comply with reasonable  
16 requests of the Secretary for—

17 “(i) any information or materials; or

18 “(ii) work on materials;

19 that the Secretary concludes is necessary to de-  
20 termine the laboratory’s continued eligibility for  
21 its certificate or continued compliance with the  
22 Secretary’s standards under subsection (f);

23 “(E) has refused a reasonable request of  
24 the Secretary, or any Federal officer or em-  
25 ployee duly designated by the Secretary, for

1 permission to inspect the laboratory and its op-  
2 erations and pertinent records during the hours  
3 the laboratory is in operation;

4 “(F) has violated or aided and abetted in  
5 the violation of any provisions of this section or  
6 of any regulation promulgated thereunder; or

7 “(G) has not complied with an inter-  
8 mediate sanction imposed under subsection (h).

9 “(2) ACTION BEFORE A HEARING.—If the Sec-  
10 retary determines that—

11 “(A) the failure of a laboratory to comply  
12 with the standards of the Secretary under sub-  
13 section (f) presents an imminent and serious  
14 risk to human health; or

15 “(B) a laboratory has engaged in an action  
16 described in subparagraph (D) or (E) of para-  
17 graph (1);

18 the Secretary may suspend or limit the certificate of  
19 the laboratory before holding a hearing under para-  
20 graph (1) regarding such failure or refusal. The op-  
21 portunity for a hearing shall be provided no later  
22 than 60 calendar days from the effective date of the  
23 suspension or limitation. A suspension or limitation  
24 under this paragraph shall stay in effect until the

1 decision of the Secretary made after the hearing  
2 under paragraph (1).

3 “(3) INELIGIBILITY TO OWN OR OPERATE LAB-  
4 ORATORIES AFTER REVOCATION.—No individual who  
5 has owned (other than through a minority interest  
6 in publicly traded stock) or directed the daily oper-  
7 ations of a laboratory which has had its certificate  
8 revoked may, within 2 years of the revocation of the  
9 certificate, own or operate a laboratory for which a  
10 certificate has been issued under this section, except  
11 that if the revocation occurs pursuant to paragraph  
12 (4) the Secretary may substitute intermediate sanc-  
13 tions under subsection (h) instead of the 2-year pro-  
14 hibition against ownership or operation which would  
15 otherwise apply under this paragraph. The certifi-  
16 cate of a laboratory which has been excluded from  
17 participation under the medicare program under title  
18 XVIII of the Social Security Act because of actions  
19 relating to the quality of the laboratory shall be sus-  
20 pended for the period the laboratory is so excluded.

21 “(4) IMPROPER REFERRALS.—

22 “(A) IN GENERAL.—Any laboratory that  
23 the Secretary determines intentionally refers its  
24 proficiency testing samples to another labora-  
25 tory for analysis may have its certificate re-

1 voked for at least one year and shall be subject  
2 to appropriate fines and penalties as provided  
3 for in subsection (h).

4 “(B) DEFINITION.—In this paragraph, the  
5 term ‘intentionally refers’—

6 “(i) means refers with specific intent  
7 to circumvent the proficiency testing re-  
8 quirements of this section; and

9 “(ii) excludes automatic referrals of  
10 samples for tests not performed by the re-  
11 ferring laboratory in the ordinary course of  
12 business.

13 “(j) INJUNCTIONS.—Whenever the Secretary has rea-  
14 son to believe that continuation of any activity by a labora-  
15 tory would constitute a significant hazard to the public  
16 health the Secretary may bring suit in the district court  
17 of the United States for the district in which such labora-  
18 tory is situated to enjoin continuation of such activity.  
19 Upon proper showing, a temporary injunction or restrain-  
20 ing order against continuation of such activity pending  
21 issuance of a final order under this subsection shall be  
22 granted without bond by such court.

23 “(k) JUDICIAL REVIEW.—

24 “(1) PETITION.—Any laboratory which has had  
25 an intermediate sanction imposed under subsection

1 (h) or has had its certificate suspended, revoked, or  
2 limited under subsection (i) may, at any time within  
3 60 calendar days after the date the action of the  
4 Secretary under subsection (i) or (h) becomes final,  
5 file a petition with the United States court of ap-  
6 peals for the circuit wherein the laboratory has its  
7 principal place of business for judicial review of such  
8 action. As soon as practicable after receipt of the pe-  
9 tition, the clerk of the court shall transmit a copy  
10 of the petition to the Secretary or other officer des-  
11 ignated by the Secretary for that purpose. As soon  
12 as practicable after receipt of the copy, the Sec-  
13 retary shall file in the court the record on which the  
14 action of the Secretary is based, as provided in sec-  
15 tion 2112 of title 28, United States Code.

