

110TH CONGRESS  
1ST SESSION

# S. 736

To provide for the regulation and oversight of laboratory tests.

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IN THE SENATE OF THE UNITED STATES

MARCH 1, 2007

Mr. KENNEDY (for himself and Mr. SMITH) introduced the following bill;  
which was read twice and referred to the Committee on Health, Edu-  
cation, Labor, and Pensions

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## A BILL

To provide for the regulation and oversight of laboratory  
tests.

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

3       **SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Laboratory Test Im-  
5       provement Act”.

6       **SEC. 2. DEFINITIONS.**

7       (a) IN GENERAL.—

8               (1) FEDERAL FOOD, DRUG, AND COSMETIC  
9       ACT.—Section 201 of the Federal Food, Drug, and  
10       Cosmetic Act (referred to in this Act as the

1 “FFDCA”) (21 U.S.C. 321) is amended by adding  
2 at the end the following:

3 “(rr) DEFINITIONS RELATED TO LABORATORY-DE-  
4 VELOPED TESTS.—

5 “(1) ANALYTICAL VALIDITY.—The term ‘ana-  
6 lytical validity’, with respect to a laboratory-devel-  
7 oped test, means the extent to which the test can be  
8 used to measure accurately and reliably the property  
9 or characteristic that the test is intended to meas-  
10 ure.

11 “(2) CLINICAL VALIDITY.—The term ‘clinical  
12 validity’, with respect to a laboratory-developed test,  
13 means the extent to which the test can be used for  
14 its intended use.

15 “(3) DIRECT-TO-CONSUMER TEST.—The term  
16 ‘direct-to-consumer test’ means a laboratory-devel-  
17 oped test that is not a prescription test.

18 “(4) INTENDED USE.—The term ‘intended use’,  
19 with respect to a laboratory-developed test, in-  
20 cludes—

21 “(A) determining predisposition of an indi-  
22 vidual to a disease or condition;

23 “(B) aiding diagnosis of a disease or con-  
24 dition of an individual;

1           “(C) aiding decision-making on how to  
2           treat a disease or condition of an individual;

3           “(D) aiding preimplantation genetic diag-  
4           nosis;

5           “(E) determining a characteristic of a  
6           human embryo or a human fetus;

7           “(F) determining whether an individual is  
8           a carrier of an allele associated with a disease  
9           or condition; or

10          “(G) otherwise obtaining information re-  
11          lated to health or disease prevention (including  
12          nutrition) for an individual.

13          “(5) IN VITRO DIAGNOSTIC PRODUCT.—The  
14          term ‘in vitro diagnostic product’ shall have the  
15          meaning given the term in section 809.3(a) of title  
16          21, Code of Federal Regulations (or successor regu-  
17          lation).

18          “(6) LABORATORY-DEVELOPED TEST.—

19                 “(A) IN GENERAL.—The term ‘laboratory-  
20                 developed test’ means—

21                         “(i) the use of analytical methods de-  
22                         veloped by a laboratory to process a bio-  
23                         logical specimen, whether at 1 laboratory  
24                         site or multiple sites, to report a test result

1 to a health care practitioner, a patient, or  
2 a consumer; and

3 “(ii) includes an in vitro diagnostic  
4 product that the laboratory has modified,  
5 unless such modification requires  
6 preclearance or preapproval of such modi-  
7 fied in vitro diagnostic product under this  
8 Act.

9 “(B) EXCEPTION.—The term ‘laboratory-  
10 developed test’ does not include—

11 “(i) the processing of a biological  
12 specimen to—

13 “(I) determine paternity;

14 “(II) aid in forensics; or

15 “(III) conduct research if the re-  
16 sult of the test is not reported to a  
17 health care provider, a patient, or a  
18 consumer;

19 “(ii) an in vitro diagnostic product; or

20 “(iii) an analyte specific reagent, as  
21 defined in section 864.4020 of title 21,  
22 Code of Federal Regulations (or successor  
23 regulation).

