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(Original Signature of Member)

112TH CONGRESS  
1ST SESSION

# H. R.

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To amend the Public Health Service Act to create a pathway for premarket notification and review of laboratory-developed tests, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

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

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# A BILL

To amend the Public Health Service Act to create a pathway for premarket notification and review of laboratory-developed tests, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

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

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Modernizing Laboratory Test Standards for Patients Act  
6 of 2011”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of  
8 this Act is as follows:

- Sec. 1. Short title; table of contents.  
Sec. 2. Notification for laboratory-developed tests.  
Sec. 3. Amendments to the Federal Food, Drug, and Cosmetic Act.  
Sec. 4. Fees.

1 **SEC. 2. NOTIFICATION FOR LABORATORY-DEVELOPED**  
2 **TESTS.**

3 Section 353 of the Public Health Service Act (42  
4 U.S.C. 263a) is amended by adding at the end the fol-  
5 lowing:

6 **“SEC. 353A. LABORATORY-DEVELOPED TESTS AND DIRECT-**  
7 **TO-CONSUMER DNA TESTS.**

8 “(a) DEFINITIONS.—In this section:

9 “(1) The term ‘analytical validity’ means the  
10 ability of a test to identify or measure the analyte  
11 or substance sought to be identified or measured.

12 “(2) The term ‘biological product’ has the  
13 meaning given to such term in section 351.

14 “(3) The term ‘clinical validity’ means the con-  
15 sistency and accuracy with which a test identifies,  
16 measures, or predicts—

17 “(A) a disease or condition in humans; or

18 “(B) characteristics related to an individ-  
19 ual’s clinical status (including phenotype).

20 “(4) The term ‘direct-to-consumer DNA test’ or  
21 ‘DTC DNA test’ means a test that—

22 “(A) is intended to identify, analyze, or in-  
23 terpret an individual’s genetic characteristics

1 for purposes of predicting, assessing the risk of,  
2 preventing, or mitigating any disease or condi-  
3 tion, including the prognosis or outcome of a  
4 treatment in an individual; and

5 “(B) is offered directly to, is ordered di-  
6 rectly by, and whose results are reported di-  
7 rectly to, an individual consumer, without a test  
8 request by a physician or other health care pro-  
9 vider who has an established provider-patient  
10 relationship with the individual consumer by  
11 which the physician or provider provides health  
12 care services (other than the test in question)  
13 to that individual.

14 “(5) The term ‘drug’ has the meaning given to  
15 such term in section 201 of the Federal Food, Drug,  
16 and Cosmetic Act.

17 “(6) The terms ‘laboratory’ and ‘clinical labora-  
18 tory’ have the meanings given to such terms in sec-  
19 tion 353.

20 “(7) The term ‘laboratory-developed test’ or  
21 ‘LDT’ means a clinical laboratory test that is—

22 “(A) developed by a clinical laboratory cer-  
23 tified under section 353;

24 “(B) performed by—

25 “(i) the clinical laboratory;

1                   “(ii) any entity that is owned or con-  
2                   trolled by the clinical laboratory;

3                   “(iii) any entity that owns or controls  
4                   the clinical laboratory (in this subpara-  
5                   graph referred to as the clinical labora-  
6                   tory’s ‘parent corporation’); or

7                   “(iv) an entity that is owned or con-  
8                   trolled by the clinical laboratory’s parent  
9                   corporation; and

10                  “(C)(i) performed solely to furnish clinical  
11                  laboratory testing services for the purpose of  
12                  providing information for the diagnosis, preven-  
13                  tion, or treatment of any disease or impairment  
14                  of, or the assessment of the health of, human  
15                  beings; and

16                  “(ii) not otherwise introduced into inter-  
17                  state commerce.

18                  “(8) The term ‘test-offering entity’ means an  
19                  entity, other than a laboratory certified under sec-  
20                  tion 353, which offers or markets direct-to-consumer  
21                  DNA tests based on testing performed by one or  
22                  more such laboratories that are not owned by the  
23                  entity.

1           “(9) The term ‘test registry data bank’ means  
2           the test registry data bank established under sub-  
3           section (b).

4           “(b) TEST REGISTRY DATA BANK.—

5           “(1) ESTABLISHMENT.—Not later than one  
6           year after the date of the enactment of this Act, the  
7           Secretary, in consultation with the Director of the  
8           National Institutes of Health, shall establish a sin-  
9           gle, publicly accessible test registry data bank.

10          “(2) PROCESS FOR SUBMISSION.—

11                 “(A) REQUIREMENT.—Each laboratory  
12                 and each test-offering entity that offers or mar-  
13                 kets an LDT or DTC DNA test shall submit  
14                 information on such LDT or DTC DNA test to  
15                 the Secretary for inclusion in the test registry  
16                 data bank.

17                 “(B) TIMING.—The submission required  
18                 by subparagraph (A) shall occur—

19                         “(i) in the case of an LDT or DTC  
20                         DNA test offered or marketed for the first  
21                         time by the laboratory or the test-offering  
22                         entity after the date of the enactment of  
23                         this section, on or before the later of—

24                                 “(I) the date that is 10 days  
25                                 after the date on which the laboratory

1 or test-offering entity first offers or  
2 markets the LDT or DTC DNA test;  
3 or

4 “(II) the date that is 3 months  
5 after the effective date of the regula-  
6 tions for carrying out this section; or

7 “(ii) in the case of an LDT or DTC  
8 DNA test offered or marketed on or before  
9 the date of enactment of this section, not  
10 later than 6 months after the effective date  
11 of the regulations for carrying out this  
12 subsection.