16 “(2) ADDITIONAL EVIDENCE.—If the petitioner  
17 applies to the court for leave to adduce additional  
18 evidence, and shows to the satisfaction of the court  
19 that such additional evidence is material and that  
20 there were reasonable grounds for the failure to ad-  
21 duce such evidence in the proceeding before the Sec-  
22 retary, the court may order such additional evidence  
23 (and evidence in rebuttal of such additional evi-  
24 dence) to be taken before the Secretary, and to be  
25 adduced upon the hearing in such manner and upon

1 such terms and conditions as the court may deem  
2 proper. The Secretary may modify the findings of  
3 the Secretary as to the facts, or make new findings,  
4 by reason of the additional evidence so taken, and  
5 the Secretary shall file such modified or new find-  
6 ings, and the recommendations of the Secretary, if  
7 any, for the modification or setting aside of his  
8 original action, with the return of such additional  
9 evidence.

10 “(3) JUDGMENT OF COURT.—Upon the filing of  
11 the petition referred to in paragraph (1), the court  
12 shall have jurisdiction to affirm the action, or to set  
13 it aside in whole or in part, temporarily or perma-  
14 nently. The findings of the Secretary as to the facts,  
15 if supported by substantial evidence, shall be conclu-  
16 sive.

17 “(4) FINALITY OF JUDGMENT.—The judgment  
18 of the court affirming or setting aside, in whole or  
19 in part, any such action of the Secretary shall be  
20 final, subject to review by the Supreme Court of the  
21 United States upon certiorari or certification as pro-  
22 vided in section 1254 of title 28, United States  
23 Code.

24 “(l) SANCTIONS.—Any person who intentionally vio-  
25 lates any requirement of this section or any regulation

1 promulgated thereunder shall be imprisoned for not more  
2 than one year or fined under title 18, United States Code,  
3 or both, except that if the conviction is for a second or  
4 subsequent violation of such a requirement such person  
5 shall be imprisoned for not more than 3 years or fined  
6 in accordance with title 18, United States Code, or both.

7 “(m) FEES.—

8 “(1) CERTIFICATE FEES.—The Secretary shall  
9 require payment of fees for the issuance and renewal  
10 of certificates, except that the Secretary shall only  
11 require a nominal fee for the issuance and renewal  
12 of certificates of waiver.

13 “(2) ADDITIONAL FEES.—The Secretary shall  
14 require the payment of fees for inspections of labora-  
15 tories which are not accredited and for the cost of  
16 performing proficiency testing on laboratories which  
17 do not participate in proficiency testing programs  
18 approved under subsection (f)(3)(C).

19 “(3) CRITERIA.—

20 “(A) FEES UNDER PARAGRAPH (1).—Fees  
21 imposed under paragraph (1) shall be sufficient  
22 to cover the general costs of administering this  
23 section, including evaluating and monitoring  
24 proficiency testing programs approved under  
25 subsection (f) and accrediting bodies and imple-

1           menting and monitoring compliance with the re-  
2           quirements of this section.

3           “(B) FEES UNDER PARAGRAPH (2).—Fees  
4           imposed under paragraph (2) shall be sufficient  
5           to cover the cost of the Secretary in carrying  
6           out the inspections and proficiency testing de-  
7           scribed in paragraph (2).

8           “(C) FEES IMPOSED UNDER PARAGRAPHS  
9           (1) AND (2).—Fees imposed under paragraphs  
10          (1) and (2) shall vary by group or classification  
11          of laboratory, based on such considerations as  
12          the Secretary determines are relevant, which  
13          may include the dollar volume and scope of the  
14          testing being performed by the laboratories.

15          “(4) CREDIT AGAINST FDA USER FEES.—Any  
16          fees paid pursuant to this subsection for the  
17          issuance or renewal of a certificate shall be a credit  
18          against any user fees due pursuant to  
19          【\_\_\_\_\_】 for the review and approval of an in  
20          vitro clinical test. Any such credit is not transferable  
21          and may only be used by the facility or affiliated en-  
22          tity actually paying such certification fee and other-  
23          wise obligated to pay a user fee pursuant to  
24          【\_\_\_\_\_】. Such credits must be used in the fis-  
25          cal year in which such certification fee is paid or the

1 immediately following fiscal year. Such credits may  
2 be applied in the form of a waiver of the user fee  
3 otherwise payable, or a waiver of such portion of the  
4 otherwise payable user fee as may be covered by the  
5 amount of the credit.