24 “(7) MANUFACTURER.—The term ‘manufac-  
25 turer’, with respect to a laboratory-developed test,

1 means the laboratory that performs the test to proc-  
2 ess a biological specimen.

3 “(8) PRESCRIPTION TEST.—The term ‘prescrip-  
4 tion test’ means a laboratory-developed test that is  
5 used to process a biological specimen only upon the  
6 written or oral authorization, based on a practi-  
7 tioner-patient relationship that is valid under appli-  
8 cable Federal and State laws, of a practitioner li-  
9 censed by law to administer or use such test.

10 “(9) TYPE.—A laboratory-developed test shall  
11 be considered of the same ‘type’ as an in vitro diag-  
12 nostic product if the test and the product—

13 “(A) use similar analytical methods;

14 “(B) measure the same, or clinically com-  
15 parable, properties or characteristics; and

16 “(C) have the same intended use.”.

17 (2) APPLICATION OF DEFINITIONS.—Any term  
18 that is used in this Act that is defined in subsection  
19 (rr) of such section 201 (as added by paragraph (1))  
20 shall, for purposes of this Act, have the meaning  
21 given such term in such subsection (rr).

22 (b) IMPLEMENTATION.—A laboratory-developed test  
23 that is a direct-to-consumer test on the date of enactment  
24 of this Act shall be deemed to be a prescription test if,  
25 on the date that is 60 days after the date of enactment

1 of this Act and thereafter, such test satisfies the require-  
 2 ments of this Act to be a prescription test.

3 **SEC. 3. LABORATORY-DEVELOPED TESTS DEEMED MED-**  
 4 **ICAL DEVICES.**

5 Section 520 of the FFDCA (21 U.S.C. 360j) is  
 6 amended by adding at the end the following:

7 “(o) LABORATORY-DEVELOPED TESTS.—Any labora-  
 8 tory-developed test shall be deemed to be a device under  
 9 section 201(h).”.

10 **SEC. 4. REPORTING ON AND PUBLIC DISCLOSURE ABOUT**  
 11 **LABORATORY-DEVELOPED TESTS.**

12 (a) LABELING OF INTENDED USE AND REGULATORY  
 13 STATUS OF LABORATORY-DEVELOPED TESTS AND TEST  
 14 RESULTS.—

15 (1) IN GENERAL.—Section 520(o) of the  
 16 FFDCA, as added by section 3, is amended by—

17 (A) striking “TESTS.—Any” and inserting  
 18 the following: “TESTS.—

19 “(1) IN GENERAL.—Any”; and

20 (B) adding at the end the following:

21 “(2) TEST RESULTS; LABELING.—

22 “(A) IN GENERAL.—Any statement by the  
 23 manufacturer of the result of a laboratory-de-  
 24 veloped test reported to a health care practi-  
 25 tioner, a patient, or a consumer, and any label-

1           ing for the test, shall prominently and conspicu-  
2           ously include—

3                   “(i) the intended use of the test; and

4                   “(ii) if the test has not been cleared  
5                   or approved under this Act for such in-  
6                   tended use, a statement that the test has  
7                   not been cleared or approved under this  
8                   Act for such intended use.

9                   “(B) EFFECT.—The statement required  
10                  under subparagraph (A) shall not include a  
11                  statement that the test is investigational or not  
12                  lawfully marketed.”.

13                  (2) IMPLEMENTATION.—The requirements of  
14                  paragraph (2) of such section 520(o) shall take ef-  
15                  fect on the date that is 60 days after the date of en-  
16                  actment of this Act.

17                  (b) REGISTRATION OF MANUFACTURERS AND LIST-  
18                  ING OF LABORATORY-DEVELOPED TESTS.—The require-  
19                  ments of section 510 of the FFDCA (21 U.S.C. 360) with  
20                  respect to the registration of the manufacturer of a labora-  
21                  tory-developed test and the listing of a laboratory-devel-  
22                  oped test shall take effect on the date that is 270 days  
23                  after the date of enactment of this Act.