13 “(C) SUPPLEMENTAL SUBMISSIONS.—

14 “(i) IN GENERAL.—With respect to a  
15 LDT or DTC DNA test offered or mar-  
16 keted by a laboratory or test-offering enti-  
17 ty, such laboratory or test-offering entity  
18 shall supplement or amend information on  
19 such test in the test registry data bank as  
20 necessary to ensure that the information is  
21 accurate and current.

22 “(ii) SUBMISSION FOLLOWING  
23 ISSUANCE OF AUTHORIZATION LETTER.—  
24 Not later than 10 working days after the  
25 Secretary issues (or is deemed to have

1 issued) an authorization letter pursuant to  
2 subsection (c)(4)(B) or (c)(4)(F) for an  
3 LDT or a DTC DNA test, the laboratory  
4 or test-offering entity shall supplement or  
5 amend information on such test in the test  
6 registry data bank, as required by clause  
7 (i).

8 “(3) CONTENT OF SUBMISSIONS.—

9 “(A) LDT OR DTC DNA TEST INFORMA-  
10 TION.—With respect to an LDT or DTC DNA  
11 test, the Secretary shall require the information  
12 submitted under paragraph (2) to consist of  
13 each of the following:

14 “(i) The location of the laboratory.

15 “(ii) The certification and licensure  
16 information of the laboratory.

17 “(iii) The purpose of the test.

18 “(iv) The claimed use or uses of the  
19 test.

20 “(v) A description of the test method-  
21 ology.

22 “(vi) Information regarding the ana-  
23 lytical validity of the test.

1           “(vii) Information regarding the clin-  
2           ical validity of the test for each of its  
3           claimed uses.

4           “(viii) Information describing the sta-  
5           tus of the test as an existing test (as de-  
6           scribed under paragraph (4)), a new test  
7           pending review (under subsection (c)), or  
8           an authorized new test (under subsection  
9           (c)(4)(B)).

10           “(B) DTC DNA TEST INFORMATION.—  
11           With respect to a DTC DNA test, the Secretary  
12           shall require the information submitted under  
13           paragraph (2) to consist of the information re-  
14           quired by subparagraph (A) and in addition  
15           each of the following:

16           “(i) The identity, location, and reg-  
17           istration information of the test-offering  
18           entity.

19           “(ii) The identity of the certified lab-  
20           oratory that will perform the test, and the  
21           certification and licensure information for  
22           such laboratory.

23           “(iii) Information to demonstrate that  
24           the consumer will be provided with access

1 to pre-test and post-test counseling by a  
2 physician or qualified genetic counselor.

3 “(4) REVIEW OF INFORMATION FOR EXISTING  
4 TESTS.—If, upon review of the information sub-  
5 mitted under paragraph (2) for an LDT or DTC  
6 DNA test that is offered or marketed on or before  
7 the date of the enactment of this section, the Sec-  
8 retary determines that there is reasonable cause to  
9 believe that there is inadequate information for a de-  
10 termination of clinical validity (as described in sub-  
11 section (c)(4)(B)) of one or more claimed uses of the  
12 LDT or DTC DNA test, the Secretary may require  
13 that the laboratory or test-offering entity submit no-  
14 tification under subsection (c) for each such claimed  
15 use.

16 “(c) NOTIFICATION PROCESS.—

17 “(1) APPLICABILITY.—

18 “(A) IN GENERAL.—This subsection ap-  
19 plies to an LDT or DTC DNA test only if—

20 “(i) the test is first offered or mar-  
21 keted by the laboratory or the test-offering  
22 entity after the date of the enactment of  
23 this section;

24 “(ii) the test is offered on or before  
25 the date of the enactment of this section

1 and, after such date, is significantly modi-  
2 fied; or

3 “(iii) the Secretary determines under  
4 subsection (b)(4) that there is reasonable  
5 cause to believe that there is inadequate  
6 information for a determination of clinical  
7 validity of one or more claimed uses of the  
8 LDT or DTC DNA test.

9 “(B) SIGNIFICANT MODIFICATION.—For  
10 purposes of subparagraph (A)(ii) and para-  
11 graph (2)(B), a significant modification  
12 means—

13 “(i) offering or marketing the test for  
14 a new claimed use;

15 “(ii) any significant change to the  
16 fundamental testing methodology; and

17 “(iii) any change that significantly af-  
18 fects the clinical validity of the test.

19 “(2) NOTIFICATION SUBMISSION.—

20 “(A) PREMARKET NOTIFICATION.—Before  
21 marketing an LDT or DTC DNA test, a lab-  
22 oratory or test-offering entity shall submit a  
23 premarket notification to the Secretary.

24 “(B) SUPPLEMENTAL NOTIFICATION FOR  
25 SIGNIFICANT MODIFICATIONS.—After any sig-

1           nificant modification (as described in paragraph  
2           (1)(B)) to an LDT or DTC DNA test for which  
3           a premarket notification under subparagraph  
4           (A) has been submitted or for which no such  
5           premarket notification was required, the labora-  
6           tory or test-offering entity shall submit a sup-  
7           plemental notification for the LDT or DTC  
8           DNA test.