6 “(n) INFORMATION.—On April 1, 1990 and annually  
7 thereafter, the Secretary shall compile and make available  
8 to physicians and the general public information, based  
9 on the previous calendar year, which the Secretary deter-  
10 mines is useful in evaluating the performance of a labora-  
11 tory, including—

12 “(1) a list of laboratories which have been con-  
13 victed under Federal or State laws relating to fraud  
14 and abuse, false billings, or kickbacks,

15 “(2) a list of laboratories—

16 “(A) which have had their certificates re-  
17 voked, suspended, or limited under subsection  
18 (i); or

19 “(B) which have been the subject of a  
20 sanction under subsection (l);

21 together with a statement of the reasons for the rev-  
22 ocation, suspension, limitation, or sanction;

23 “(3) a list of laboratories subject to inter-  
24 mediate sanctions under subsection (h) together with  
25 a statement of the reasons for the sanctions;

1           “(4) a list of laboratories whose accreditation  
2           has been withdrawn or revoked together with a  
3           statement of the reasons for the withdrawal or rev-  
4           ocation;

5           “(5) a list of laboratories against which the  
6           Secretary has taken action under subsection (j) to-  
7           gether with a statement of the reasons for such ac-  
8           tion; and

9           “(6) a list of laboratories which have been ex-  
10          cluded from participation under title XVIII or XIX  
11          of the Social Security Act.

12 The information to be compiled under paragraphs (1)  
13 through (6) shall be information for the calendar year pre-  
14 ceding the date the information is to be made available  
15 to the public and shall be accompanied by such explana-  
16 tory information as may be appropriate to assist in the  
17 interpretation of the information compiled under such  
18 paragraphs.

19          “(o) DELEGATION.—In carrying out this section, the  
20 Secretary may, pursuant to agreement, use the services  
21 or facilities of any Federal or State or local public agency  
22 or nonprofit private organization, and may pay therefor  
23 in advance or by way of reimbursement, and in such in-  
24 stallments, as the Secretary may determine.

25          “(p) STATE LAWS.—

1           “(1) IN GENERAL.—Except as provided in sub-  
2           paragraph (2), no State, tribal or local government  
3           (or political subdivision thereof) may establish or  
4           continue in effect with respect to a laboratory, a  
5           clinical laboratory, or laboratory operations any re-  
6           quirement which is different from, or in addition to,  
7           any requirement applicable under this section to  
8           such laboratory, clinical laboratory, or laboratory op-  
9           erations.

10           “(2) EXCEPTIONS.—Paragraph (1) shall not be  
11           construed to affect the authority of a State, tribal,  
12           or local government—

13           “(A) to license health care practitioners or  
14           health care facilities or to regulate any aspect  
15           of a health care practitioner-patient relation-  
16           ship; or

17           “(B) to enforce laws of general applica-  
18           bility, such as zoning laws, environmental laws,  
19           labor laws, and general business laws.

20           “(3) CLARIFICATION.—This section shall not be  
21           construed to shift liability to health care practi-  
22           tioners.

23           “(q) CONSULTATIONS.—In carrying out this section,  
24           the Secretary shall consult with appropriate private orga-

1 nizations and public agencies, including the Food and  
2 Drug Administration.”.

3 **SEC. 6. TRANSITIONAL PROVISIONS.**

4 (a) CLASSIFICATION.—With respect to an in vitro  
5 clinical test that is sought to be first offered after the date  
6 of enactment of this Act, but before the effective date of  
7 regulations implementing section 590A of the Federal  
8 Food, Drug, and Cosmetic Act, as added by section 3 of  
9 this Act, the Secretary shall, by regulation—

10 (1) classify such in vitro clinical test as a low-  
11 risk, moderate-risk, or high-risk in vitro clinical test  
12 pursuant to such section 590A; and

13 (2) classify any finished product pursuant to  
14 section 513 of the Federal Food, Drug, and Cos-  
15 metic Act (21 U.S.C. 360e).