24                  (c) ADVERSE EVENT REPORTING FOR LABORATORY-  
25                  DEVELOPED TESTS.—The requirements of section 519 of

1 the FFDCA (21 U.S.C. 360i) with respect to records and  
2 reports on a laboratory-developed test shall take effect on  
3 the date that is 1 year after the date of enactment of this  
4 Act.

5 (d) PUBLIC DATABASE OF INFORMATION ON VALID-  
6 ITY OF LABORATORY-DEVELOPED TESTS.—

7 (1) IN GENERAL.—Section 520(o) of the  
8 FFDCA, as amended by subsection (a), is amended  
9 by adding at the end the following:

10 “(3) DATABASE ON INFORMATION OF ANALYT-  
11 ICAL AND CLINICAL VALIDITY.—

12 “(A) IN GENERAL.—

13 “(i) SUBMISSION.—Unless a labora-  
14 tory-developed test is cleared under section  
15 510(k) or approved under section 515 or  
16 520(m) for its intended use, the manufac-  
17 turer of the test shall electronically submit  
18 to the Secretary information (in a form  
19 specified by the Secretary and certified as  
20 truthful and accurate) on the analytical  
21 and clinical validity of the test for its in-  
22 tended use.

23 “(ii) ANALYTIC INTENDED USE.—If  
24 the intended use of a laboratory-developed  
25 test is limited solely to the measurement of

1 an analytical property or characteristic, the  
2 manufacturer of the test shall not submit  
3 any information with respect to the clinical  
4 validity of the test under clause (i) other  
5 than the following statement: ‘This test is  
6 intended to measure only the property or  
7 characteristic that is reported as a result  
8 of use of the test. The test is not intended  
9 to be used to diagnose or screen for any  
10 disease or condition, or to otherwise aid in  
11 decision-making with respect to health, and  
12 this laboratory makes no representations  
13 as to its usefulness for any such purpose.’.

14 “(B) INCLUSION.—The Secretary shall  
15 provide for the automated inclusion of the in-  
16 formation submitted under subparagraph (A) in  
17 a database of such information on all labora-  
18 tory-developed tests that shall be available to,  
19 and searchable by, the public on the Internet  
20 website of the Food and Drug Administration.

21 “(C) NOTICE.—The Secretary may give  
22 written notice to the manufacturer of a labora-  
23 tory-developed test that—

1 “(i) the information submitted by the  
2 manufacturer for such test under subpara-  
3 graph (A)—

4 “(I) does not adequately dem-  
5 onstrate the analytical validity of the  
6 test for its intended use;

7 “(II) does not adequately sum-  
8 marize the peer-reviewed biomedical  
9 literature about the clinical validity of  
10 the test for its intended use;

11 “(III) relies on, or includes, in-  
12 formation or data on the clinical valid-  
13 ity of the test for its intended use that  
14 has not been published in a peer-re-  
15 viewed biomedical journal;

16 “(IV) does not adequately dem-  
17 onstrate the clinical validity of the  
18 test for its intended use; or

19 “(V) does not demonstrate that  
20 the analytical validity or the clinical  
21 validity of such test for its intended  
22 use is comparable to the analytical va-  
23 lidity or the clinical validity, as the  
24 case may be, of an in vitro diagnostic  
25 product of the same type that has

1           been cleared under section 510(k) or  
2           approved under section 515 or section  
3           520(m); and

4           “(ii) information about an intended  
5           use that is not limited solely to the meas-  
6           urement of an analytical property or char-  
7           acteristic, as provided for in the statement  
8           described under subparagraph (A)(ii), has  
9           been included—

10                   “(I) with a result of the test re-  
11                   ported by the manufacturer to a  
12                   health care practitioner, a patient, or  
13                   a consumer; or

14                   “(II) in labeling for the test.