9           “(C) SUPPLEMENTAL NOTIFICATION IN  
10          CASE OF INADEQUATE EVIDENCE.—If a labora-  
11          tory or test-offering entity determines, at any  
12          time, that the evidence of clinical validity is in-  
13          adequate to support one or more of the claimed  
14          uses in a notification under subparagraph (A)  
15          or (B), then not later than 30 calendar days  
16          after making such determination the laboratory  
17          or test-offering entity shall—

18                 “(i) submit a supplemental notifica-  
19                 tion containing additional information sup-  
20                 porting the clinical validity of the claimed  
21                 uses; or

22                 “(ii) submit a supplemental notifica-  
23                 tion withdrawing one or more claimed  
24                 uses.

1           “(D) CONCURRENT SUBMISSION FOR TEST  
2           REGISTRY DATA BANK.—Subject to the dead-  
3           lines and other requirements of subsection (b),  
4           a laboratory or test-offering entity may submit  
5           information for inclusion in the test registry  
6           data bank under subsection (b) concurrently  
7           with a notification under this paragraph.

8           “(E) ACKNOWLEDGMENT OF RECEIPT.—  
9           Upon receipt of a notification under this para-  
10          graph, the Secretary shall send written notice  
11          to the submitter—

12                   “(i) acknowledging receipt of the noti-  
13                   fication; and

14                   “(ii) indicating the date on which the  
15                   Secretary received the notification.

16          “(3) CONTENT OF NOTIFICATIONS.—

17                   “(A) LDT NOTIFICATIONS.—With respect  
18                   to a premarket or supplemental notification for  
19                   an LDT under paragraph (2)(A) or (2)(B), the  
20                   Secretary shall require the notification to con-  
21                   sist of each of the types of information listed in  
22                   clauses (i) through (vii) of subsection (b)(3)(A).

23                   “(B) DTC DNA TEST NOTIFICATIONS.—  
24                   With respect to a premarket or supplemental  
25                   notification for a DTC DNA test under para-

1 graph (2)(A) or (2)(B), the Secretary shall re-  
2 quire the notification to consist of each of the  
3 following:

4 “(i) The types of information listed in  
5 clauses (i) and (ii) of subsection (b)(3)(B).

6 “(ii) If informed consent for the per-  
7 formance of the test is required by State  
8 or Federal law, a copy of the standard in-  
9 formed consent document to be signed by  
10 the individual to signify such consent.

11 “(iii) Information to demonstrate that  
12 the consumer will be provided with access  
13 to pre-test and post-test counseling by a  
14 physician or qualified genetic counselor.

15 “(C) TESTS OFFERED OR MARKETED ONLY  
16 BY LABORATORY.—If a laboratory offers a DTC  
17 DNA test that is not offered or marketed by a  
18 test-offering entity—

19 “(i) the laboratory is only required to  
20 submit one premarket notification under  
21 paragraph (2)(A) for the test; and

22 “(ii) such notification shall include, as  
23 applicable, the information required by  
24 subparagraph (A) for an LDT and the in-

1                   formation required by subparagraph (B)  
2                   for a DTC DNA test.

3                   “(D) TESTS PREVIOUSLY CLEARED OR AP-  
4                   PROVED BY FDA.—Notwithstanding the clear-  
5                   ance or approval of an LDT or DTC DNA test  
6                   under the Federal, Food, Drug, and Cosmetic  
7                   Act before the date of the enactment of this  
8                   Act, any review by the Department of Health  
9                   and Human Services of the LDT or DTC DNA  
10                  test (or any modification thereto) that occurs  
11                  on or after such date shall be conducted exclu-  
12                  sively under this section and not under the Fed-  
13                  eral Food, Drug, and Cosmetic Act.

14                  “(4) REVIEW AND AUTHORIZATION OF NOTIFI-  
15                  CATIONS.—

16                  “(A) IN GENERAL.—Not later than 90 cal-  
17                  endar days after the date on which the Sec-  
18                  retary receives a notification under paragraph  
19                  (2)(A), (2)(B), or (2)(C)(i), the Secretary shall,  
20                  with respect to each claimed use of a test, re-  
21                  view the notification, make a determination as  
22                  to whether the notification under paragraph (2)  
23                  demonstrates clinical validity, and—

24                                 “(i) issue an authorization letter in  
25                                 accordance with subparagraph (B); or

1           “(ii) provide notice under subpara-  
2 graph (C)(i) that the submitted informa-  
3 tion is not adequate to demonstrate clinical  
4 validity.

5           “(B) AUTHORIZATION LETTERS; DETER-  
6 MINATION OF CLINICAL VALIDITY.—

7           “(i) ISSUANCE OF AUTHORIZATION  
8 LETTERS.—If the Secretary determines,  
9 with respect to one or more claimed uses  
10 of a test, that a notification under para-  
11 graph (2) demonstrates clinical validity,  
12 the Secretary shall issue an authorization  
13 letter for such claimed uses to the sub-  
14 mitter of the notification.

15           “(ii) STANDARD FOR ISSUANCE.—The  
16 Secretary shall issue such an authorization  
17 letter if the notification provides reason-  
18 able assurance of the clinical validity of  
19 such claimed uses. One or more studies  
20 published in a peer-reviewed journal that is  
21 generally recognized to be of national scope  
22 and reputation, or data from unpublished  
23 studies conducted by the submitter or for  
24 which the submitter has obtained a right  
25 of reference, shall be sufficient to con-

1           stitute reasonable assurance of the clinical  
2           validity of the claimed uses.

3           “(iii) PROHIBITION.—The Secretary  
4           shall not require a laboratory or test-offer-  
5           ing entity to include (for purposes of dem-  
6           onstrating clinical validity) evidence of—

7                     “(I) clinical utility; or

8                     “(II) the ability of a physician,  
9           provider, or consumer to interpret a  
10          test result or to apply a test result to  
11          achieve a particular health or clinical  
12          outcome.

