I

112TH CONGRESS
1ST SESSION

H. R. 3207

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

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 14, 2011

Mr. BURGESS (for himself, Mr. PAULSEN, Mr. LATTA, and Mrs. BLACKBURN) introduced the following bill; which was referred to the Committee on Energy and Commerce

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Modernizing Laboratory Test Standards for Patients Act of 2011''.

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

SEC. 2. NOTIFICATION FOR LABORATORY-DEVELOPED TESTS.

Section 353 of the Public Health Service Act (42 U.S.C. 263a) is amended by adding at the end the following:

"SEC. 353A. LABORATORY-DEVELOPED TESTS AND DIRECT-TO-CONSUMER DNA TESTS.

''(a) DEFINITIONS.—In this section:

''(1) The term 'analytical validity' means the ability of a test to identify or measure the analyte or substance sought to be identified or measured.

''(2) The term 'biological product' has the meaning given to such term in section 351.

''(3) The term 'clinical validity' means the consistency and accuracy with which a test identifies, measures, or predicts—

''(A) a disease or condition in humans; or

''(B) characteristics related to an individual's clinical status (including phenotype).

''(4) The term 'direct-to-consumer DNA test' or 'DTC DNA test' means a test that—

''(A) is intended to identify, analyze, or interpret an individual's genetic characteristics for purposes of predicting, assessing the risk of,

preventing, or mitigating any disease or condition, including the prognosis or outcome of a treatment in an individual; and

"(B) is offered directly to, is ordered directly by, and whose results are reported directly to, an individual consumer, without a test request by a physician or other health care provider who has an established provider-patient relationship with the individual consumer by which the physician or provider provides health care services (other than the test in question) to that individual.

"(5) The term 'drug' has the meaning given to such term in section 201 of the Federal Food, Drug, and Cosmetic Act.

"(6) The terms 'laboratory' and 'clinical laboratory' have the meanings given to such terms in section 353.

"(7) The term 'laboratory-developed test' or 'LDT' means a clinical laboratory test that is—

"(A) developed by a clinical laboratory certified under section 353;

"(B) performed by—

"(i) the clinical laboratory;

"(ii) any entity that is owned or controlled by the clinical laboratory;

"(iii) any entity that owns or controls the clinical laboratory (in this subparagraph referred to as the clinical laboratory's 'parent corporation'); or

"(iv) an entity that is owned or controlled by the clinical laboratory's parent corporation; and

"(C)(i) performed solely to furnish clinical laboratory testing services for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and

"(ii) not otherwise introduced into interstate commerce.

"(8) The term 'test-offering entity' means an entity, other than a laboratory certified under section 353, which offers or markets direct-to-consumer DNA tests based on testing performed by one or more such laboratories that are not owned by the entity.

''(9) The term 'test registry data bank' means the test registry data bank established under subsection (b).

''(b) TEST REGISTRY DATA BANK.—

''(1) ESTABLISHMENT.—Not later than one year after the date of the enactment of this Act, the Secretary, in consultation with the Director of the National Institutes of Health, shall establish a single, publicly accessible test registry data bank.

''(2) PROCESS FOR SUBMISSION.—

''(A) REQUIREMENT.—Each laboratory and each test-offering entity that offers or markets an LDT or DTC DNA test shall submit information on such LDT or DTC DNA test to the Secretary for inclusion in the test registry data bank.

''(B) TIMING.—The submission required by subparagraph (A) shall occur—

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

''(I) the date that is 10 days after the date on which the laboratory

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

"(II) the date that is 3 months after the effective date of the regulations for carrying out this section; or

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

"(C) SUPPLEMENTAL SUBMISSIONS.—

"(i) IN GENERAL.—With respect to a LDT or DTC DNA test offered or marketed by a laboratory or test-offering entity, such laboratory or test-offering entity shall supplement or amend information on such test in the test registry data bank as necessary to ensure that the information is accurate and current.

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

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

''(3) CONTENT OF SUBMISSIONS.—

''(A) LDT OR DTC DNA TEST INFORMATION.—With respect to an LDT or DTC DNA test, the Secretary shall require the information submitted under paragraph (2) to consist of each of the following:

''(i) The location of the laboratory.

''(ii) The certification and licensure information of the laboratory.

''(iii) The purpose of the test.

''(iv) The claimed use or uses of the test.

''(v) A description of the test methodology.

''(vi) Information regarding the analytical validity of the test.

"(vii) Information regarding the clinical validity of the test for each of its claimed uses.