15           “(D) SECOND NOTICE.—The Secretary  
16           shall provide to the manufacturer of a labora-  
17           tory-developed test that has received a notice  
18           under subparagraph (C) a second notice if—

19                   “(i) the manufacturer has submitted  
20                   corrected information under subparagraph  
21                   (A) for such test within 90 days of having  
22                   received a notice under subparagraph (C);  
23                   and

1                   “(ii)(I) 1 or more of subclauses (I)  
2                   through (V) of subparagraph (C)(i) applies  
3                   to such corrected information; or

4                   “(II) the manufacturer has failed to  
5                   include in such corrected information nec-  
6                   essary information about the intended use  
7                   referred to in subparagraph (C)(ii).”.

8                   (2) IMPLEMENTATION.—

9                   (A) ELECTRONIC SUBMISSION.—Not later  
10                  than 1 year after the date of enactment of this  
11                  Act, the Secretary of Health and Human Serv-  
12                  ices (referred to in this Act as the “Secretary”)  
13                  shall develop a portal on the Internet website of  
14                  the Food and Drug Administration through  
15                  which the information required by paragraph  
16                  (3) of such section 520(o), as added by this  
17                  subsection, shall be submitted to the Secretary.

18                  (B) ELECTRONIC CERTIFICATION.—The  
19                  Secretary shall require as a condition of submit-  
20                  ting the information required by paragraph (3)  
21                  of such section 520(o) that an individual sub-  
22                  mitting such information certify electronically  
23                  the truthfulness and accuracy of such informa-  
24                  tion.

1           (C) PUBLICLY ACCESSIBLE DATABASE OF  
2 INFORMATION.—Not later than 1 year after the  
3 date of enactment of this Act, the Secretary  
4 shall develop a database of the information sub-  
5 mitted under paragraph (3) of such section  
6 520(o) that shall be available to, and searchable  
7 by, the public on the Internet website of the  
8 Food and Drug Administration and to which  
9 such information shall be automatically in-  
10 cluded upon submission.

11           (D) LITERATURE REVIEWS AND CLINICAL  
12 VALIDITY.—Not later than 270 days after the  
13 date of enactment of this Act, the Secretary  
14 shall issue a guidance document to facilitate the  
15 use of reviews of the peer-reviewed biomedical  
16 literature and other information and data about  
17 the clinical validity of laboratory-developed tests  
18 and in vitro diagnostic products when clearing  
19 or approving such tests and products under the  
20 FFDCFA.

21           (E) MODIFICATIONS.—Not later than 18  
22 months after the date of enactment of this Act,  
23 the Secretary shall issue a guidance document  
24 to clarify when modifications to a laboratory-de-  
25 veloped test require updating of the information

1 submitted under paragraph (3) of such section  
2 520(o). To the extent practicable, under such  
3 guidance, modifications to a laboratory-devel-  
4 oped test under such paragraph (3) shall be re-  
5 quired under the same circumstances as the  
6 submission of a report under section 510(k) of  
7 the FFDCA (21 U.S.C. 360(k)) or a supple-  
8 mental premarket application under section 515  
9 of the FFDCA (21 U.S.C. 360e) is required for  
10 modifications to a laboratory-developed test or  
11 an in vitro diagnostic product that is cleared or  
12 approved under the FFDCA.

13 (F) SUBMISSION OF INFORMATION.—The  
14 requirements of paragraph (3) of such section  
15 520(o) shall take effect on the date that is 18  
16 months after the date of enactment of this Act.

17 **SEC. 5. CLASSIFICATION AND FDA REVIEW OF LABORA-**  
18 **TORY-DEVELOPED TESTS.**

19 (a) CLASSIFICATION OF LABORATORY-DEVELOPED  
20 TESTS.—

21 (1) IN GENERAL.—Section 520(o) of the  
22 FFDCA, as amended by section 4, is amended by  
23 adding at the end the following:

24 “(4) CLASSIFICATION.—

1           “(A) IN GENERAL.—Notwithstanding sec-  
2           tion 513(f)(1), a laboratory-developed test shall  
3           be classified in class II, as defined in section  
4           513(a)(1)(B), subject to both general and spe-  
5           cial controls.