13          “(iv) PARTIAL DEMONSTRATION OF  
14          CLINICAL VALIDITY.—If a notification  
15          under paragraph (2) demonstrates clinical  
16          validity for some but not all of the claimed  
17          uses of a test, the Secretary shall issue an  
18          authorization letter under clause (i) with  
19          respect to each claimed use for which clin-  
20          ical validity has been demonstrated.

21          “(C) NOTICE OF INADEQUACY; REPLY;  
22          FINAL DETERMINATION.—If the Secretary de-  
23          termines, with respect to one or more claimed  
24          uses of a test, that a notification under para-

1 graph (2) is not adequate to demonstrate clin-  
2 ical validity—

3 “(i) the Secretary shall notify the sub-  
4 mitter about such determination and shall  
5 specify in the notice the information which  
6 is required to demonstrate clinical validity  
7 for each such clinical use;

8 “(ii) not later than the 90-calendar-  
9 day period following receipt of a notice  
10 under clause (i), the submitter may file a  
11 response with the Secretary; and

12 “(iii) not later than 60 calendar days  
13 after receipt of a response under clause  
14 (ii), the Secretary shall issue a final deter-  
15 mination regarding the clinical validity of  
16 each clinical use subject to the notice  
17 under clause (i).

18 “(D) OFFERING OR MARKETING TEST  
19 PENDING AGENCY ACTION.—

20 “(i) APPLICABLE TIME PERIOD.—This  
21 subparagraph applies, with respect to a  
22 claimed use of a test, during the period be-  
23 tween—

24 “(I) submission of a notification  
25 under paragraph (2); and

1                   “(II) final action by the Sec-  
2                   retary on such notification under sub-  
3                   paragraph (A)(i), (C)(iii), or (G), as  
4                   applicable, or the failure to file a re-  
5                   sponse under clause (ii) of subpara-  
6                   graph (C) within the period specified  
7                   in such clause.

8                   “(ii) CONTINUED OFFERING OR MAR-  
9                   KETING.—During a period described in  
10                  clause (i) with respect to any claimed use  
11                  of a test, the laboratory or test-offering en-  
12                  tity may continue to offer or market the  
13                  test with respect to such claimed use as if  
14                  the Secretary had issued an authorization  
15                  letter under subparagraph (B) for such  
16                  claimed use.

17                  “(iii) RELATION TO TEST REGISTRY  
18                  DATA BANK.—This subparagraph shall not  
19                  be construed to affect the Secretary’s au-  
20                  thority under subsection (b).

21                  “(iv) EXCEPTION FOR WITHDRAWN  
22                  NOTIFICATION.—Clause (ii) does not apply  
23                  with respect to a claimed use of a test for  
24                  which notification has been withdrawn  
25                  under paragraph (2)(C)(ii).

1           “(E) MARKETING PENDING AUTHORIZA-  
2           TION.—Beginning on the date of submission of  
3           a notification under paragraph (2)(A), (2)(B),  
4           or (2)(C)(i), the laboratory or test-offering enti-  
5           ty may offer or market the test while the notifi-  
6           cation is pending, provided that the required in-  
7           formation about the test has first been sub-  
8           mitted to the test registry data bank as re-  
9           quired by subsection (b).

10           “(F) FAILURE BY SECRETARY TO MAKE A  
11           DETERMINATION.—The Secretary is deemed to  
12           have issued an authorization letter under sub-  
13           paragraph (B) with respect to a claimed use of  
14           a test if—

15                   “(i) the 90-day period under subpara-  
16                   graph (A) expires and the Secretary has  
17                   not, with respect to such claim, issued an  
18                   authorization letter under subparagraph  
19                   (B) or provided notice under subparagraph  
20                   (C)(i); or

21                   “(ii) the 60-day period under subpara-  
22                   graph (C)(iii) expires and the Secretary  
23                   has not, with respect to such claim, issued  
24                   a final determination regarding clinical va-  
25                   lidity.

1 “(G) RISK OF IMMEDIATE HARM.—

2 “(i) ORDER.—The Secretary may  
3 order a laboratory or test-offering entity to  
4 cease offering or marketing a test with re-  
5 spect to one or more claimed uses if the  
6 Secretary makes a final determination  
7 that—

8 “(I) the information submitted in  
9 notifications under paragraph (2) for  
10 such uses does not demonstrate the  
11 clinical validity of the claimed uses;  
12 and

13 “(II) the test poses a risk of im-  
14 mediate harm to the public health  
15 with respect to such claimed uses.

16 “(ii) EFFECTIVE UPON RECEIPT.—An  
17 order under clause (i) shall be effective im-  
18 mediately upon receipt by the laboratory or  
19 test-offering entity.

20 “(iii) CONTENTS.—An order under  
21 clause (i) shall set forth with specificity the  
22 reasons for the determinations under each  
23 of subclauses (I) and (II) of clause (i) and  
24 shall notify the recipient of the right to ap-

1                   peal the Secretary's determinations and  
2                   the procedures for such appeal.