16 (b) QUALITY REQUIREMENTS.—

17 (1) MANUFACTURERS.—A manufacturer of an  
18 in vitro clinical test—

19 (A) prior to the date of promulgation of  
20 final regulations under section 3(e), shall, with  
21 respect to such in vitro clinical test, comply  
22 with the quality system requirements applicable  
23 to devices under the Federal Food, Drug, and  
24 Cosmetic Act (21 U.S.C. 301 et seq.), including  
25 part 820 of title 21, Code of Federal Regula-

1           tions, as in effect on the date of enactment of  
2           this Act; and

3                   (B) on or after the date of promulgation of  
4           final regulations under section 3(e) and before  
5           the effective date of such regulations under sec-  
6           tion 3(e)(2)(A), shall, with respect to such in  
7           vitro clinical test, comply with, at the election  
8           of the manufacturer—

9                           (i) the quality system requirements  
10                           described in subparagraph (A); or

11                           (ii) the quality requirements under  
12                           section 590D of the Federal Food, Drug,  
13                           and Cosmetic Act, as added by section  
14                           3(a).

15           (2) LABORATORY DEVELOPERS.—A laboratory  
16           developer of an in vitro clinical test—

17                   (A) prior to the date of promulgation of  
18           final regulations under section 3(e), shall, with  
19           respect to such in vitro clinical test, comply  
20           with any applicable quality requirements under  
21           section 353 of the Public Health and Service  
22           Act (42 U.S.C. 263a), as in effect on the day  
23           before the date of enactment of this Act; and

24                   (B) on or after the date of promulgation of  
25           final regulations under section 3(e) and before

1 the effective date of such regulations under sec-  
2 tion 3(e)(2)(A), shall, with respect to such in  
3 vitro clinical test, comply with, at the election  
4 of the manufacturer—

5 (i) any applicable quality requirements  
6 under section 353 of the Public Health  
7 and Service Act (42 U.S.C. 263a), as in ef-  
8 fect on the day before the date of enact-  
9 ment of this Act; or

10 (ii) the quality requirements under  
11 section 590D of the Federal Food, Drug,  
12 and Cosmetic Act, as added by section  
13 3(a).

14 (c) SUBMISSION REQUIREMENTS.—

15 (1) MANUFACTURERS.—A manufacturer of an  
16 in vitro clinical test—

17 (A) with respect to an in vitro clinical test  
18 first offered prior to the effective date of final  
19 regulations under section 3(e)(2)(B), shall com-  
20 ply with the approval process under section 515  
21 of the Federal Food, Drug, and Cosmetic Act  
22 (21 U.S.C. 360e), the clearance process under  
23 section 510(k) of such Act (21 U.S.C. 360(k)),  
24 or the listing process under section 510(j) of

1           such Act (21 U.S.C. 360(j)), as applicable, in  
2           effect on the date of enactment of this Act; and

3                   (B) with respect to an in vitro clinical test  
4           first in use on or after the effective date of final  
5           regulations under section 3(e)(2)(B), shall com-  
6           ply with the premarket submission requirements  
7           of sections 590A, 590B, and 590D of the Fed-  
8           eral Food, Drug, and Cosmetic Act, as added  
9           by section 3(a).

10          (2) LABORATORIES.—

11                   (A) With respect to an in vitro clinical test  
12           first offered on or after the date of enactment  
13           of this Act, a laboratory developer of such in  
14           vitro clinical test shall—

15                           (i) comply with any applicable pre-  
16           market requirements pursuant to section  
17           353 of the Public Health and Service Act  
18           (42 U.S.C. 263a), as in effect on the day  
19           before the date of enactment of this Act;  
20           or

21                           (ii) comply with the premarket sub-  
22           mission requirements of sections 590A,  
23           590B, and 590D of the Federal Food,  
24           Drug, and Cosmetic Act, as added by sec-  
25           tion 3(a).

1 (B) If a laboratory developer elects to com-  
2 ply with the premarket requirements specified  
3 in subparagraph (A)(i), the laboratory developer  
4 shall submit to the Secretary postmarket data  
5 establishing a reasonable assurance that the in  
6 vitro clinical test is analytically valid and clini-  
7 cally valid. Such data shall be provided not  
8 later than 3 years after the promulgation of  
9 final regulations under section 3(e) and shall be  
10 subject to fees pursuant to [section \_\_\_\_].

11 (C) If a laboratory developer elects to com-  
12 ply with the premarket submission requirements  
13 specified in subparagraph (A)(ii), the laboratory  
14 developer may immediately offer the in vitro  
15 clinical test for use but—

16 (i) not later than the two years after  
17 the promulgation of final regulations under  
18 section 3(e), the laboratory developer shall  
19 comply with such premarket submission re-  
20 quirements; and

21 (ii) the corresponding application, no-  
22 tification, or listing for the in vitro clinical  
23 test shall not be subject to fees pursuant  
24 to [section \_\_\_\_].