6           “(B) CLASS III.—Notwithstanding sub-  
7           paragraph (A), a laboratory-developed test shall  
8           be classified in class III if—

9                   “(i) the Secretary gives notice to the  
10                  manufacturer of such test that such test  
11                  meets the requirements of section  
12                  513(a)(1)(C) to be in class III;

13                  “(ii)(I) such test is intended for use in  
14                  the diagnosis of a contagious disease or  
15                  condition that is highly likely to result in  
16                  a fatal outcome; and

17                  “(II) prompt, accurate diagnosis of  
18                  the disease or condition offers the oppor-  
19                  tunity to mitigate the public health impact  
20                  of the disease or condition; or

21                  “(iii) such test is intended for use in  
22                  donor screening of a disease or condition  
23                  for which the Secretary has recommended  
24                  or required testing to—

25                           “(I) safeguard the blood supply;

1                   “(II) establish the safe use of  
2                   blood and blood products; or

3                   “(III) establish the safe use of  
4                   tissue and tissue products.

5                   “(C) CLASS I.—Notwithstanding subpara-  
6                   graph (A), the Secretary may classify a labora-  
7                   tory-developed test in class I if such test meets  
8                   the requirements of section 513(a)(1)(A) to be  
9                   in class I.”.

10                  (2) IMPLEMENTATION.—

11                  (A) CLASS III.—The Secretary may not  
12                  give notice under paragraph (4)(B)(i) of such  
13                  section 520(o) to the manufacturer of a labora-  
14                  tory-developed test that is not a direct-to-con-  
15                  sumer test before the date that is 2 years after  
16                  the date of enactment of this Act.

17                  (B) CLASS I.—The Secretary may not clas-  
18                  sify a type of laboratory-developed test in class  
19                  I under paragraph (4)(C) of such section  
20                  520(o) before the date that is 18 months after  
21                  the date of enactment of this Act.

22                  (C) SPECIAL CONTROLS.—Not later than 2  
23                  years after the date of enactment of this Act,  
24                  the Secretary shall identify in guidance docu-  
25                  ments whether there are special controls to

1           which all laboratory-developed tests, subcat-  
2           egories of such tests, or specific such tests shall  
3           be subject under section 514 of the FFDCA  
4           (21 U.S.C. 360d).

5           (b) CLEARANCE AND APPROVAL OF LABORATORY-  
6 DEVELOPED TESTS.—

7           (1) IN GENERAL.—Section 520(o) of the  
8           FFDCA, as amended by subsection (a), is amended  
9           by adding at the end the following:

10           “(5) APPLICATION OF SECTION 510(k), SEC-  
11           TION 515, OR SECTION 520(m).—A laboratory-devel-  
12           oped test shall be exempt from the requirements of  
13           section 510(k), section 515, and section 520(m), ex-  
14           cept that the manufacturer of a laboratory-developed  
15           test shall submit—

16           “(A) a report under section 510(k) if—

17           “(i) the test is classified in class II;

18           and

19           “(ii) the test is—

20           “(I) a direct-to-consumer test;

21           “(II) a test for which the manu-  
22           facturer has not submitted corrected  
23           information under paragraph (3)(A)  
24           within 90 days of having received a  
25           notice under paragraph (3)(C); or

1                   “(III) a test for which the Sec-  
2                   retary has given second notice under  
3                   paragraph (3)(D) to the manufacturer  
4                   of such test; or

5                   “(B) an application under section 515 or  
6                   section 520(m), as appropriate, if such test is  
7                   classified in class III.”.