3                   “(5) ADMINISTRATIVE APPEAL.—If the Sec-  
4                   retary makes a final determination under paragraph  
5                   (4)(A) or (4)(C)(iii) that clinical validity has not  
6                   been established, or issues an order under paragraph  
7                   (4)(G), with respect to one or more clinical uses of  
8                   a test, the laboratory or test-offering entity may, not  
9                   later than 30 days after the date of the final deter-  
10                  mination or issuance of the order, bring an adminis-  
11                  trative appeal by selecting the procedures set forth  
12                  in one (and only one) of the following subpara-  
13                  graphs:

14                  “(A) DISPUTE RESOLUTION BY ADVISORY  
15                  COMMITTEE.—

16                  “(i) IN GENERAL.—The laboratory or  
17                  test-offering entity may seek dispute reso-  
18                  lution by referral to an advisory committee  
19                  of non-governmental experts who are quali-  
20                  fied by training and experience to make a  
21                  recommendation regarding the clinical va-  
22                  lidity of the claimed uses of the test.

23                  “(ii) PROCESS.—In the case of an ap-  
24                  peal under this subparagraph, the com-  
25                  mittee shall hold a hearing to consider the

1 evidence of clinical validity, shall keep a  
2 written record of the hearing, and shall  
3 provide an opportunity for testimony from  
4 experts presented by both the appellant  
5 and the Secretary. The committee shall  
6 make a recommendation to the Secretary  
7 at the conclusion of the hearing. The Sec-  
8 retary shall consider the record and the  
9 recommendations of the committee and  
10 shall make a decision within 90 calendar  
11 days after the conclusion of the hearing.

12 “(iii) SELECTION OF COMMITTEE  
13 MEMBERS.—The members of an advisory  
14 committee under this subparagraph shall  
15 be selected by the Secretary from among  
16 individuals, including physicians, with dem-  
17 onstrated expertise in and experience with  
18 the analytical validity and clinical validity  
19 of laboratory-developed tests and the lit-  
20 erature related to the validity of such tests.

21 “(B) REVIEW BY ADMINISTRATIVE LAW  
22 JUDGE.—The laboratory or test-offering entity  
23 may seek review by an administrative law judge  
24 pursuant to procedures established by the Sec-  
25 retary.

1 “(6) FINAL AGENCY ACTION.—

2 “(A) IN GENERAL.—Subject to judicial re-  
3 view under subsection (h), upon final agency ac-  
4 tion under paragraphs (4) and (5) determining  
5 that clinical validity of one or more claimed  
6 uses of a test has not been established or upon  
7 issuance of an order under paragraph (4)(G)  
8 for one or more claimed uses of a test, the lab-  
9 oratory or test-offering entity shall imme-  
10 diately—

11 “(i) cease offering the test for such  
12 uses; and

13 “(ii) cease reporting test results to  
14 health care providers or individuals for  
15 such uses.

16 “(B) REPORTING FOR CERTAIN SPECI-  
17 MENS.—For specimens that have been received  
18 or tests that have been ordered but results not  
19 yet reported, the laboratory or test-offering en-  
20 tity shall notify the person who ordered the test  
21 that test results will not be reported because  
22 clinical validity for such clinical uses has not  
23 been established.

24 “(7) COMPANION DIAGNOSTIC TESTS.—An  
25 LDT may be authorized under this subsection for a

1 claimed use as a companion diagnostic test for pur-  
2 poses of specifying the use of a drug or biological  
3 product for therapeutic purposes. An LDT for use  
4 as a companion diagnostic test shall be reviewed ex-  
5 clusively pursuant to the requirements of this section  
6 and not under the Federal Food, Drug, and Cos-  
7 metic Act.

8 “(d) REGISTRATION BY TEST-OFFERING ENTI-  
9 TIES.—

10 “(1) REGISTRATION REQUIREMENT.—A test-of-  
11 fering entity may not offer or market a DTC DNA  
12 test unless the entity registers with the Secretary in  
13 accordance with this subsection and maintains such  
14 registration in effect.

15 “(2) TIMING.—

16 “(A) IN GENERAL.—Except as provided in  
17 subparagraph (B), registration by a test-offer-  
18 ing entity under this subsection shall occur be-  
19 fore—

20 “(i) the entity offers or markets a  
21 DTC DNA test; or

22 “(ii) submits a premarket notification  
23 under subsection (c)(2)(A).

24 “(B) EXCEPTIONS.—

1                   “(i) ENTITIES ALREADY OFFERING OR  
2                   MARKETING TESTS.—In the case of a test-  
3                   offering entity that is offering or mar-  
4                   keting a DTC DNA test as of the date on  
5                   which the Secretary establishes interim  
6                   procedures for carrying out this subsection  
7                   under paragraph (4)(B), registration by  
8                   the entity shall occur not later than 60  
9                   days after such date.

10                   “(ii) AUTHORITY TO ESTABLISH  
11                   OTHER EXCEPTIONS.—The Secretary may  
12                   establish exceptions to clause (i) in the  
13                   regulations required by paragraph (4)(A).

14                   “(3) INAPPLICABILITY TO CERTIFIED LABORA-  
15                   TORIES.—If a certified laboratory offers a DTC  
16                   DNA test that is not offered or marketed by a test-  
17                   offering entity, such laboratory—

18                   “(A) is not required to register as a test-  
19                   offering entity under this subsection; and

20                   “(B) shall not, because of offering such  
21                   test, be regulated as a test-offering entity in-  
22                   stead of a laboratory under section 353 or this  
23                   section.

24                   “(4) REGULATIONS.—

1           “(A) IN GENERAL.—In promulgating regu-  
2           lations under subsection (i)(1), the Secretary  
3           shall include regulations governing registration  
4           under this subsection.