"(viii) Information describing the status of the test as an existing test (as described under paragraph (4)), a new test pending review (under subsection (c)), or an authorized new test (under subsection (c)(4)(B)).

"(B) DTC DNA TEST INFORMATION.—With respect to a DTC DNA test, the Secretary shall require the information submitted under paragraph (2) to consist of the information required by subparagraph (A) and in addition each of the following:

"(i) The identity, location, and registration information of the test-offering entity.

"(ii) The identity of the certified laboratory that will perform the test, and the certification and licensure information for such laboratory.

"(iii) Information to demonstrate that the consumer will be provided with access

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

''(4) REVIEW OF INFORMATION FOR EXISTING TESTS.—If, upon review of the information submitted under paragraph (2) for an LDT or DTC DNA test that is offered or marketed on or before the date of the enactment of this section, the Secretary determines that there is reasonable cause to believe that there is inadequate information for a determination of clinical validity (as described in subsection (c)(4)(B)) of one or more claimed uses of the LDT or DTC DNA test, the Secretary may require that the laboratory or test-offering entity submit notification under subsection (c) for each such claimed use.

''(c) NOTIFICATION PROCESS.—

''(1) APPLICABILITY.—

''(A) IN GENERAL.—This subsection applies to an LDT or DTC DNA test only if—

''(i) the test is first offered or marketed by the laboratory or the test-offering entity after the date of the enactment of this section;

''(ii) the test is offered on or before the date of the enactment of this section

and, after such date, is significantly modified; or

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

"(B) SIGNIFICANT MODIFICATION.—For purposes of subparagraph (A)(ii) and paragraph (2)(B), a significant modification means—

"(i) offering or marketing the test for a new claimed use;

"(ii) any significant change to the fundamental testing methodology; and

"(iii) any change that significantly affects the clinical validity of the test.

"(2) NOTIFICATION SUBMISSION.—

"(A) PREMARKET NOTIFICATION.—Before marketing an LDT or DTC DNA test, a laboratory or test-offering entity shall submit a premarket notification to the Secretary.

"(B) SUPPLEMENTAL NOTIFICATION FOR SIGNIFICANT MODIFICATIONS.—After any sig-

nificant modification (as described in paragraph (1)(B)) to an LDT or DTC DNA test for which a premarket notification under subparagraph (A) has been submitted or for which no such premarket notification was required, the laboratory or test-offering entity shall submit a supplemental notification for the LDT or DTC DNA test.

"(C) SUPPLEMENTAL NOTIFICATION IN CASE OF INADEQUATE EVIDENCE.—If a laboratory or test-offering entity determines, at any time, that the evidence of clinical validity is inadequate to support one or more of the claimed uses in a notification under subparagraph (A) or (B), then not later than 30 calendar days after making such determination the laboratory or test-offering entity shall—

"(i) submit a supplemental notification containing additional information supporting the clinical validity of the claimed uses; or

"(ii) submit a supplemental notification withdrawing one or more claimed uses.

''(D) CONCURRENT SUBMISSION FOR TEST REGISTRY DATA BANK.—Subject to the deadlines and other requirements of subsection (b), a laboratory or test-offering entity may submit information for inclusion in the test registry data bank under subsection (b) concurrently with a notification under this paragraph.

''(E) ACKNOWLEDGMENT OF RECEIPT.—Upon receipt of a notification under this paragraph, the Secretary shall send written notice to the submitter—

''(i) acknowledging receipt of the notification; and

''(ii) indicating the date on which the Secretary received the notification.

''(3) CONTENT OF NOTIFICATIONS.—

''(A) LDT NOTIFICATIONS.—With respect to a premarket or supplemental notification for an LDT under paragraph (2)(A) or (2)(B), the Secretary shall require the notification to consist of each of the types of information listed in clauses (i) through (vii) of subsection (b)(3)(A).

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

graph (2)(A) or (2)(B), the Secretary shall require the notification to consist of each of the following:

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

"(ii) If informed consent for the performance of the test is required by State or Federal law, a copy of the standard informed consent document to be signed by the individual to signify such consent.

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

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

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

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

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

''(D) TESTS PREVIOUSLY CLEARED OR APPROVED BY FDA.—Notwithstanding the clearance or approval of an LDT or DTC DNA test under the Federal, Food, Drug, and Cosmetic Act before the date of the enactment of this Act, any review by the Department of Health and Human Services of the LDT or DTC DNA test (or any modification thereto) that occurs on or after such date shall be conducted exclusively under this section and not under the Federal Food, Drug, and Cosmetic Act.