8                   (2) IMPLEMENTATION.—

9                   (A) DIRECT-TO-CONSUMER TESTS.—The  
10                  requirement to submit a report under section  
11                  510(k) of the FFDCA (21 U.S.C. 360(k)) or an  
12                  application under section 515 or section 520(m)  
13                  of the FFDCA (21 U.S.C. 360e or 360j(m)), as  
14                  the case may be, under paragraph (5) of such  
15                  section 520(o), as added by this subsection, for  
16                  a direct-to-consumer test as provided in clause  
17                  (ii) of such paragraph shall take effect on the  
18                  date that is 180 days after the date of enact-  
19                  ment of this Act.

20                  (B) CLASS II PRESCRIPTION TESTS.—The  
21                  requirement to submit a report under such sec-  
22                  tion 510(k) under paragraph (5) of such section  
23                  520(o) for a class II prescription device shall  
24                  take effect on the date that is 90 days after the  
25                  date of the notice to the manufacturer of such

1 test referred to in subclause (II) or (III) of  
2 paragraph (5)(A)(ii) of such section 520(o).

3 (C) CLASS III PRESCRIPTION TESTS.—The  
4 requirement to submit an application under  
5 such section 515 or such section 520(m) under  
6 paragraph (5) of such section 520(o) for a class  
7 III prescription device shall take effect on the  
8 date that is—

9 (i) 1 year after the date on which the  
10 Secretary gives notice to the manufacturer  
11 of such test that such test is classified in  
12 class III as provided under paragraph  
13 (4)(B)(i) of such section 520(o); or

14 (ii) 1 year after the date of enactment  
15 of this Act if such test is classified in class  
16 III as provided under clause (ii) or (iii) of  
17 paragraph (4)(B) of such section 520(o).

18 (c) REMOVAL OF LABORATORY-DEVELOPED TESTS  
19 FROM THE MARKET.—Section 520(o) of the FFDCA, as  
20 amended by subsection (b), is amended by adding at the  
21 end the following:

22 “(6) FAILURE TO MAKE SUBMISSION; NON-  
23 CLEARANCE OR DISAPPROVAL.—The manufacturer  
24 of a laboratory-developed test—

1           “(A) may commence and continue to re-  
2           port, or offer to report, a result of such test to  
3           any person until the date that—

4                   “(i)(I) the manufacturer is required to  
5                   submit information under paragraph  
6                   (3)(A); and

7                   “(II) the manufacturer fails to submit  
8                   such information;

9                   “(ii)(I) the manufacturer has received  
10                  a notice under paragraph (3)(C); and

11                  “(II) the manufacturer has failed to  
12                  submit corrected information under para-  
13                  graph (3)(A);

14                  “(iii)(I) the manufacturer is required  
15                  to submit under paragraph (5)—

16                          “(aa) a report with respect to  
17                          such test under section 510(k); or

18                          “(bb) an application under sec-  
19                          tion 515 or 520(m); and

20                  “(II) the manufacturer fails to submit  
21                  such report or application, as the case may  
22                  be;

23                  “(iv) the report with respect to such  
24                  test under section 510(k) is not cleared by  
25                  the Secretary; or

1                   “(v) approval of such application is  
2                   denied by the Secretary; and

3                   “(B) shall immediately cease to report, or  
4                   offer to report, a result of such test to any per-  
5                   son on such date.”.

6 **SEC. 6. INSPECTION OF LABORATORIES; EXEMPTION FROM**  
7                   **REQUIREMENT FOR FDA TO INSPECT EVERY**  
8                   **2 YEARS.**

9                   Section 520(o) of the FFDCA, as amended by section  
10 4, is amended by adding at the end the following:

11                   “(7) INSPECTION.—The requirement of section  
12                   510(h) with respect to the inspection of a registered  
13                   establishment at least once in every 2-year period  
14                   shall not apply to a manufacturer of a laboratory-  
15                   developed test that is classified in class II, unless  
16                   section 510(h) applies to such establishment because  
17                   of a drug or another device classified in class II or  
18                   III.”.