5           “(B) INTERIM PROCEDURES.—The Sec-  
6           retary shall establish interim procedures gov-  
7           erning registration under this subsection during  
8           the period beginning on the date of the enact-  
9           ment of this section and ending on the effective  
10          date of the regulations required by subpara-  
11          graph (A). The Secretary shall establish such  
12          interim procedures not later than 90 calendar  
13          days after the date of the enactment of this sec-  
14          tion. The Secretary may establish such interim  
15          procedures by a guidance document or other  
16          means of public notification.

17          “(e) INFORMATION REGARDING TEST CAPABILITIES  
18          AND LIMITATIONS.—

19                 “(1) INCLUSION OF INFORMATION.—A labora-  
20                 tory or test-offering entity that offers an LDT or a  
21                 DTC DNA test shall include in its test result re-  
22                 ports, directories of services, marketing materials,  
23                 and advertising—

1           “(A) truthful, accurate, and nondeceptive  
2 information regarding the capabilities and limi-  
3 tations of the tests; and

4           “(B) a statement that the test has been  
5 validated by the laboratory performing the test  
6 in accordance with the requirements of the  
7 Clinical Laboratory Improvement Amendments  
8 (referred to in this section as ‘CLIA’).

9           “(2) CLAIMS NOT IMPUTED TO LABORATORY.—  
10 A laboratory shall not be subject to a sanction or  
11 other action under section 353 or this section be-  
12 cause of a claim made by a test-offering entity.

13          “(f) REPORTING.—

14           “(1) DEATH OR SERIOUS INJURY REPORT.—If  
15 a laboratory or test-offering entity that offers or  
16 markets an LDT or DTC DNA test has reason to  
17 believe that the test may have caused or contributed  
18 to a death or serious bodily injury—

19           “(A) the laboratory or entity shall prompt-  
20 ly investigate the incident;

21           “(B) if the laboratory or entity determines  
22 that the LDT or DTC DNA test may have  
23 caused or contributed to a death or serious bod-  
24 ily injury, within 10 working days of making

1           such determination the laboratory or entity  
2           shall report the incident to the Secretary; and

3           “(C) the laboratory or entity shall provide  
4           such additional information regarding the inci-  
5           dent or the test associated with the incident as  
6           the Secretary may request.

7           “(2) COMPLAINT RECORDS.—A laboratory or  
8           test-offering entity that offers or markets an LDT  
9           or DTC DNA test shall maintain a record of—

10           “(A) each incident investigated under  
11           paragraph (1)(A), and each report made under  
12           paragraph (1)(B), with respect to the test; and

13           “(B) for any incident that was determined  
14           under paragraph (1)(B) not to meet the re-  
15           quirements for reporting to the Secretary, the  
16           basis for such determination.

17           “(3) NO ADMISSION OF CAUSATION.—A report  
18           submitted under this subsection with respect to an  
19           event shall not be treated as an admission that the  
20           test, or the laboratory or its employees, caused or  
21           contributed to the event.

22           “(g) SANCTIONS.—

23           “(1) APPLICABILITY OF SANCTIONS TO CLIN-  
24           ICAL LABORATORIES.—

1           “(A) INTERMEDIATE SANCTIONS.—The  
2 reference in section 353(h)(1) to the ‘require-  
3 ments for the issuance of a certificate’ is  
4 deemed to include the requirements of this sec-  
5 tion.

6           “(B) SUSPENSION, REVOCATION, AND LIM-  
7 ITATION OF CERTIFICATE.—

8           “(i) The reference in section  
9 353(i)(1)(A) to ‘misrepresentation in ob-  
10 taining the certificate’ is deemed to include  
11 any misrepresentation of information in a  
12 submission to the Secretary pursuant to  
13 this section.

14           “(ii) The reference in section  
15 353(i)(1)(F) to ‘any provisions of this sec-  
16 tion’ is deemed to include any provisions of  
17 this section.

18           “(2) APPLICABILITY OF SANCTIONS TO TEST-  
19 OFFERING ENTITIES.—

20           “(A) INTERMEDIATE SANCTIONS.—

21           “(i) IN GENERAL.—If the Secretary  
22 determines that a test-offering entity reg-  
23 istered under subsection (d) is no longer  
24 meeting the requirements of this section,  
25 the Secretary may impose intermediate

1 sanctions in lieu of the actions authorized  
2 by subparagraph (B).

3 “(ii) TYPES OF SANCTIONS; PROCE-  
4 DURES.—The provisions of paragraphs (2)  
5 and (3) of section 353(h) shall apply with  
6 respect to intermediate sanctions against a  
7 test-offering entity under clause (i) to the  
8 same extent and in the same manner as  
9 such provisions apply with respect to inter-  
10 mediate sanctions against a laboratory  
11 under section 353(h).

12 “(B) SUSPENSION, REVOCATION, AND LIM-  
13 ITATION OF REGISTRATION.—The registration  
14 of a test-offering entity under subsection (d)  
15 may be suspended, revoked, or limited if the  
16 Secretary finds, using the procedures applicable  
17 under section 353(i)(1) to suspension, revoca-  
18 tion, or limitation of a laboratory’s certificate,  
19 that the owner or operator or any employee of  
20 the test-offering entity—

21 “(i) has misrepresented information in  
22 a submission to the Secretary pursuant to  
23 this section;

24 “(ii) has failed to comply with the re-  
25 quirements of this section;

1           “(iii) has failed to comply with rea-  
2           sonable requests of the Secretary for—

3                   “(I) any information or materials  
4                   that the Secretary concludes are nec-  
5                   essary to determine the test-offering  
6                   entity’s continued compliance with the  
7                   requirements of this section; or