25 (d) POSTMARKET REQUIREMENTS.—

1           (1) MANUFACTURERS.—A manufacturer of an  
2           in vitro clinical test—

3                   (A) prior to the date of promulgation of  
4                   final regulations under section 3(e), shall, with  
5                   respect to such in vitro clinical test, comply  
6                   with the postmarket requirements applicable to  
7                   devices under the Federal Food, Drug, and  
8                   Cosmetic Act (21 U.S.C. 301 et seq.), including  
9                   part 803 of title 21, Code of Federal Regula-  
10                  tions, as in effect on the date of enactment of  
11                  this Act; and

12                   (B) on or after the date of promulgation of  
13                   final regulations under section 3(e) and before  
14                   the effective date of such regulations under sec-  
15                   tion 3(e)(2)(A), shall, with respect to such in  
16                   vitro clinical test, comply with, at the election  
17                   of the manufacturer—

18                           (i) the postmarket requirements appli-  
19                           cable to devices under the Federal Food,  
20                           Drug, and Cosmetic Act (21 U.S.C. 301 et  
21                           seq.), including part 803 of title 21, Code  
22                           of Federal Regulations, as in effect on the  
23                           date of enactment of this Act; or

24                           (ii) the postmarket requirements  
25                           under section 590E of the Federal Food,

1 Drug, and Cosmetic Act, as added by sec-  
2 tion 3(a).

3 (2) LABORATORY DEVELOPERS.—A laboratory  
4 developer of an in vitro clinical test—

5 (A) prior to the date of promulgation of  
6 final regulations under section 3(e), shall, with  
7 respect to such in vitro clinical test, comply  
8 with any applicable postmarket requirements  
9 under section 353 of the Public Health and  
10 Service Act (42 U.S.C. 263a), as in effect on  
11 the day before the date of enactment of this  
12 Act; and

13 (B) on or after the date of promulgation of  
14 final regulations under section 3(e) and before  
15 the effective date of such regulations under sec-  
16 tion 3(e)(2)(A), shall, with respect to such in  
17 vitro clinical test, comply with, at the election  
18 of the manufacturer—

19 (i) any applicable postmarket require-  
20 ments under section 353 of the Public  
21 Health and Service Act (42 U.S.C. 263a),  
22 as in effect on the day before the date of  
23 enactment of this Act; or

24 (ii) the postmarket requirements  
25 under section 590E of the Federal Food,

1 Drug, and Cosmetic Act, as added by sec-  
2 tion 3(a).

3 (e) DEFINITIONS.—In this section:

4 (1) The term “developer” has the meaning  
5 given to such term in section 590 of the Federal  
6 Food, Drug, and Cosmetic Act, as added by section  
7 3(a).

8 (2) The term “device” has the meaning given to  
9 such term in section 201 of the Federal Food, Drug,  
10 and Cosmetic Act (21 U.S.C. 321).

11 (3) The term “finished product” has the mean-  
12 ing given to such term in section 201(ss) of the Fed-  
13 eral Food, Drug, and Cosmetic Act, as added by sec-  
14 tion 2.

15 (4) The term “in vitro clinical test” has the  
16 meaning given to such term in section 201(ss) of the  
17 Federal Food, Drug, and Cosmetic Act, as added by  
18 section 2.

19 (5) The term “laboratory developer” means a  
20 laboratory that is the developer of—

21 (A) an in vitro clinical test first offered  
22 prior to the date of enactment of this Act for  
23 which the Secretary did not require an approval  
24 under section 515 of the Federal Food, Drug,  
25 and Cosmetic Act (21 U.S.C. 360e), a clearance

1 under section 510(k) of such Act (21 U.S.C.  
2 360(k)), or notification under section 510(j) of  
3 such Act (21 U.S.C. 360(j)) or otherwise as-  
4 serted enforcement discretion with regard to  
5 such sections and implementing regulations  
6 thereunder; or

7 (B) an in vitro clinical test first offered on  
8 or after the date of enactment of this Act for  
9 which, prior to such date of enactment, the Sec-  
10 retary would not have required an approval  
11 under such section 515, a clearance under such  
12 section 510(k), or notification under such sec-  
13 tion 510(j) or otherwise would have asserted en-  
14 forcement discretion with regard to such sec-  
15 tions and implementing regulations thereunder.

16 (6) The term “manufacturer” means the devel-  
17 oper of an in vitro clinical test other than a labora-  
18 tory developer.