19 **SEC. 7. THE CLINICAL LABORATORY IMPROVEMENT**  
20                   **AMENDMENTS OF 1988.**

21                   (a) COMPLIANCE WITH THIS ACT.—Compliance with  
22 the requirements under this Act shall have no effect on  
23 the obligation to comply with any requirement under sec-  
24 tion 353 of the Public Health Service Act (42 U.S.C.  
25 263a).

1 (b) COMPLIANCE WITH CLIA OF 1988.—Except as  
2 provided in subsection (c), compliance with the require-  
3 ments under section 353 of the Public Health Service Act  
4 (42 U.S.C. 263a) shall have no effect on the obligation  
5 to comply with any requirement of this Act.

6 (c) GOOD MANUFACTURING PRACTICE REQUIRE-  
7 MENTS AND CLIA OF 1988.—For a laboratory-developed  
8 test, compliance with the requirements under section 353  
9 of the Public Health Service Act (42 U.S.C. 263a) shall  
10 be deemed to satisfy the requirements under section  
11 520(f) of the FFDCA (21 U.S.C. 360j(f)) unless and  
12 until, after providing for public comment, the Secretary  
13 issues a final guidance document—

14 (1) in which the Secretary finds that—

15 (A) compliance with the requirements  
16 under such section 353 does not satisfy the re-  
17 quirements under such section 520(f); and

18 (B) compliance with the requirements of  
19 such section 520(f) are necessary to protect the  
20 public health;

21 (2) explaining the least burdensome approach  
22 for manufacturers of laboratory-developed tests to  
23 comply with the requirements of such section 520(f);  
24 and

1           (3) providing for coordination of inspection ef-  
2           forts to ensure compliance with such section 353  
3           and such section 520(f).

4           (d) RULEMAKING BY SECRETARY.—

5           (1) PROPOSED RULE.—Not later than 1 year  
6           after the date of enactment of this Act, the Sec-  
7           retary shall issue a proposed rule to establish a spe-  
8           cialty area under section 353 of the Public Health  
9           Service Act (42 U.S.C. 263a) for laboratory-devel-  
10          oped tests to acquire genetic information, including  
11          mutations, genotypes, gene expression, and chromo-  
12          somal structure.

13          (2) FINAL RULE.—

14           (A) IN GENERAL.—The Secretary shall  
15           issue a final rule not later than the date that  
16           is 3 years after the date of enactment of this  
17           Act, which shall be effective 1 year after the  
18           date such rule is issued.

19           (B) CONTENT.—Such final rule shall in-  
20           clude standards for proficiency testing of such  
21           laboratory-developed tests, as provided under  
22           section 353 of the Public Health Service Act  
23           (42 U.S.C. 263a).

24          (3) EFFECT OF FAILURE TO ISSUE FINAL  
25          RULE.—If the Secretary fails to issue the final rule

1 on or before the date that is 3 years after the date  
2 of enactment of this Act, such laboratory-developed  
3 tests shall be subject to the requirements of such  
4 section 520(f) after such date and until such final  
5 rule becomes effective.

6 **SEC. 8. ENHANCED REIMBURSEMENT UNDER FEDERAL**  
7 **HEALTH PROGRAMS.**

8 The Secretary shall develop a mechanism to provide  
9 enhanced reimbursement under Federal health programs  
10 for in vitro diagnostic products and laboratory-developed  
11 tests that are cleared under section 510(k) of the FFDCA  
12 (21 U.S.C. 360(k)), or approved under section 515 or  
13 520(m) of such Act (21 U.S.C. 360e or 21 U.S.C. 360j).

14 **SEC. 9. AUTHORIZATION OF APPROPRIATIONS.**

15 There are authorized to be appropriated such sums  
16 as may be necessary for each of fiscal years 2007 through  
17 2010 to carry out this Act.

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