8                   “(II) work on materials, that the  
9                   Secretary concludes is necessary to  
10                  determine the test-offering entity’s  
11                  continued compliance with the re-  
12                  quirements of this section;

13                  “(iv) has refused a reasonable request  
14                  of the Secretary (or, if designated by the  
15                  Secretary, any Federal officer, government  
16                  employee, or a nongovernmental organiza-  
17                  tion or an accreditation body designated  
18                  under subsection (k)) for permission to in-  
19                  spect the test-offering entity and its oper-  
20                  ations and pertinent records during the  
21                  hours the test-offering entity is in oper-  
22                  ation;

23                  “(v) has violated or aided and abetted  
24                  in the violation of any provisions of this

1 section or of any regulation promulgated  
2 thereunder; or

3 “(vi) has not complied with an inter-  
4 mediate sanction imposed under subpara-  
5 graph (A).

6 “(C) ACTION BEFORE A HEARING.—If the  
7 Secretary determines that—

8 “(i) the failure of a test-offering enti-  
9 ty to comply with the requirements of this  
10 section presents an imminent and serious  
11 risk to human health; or

12 “(ii) a test-offering entity has engaged  
13 in an action described in clause (iv) or (v)  
14 of subparagraph (B),

15 the Secretary may suspend or limit the registra-  
16 tion of the laboratory before holding a hearing  
17 under subparagraph (B) regarding such failure  
18 or refusal. The opportunity for a hearing shall  
19 be provided no later than 60 days from the ef-  
20 fective date of the suspension or limitation. A  
21 suspension or limitation under this subpara-  
22 graph shall stay in effect until the decision of  
23 the Secretary made after the hearing under  
24 subparagraph (B).

1           “(D) INJUNCTIONS.—If the Secretary has  
2           reason to believe the continuation of any activ-  
3           ity by a test-offering entity would constitute a  
4           significant hazard to the public health, the Sec-  
5           retary may bring suit in any district court of  
6           the United States that has jurisdiction over  
7           such entity to enjoin continuation of such activ-  
8           ity. Upon proper showing, a temporary injunc-  
9           tion or restraining order against continuation of  
10          such activity pending issuance of a final order  
11          under this subparagraph shall be granted with-  
12          out bond by such court.

13          “(3) APPLICABILITY OF CRIMINAL SANCTIONS  
14          TO ALL PERSONS.—The reference in section 353(l)  
15          to ‘any requirement of this section’ is deemed to in-  
16          clude any requirement of this section.

17          “(4) REPORTING.—In promulgating regulations  
18          under subsection (i)(1), the Secretary may include  
19          sanctions specific to violations of subsection (f) (re-  
20          garding reporting), including the following:

21                 “(A) Civil money penalties in an amount  
22                 not to exceed \$10,000 for each such violation.

23                 “(B) Directed plans of correction.

24                 “(C) For repeat or intentional violations,  
25                 an order requiring the test-offering entity to

1           cease offering or marketing the DTC DNA test  
2           involved for one or more claimed uses.

3           “(h) JUDICIAL REVIEW.—If a laboratory or test-of-  
4   fering entity is subject to a sanction or other action pursu-  
5   ant to subsection (g) or is adversely affected by final agen-  
6   cy action under subsection (c), the laboratory or entity  
7   may appeal such sanction or action by filing a petition  
8   for judicial review with the United States court of appeals  
9   for the circuit where the laboratory or entity has its prin-  
10   cipal place of business. The provisions of section 353(k)  
11   applicable to judicial review of sanctions and actions under  
12   section 353 shall apply to judicial review of sanctions and  
13   actions under this section.

14          “(i) REGULATIONS.—

15               “(1) IN GENERAL.—Not later than 1 year after  
16   the date of the enactment of this section, the Sec-  
17   retary shall promulgate final regulations to carry out  
18   this section.

19               “(2) RARE DISEASES AND CONDITIONS.—In  
20   carrying out paragraph (1), the Secretary shall in-  
21   clude regulations specific to any LDT or DTC DNA  
22   test used in connection with a rare disease or condi-  
23   tion (as such term is defined in section 526(a)(2) of  
24   the Federal Food, Drug, and Cosmetic Act). Such  
25   regulations—

1           “(A) shall provide for expedited review of  
2           premarket notifications under subsection  
3           (c)(2)(A) for such tests;

4           “(B) shall contain standards of evidence  
5           for demonstrating the clinical validity of such  
6           test that takes into account special issues relat-  
7           ing to studies in small populations;

8           “(C) shall take into account relevant tech-  
9           nical standards and guidelines applicable to  
10          testing for such a rare disease and condition;  
11          and

12          “(D) may authorize the Secretary to waive  
13          any requirement of this section if the Secretary  
14          determines that application of such requirement  
15          would unreasonably delay or prevent access to  
16          such test.

17          “(3) EMERGENCY USE.—In carrying out para-  
18          graph (1), the Secretary shall include regulations  
19          authorizing the Secretary to waive any requirement  
20          of this section in order to allow the emergency use  
21          of an LDT for detecting or diagnosing serious or  
22          life-threatening infectious pathogens or diseases.  
23          Such regulations shall apply standards of evidence  
24          for demonstrating the clinical validity of such a test

1 that take into account special issues relating to in-  
2 fectious pathogens and public health threats.

3 “(4) EXTERNAL QUALITY ASSESSMENT.—In  
4 carrying out paragraph (1), the Secretary, in con-  
5 sultation with proficiency testing organizations ap-  
6 proved under section 353(f)(C), shall include regula-  
7 tions establishing an external review process to  
8 evaluate the analytical validity of LDTs.

9 “(j) INSPECTIONS.—

10 “(1) LABORATORIES.—During an inspection  
11 under section 353(g), the Secretary—

12 “(A) may use the authorities specified in  
13 section 353(g)(1) for purposes of determining  
14 compliance with this section; and

15 “(B) may require a laboratory to provide  
16 evidence of clinical validity for any claim made  
17 for an LDT offered by that laboratory.

18 “(2) TEST-OFFERING ENTITIES.—The Sec-  
19 retary—

20 “(A) shall have the same authority to con-  
21 duct inspections of a test-offering entity for  
22 purposes of determining compliance with this  
23 section as the Secretary has under paragraph  
24 (1) and section 353(g)(1) to conduct inspec-

1           tions of laboratories for compliance with this  
2           section and section 353; and

3                   “(B) during an inspection under subpara-  
4           graph (A), may require a test-offering entity to  
5           provide evidence of clinical validity for any  
6           claim made for a DTC DNA test offered or  
7           marketed by that entity.

8                   “(3) PROPRIETARY OR CONFIDENTIAL INFOR-  
9           MATION.—The Secretary shall establish procedures  
10          to protect any proprietary or confidential informa-  
11          tion concerning an LDT or DTC DNA test that may  
12          be disclosed during an inspection under this sub-  
13          section.

14                  “(k) DELEGATION.—The Secretary shall administer  
15          this section solely through the Centers for Medicare &  
16          Medicaid Services. The Administrator may—

17                   “(1) pursuant to agreement, designate a non-  
18          governmental organization that has qualifications  
19          and expertise in the evaluation of laboratory testing  
20          and in evaluating the analytical and clinical validity  
21          of laboratory tests to assist in the review of pre-  
22          market notifications and test registry data bank in-  
23          formation and in the performance of inspections au-  
24          thorized under subsection (j); and

1           “(2) subject to the provisions of section 353(e),  
2           designate an accreditation organization to assist in  
3           the review of premarket notifications and test reg-  
4           istry data bank information and in the performance  
5           of inspections authorized under subsection (j).

6           “(l) FEDERAL TRADE COMMISSION.—Nothing in this  
7           section shall be construed to limit regulation of advertising  
8           under the Federal Trade Commission Act.”.

9           **SEC. 3. AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND**  
10           **COSMETIC ACT.**

11           (a) DEVICE DEFINITION.—Section 201(h) of the  
12           Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
13           321(h)) is amended by adding at the end the following:  
14           “The term ‘device’ does not include a laboratory-developed  
15           test or a direct-to-consumer DNA test as defined in sec-  
16           tion 353A of the Public Health Service Act.”.

17           (b) REGISTRATION EXCLUSION.—Section 510(g) of  
18           the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
19           360(g)) is amended—

20                   (1) by redesignating paragraphs (4) and (5) as  
21                   (5) and (6), respectively; and

22                   (2) by inserting after paragraph (3) the fol-  
23           lowing:

1           “(4) clinical laboratories certified under section  
2           353 of the Public Health Service Act insofar as such  
3           laboratories—

4                   “(A) use devices to perform laboratory  
5           tests; or

6                   “(B) create and perform laboratory-devel-  
7           oped tests as defined in section 353A of such  
8           Act;”.

9   **SEC. 4. FEES.**

10          Section 353(m) of the Public Health Service Act (42  
11   U.S.C. 263a(m)) is amended—

12           (1) in paragraph (2), by adding at the end the  
13          following sentence: “In the case of a laboratory or  
14          test-offering entity that is required to submit infor-  
15          mation under section 353A(b)(2)(A), the Secretary  
16          shall also require the payment of fees for reviews of  
17          premarket notifications and supplemental notifica-  
18          tions submitted pursuant to subparagraph (A), (B),  
19          or (C) of section 353A(c)(2), registration of test-of-  
20          fering entities under section 353A(d), and inspec-  
21          tions conducted pursuant to section 353A(j).”;

22           (2) in paragraph (3)(B)—

23                   (A) by striking “inspections and pro-  
24           ficiency testing described in paragraph (2)” and  
25           inserting “inspections and proficiency testing

1 described in the first sentence of paragraph  
2 (2)”; and

3 (B) by striking the period at the end and  
4 inserting “, review of premarket notifications  
5 and supplemental notifications submitted pursu-  
6 ant to subparagraph (A), (B), or (C) of section  
7 353A(e)(2), registration of test-offering entities  
8 under section 353A(d), and inspections con-  
9 ducted pursuant to section 353A(j)”; and

10 (3) by adding at the end the following new  
11 paragraph:

12 “(4) FISCAL REPORT.—By December 31, 2011,  
13 and by the end of each calendar year thereafter, the  
14 Secretary shall prepare and submit to the Com-  
15 mittee on Energy and Commerce of the House of  
16 Representatives and the Committee on Health, Edu-  
17 cation, Labor, and Pensions of the Senate a report  
18 on the amount of fees collected during the preceding  
19 fiscal year under this subsection and the amount of  
20 fees collected under this subsection available to sup-  
21 port activities under this section and section 353A.  
22 Before increasing the amount of any fee required by  
23 this subsection, the Secretary shall include in a re-  
24 port under this paragraph an explanation of the  
25 need for such an increase, including the likely reve-

1       nues and expenses expected to be incurred. The ef-  
2       fective date of any such increase shall not be sooner  
3       than the date that is 120 days after the submission  
4       of the report containing such explanation.”.