''(4) REVIEW AND AUTHORIZATION OF NOTIFICATIONS.—

''(A) IN GENERAL.—Not later than 90 calendar days after the date on which the Secretary receives a notification under paragraph (2)(A), (2)(B), or (2)(C)(i), the Secretary shall, with respect to each claimed use of a test, review the notification, make a determination as to whether the notification under paragraph (2) demonstrates clinical validity, and—

''(i) issue an authorization letter in accordance with subparagraph (B); or

"(ii) provide notice under subparagraph (C)(i) that the submitted information is not adequate to demonstrate clinical validity.

"(B) AUTHORIZATION LETTERS; DETERMINATION OF CLINICAL VALIDITY.—

"(i) ISSUANCE OF AUTHORIZATION LETTERS.—If the Secretary determines, with respect to one or more claimed uses of a test, that a notification under paragraph (2) demonstrates clinical validity, the Secretary shall issue an authorization letter for such claimed uses to the submitter of the notification.

"(ii) STANDARD FOR ISSUANCE.—The Secretary shall issue such an authorization letter if the notification provides reasonable assurance of the clinical validity of such claimed uses. One or more studies published in a peer-reviewed journal that is generally recognized to be of national scope and reputation, or data from unpublished studies conducted by the submitter or for which the submitter has obtained a right of reference, shall be sufficient to con-

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

"(iii) PROHIBITION.—The Secretary shall not require a laboratory or test-offering entity to include (for purposes of demonstrating clinical validity) evidence of—

"(I) clinical utility; or

"(II) the ability of a physician, provider, or consumer to interpret a test result or to apply a test result to achieve a particular health or clinical outcome.

"(iv) PARTIAL DEMONSTRATION OF CLINICAL VALIDITY.—If a notification under paragraph (2) demonstrates clinical validity for some but not all of the claimed uses of a test, the Secretary shall issue an authorization letter under clause (i) with respect to each claimed use for which clinical validity has been demonstrated.

"(C) NOTICE OF INADEQUACY; REPLY; FINAL DETERMINATION.—If the Secretary determines, with respect to one or more claimed uses of a test, that a notification under para-

graph (2) is not adequate to demonstrate clinical validity—

"(i) the Secretary shall notify the submitter about such determination and shall specify in the notice the information which is required to demonstrate clinical validity for each such clinical use;

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

"(iii) not later than 60 calendar days after receipt of a response under clause (ii), the Secretary shall issue a final determination regarding the clinical validity of each clinical use subject to the notice under clause (i).

"(D) OFFERING OR MARKETING TEST PENDING AGENCY ACTION.—

"(i) APPLICABLE TIME PERIOD.—This subparagraph applies, with respect to a claimed use of a test, during the period between—

"(I) submission of a notification under paragraph (2); and

''(II) final action by the Secretary on such notification under subparagraph (A)(i), (C)(iii), or (G), as applicable, or the failure to file a response under clause (ii) of subparagraph (C) within the period specified in such clause.

''(ii) CONTINUED OFFERING OR MARKETING.—During a period described in clause (i) with respect to any claimed use of a test, the laboratory or test-offering entity may continue to offer or market the test with respect to such claimed use as if the Secretary had issued an authorization letter under subparagraph (B) for such claimed use.

''(iii) RELATION TO TEST REGISTRY DATA BANK.—This subparagraph shall not be construed to affect the Secretary's authority under subsection (b).

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

"(E) MARKETING PENDING AUTHORIZATION.—Beginning on the date of submission of a notification under paragraph (2)(A), (2)(B), or (2)(C)(i), the laboratory or test-offering entity may offer or market the test while the notification is pending, provided that the required information about the test has first been submitted to the test registry data bank as required by subsection (b).

"(F) FAILURE BY SECRETARY TO MAKE A DETERMINATION.—The Secretary is deemed to have issued an authorization letter under subparagraph (B) with respect to a claimed use of a test if—

"(i) the 90-day period under subparagraph (A) expires and the Secretary has not, with respect to such claim, issued an authorization letter under subparagraph (B) or provided notice under subparagraph (C)(i); or

"(ii) the 60-day period under subparagraph (C)(iii) expires and the Secretary has not, with respect to such claim, issued a final determination regarding clinical validity.

''(G) RISK OF IMMEDIATE HARM.—

''(i) ORDER.—The Secretary may order a laboratory or test-offering entity to cease offering or marketing a test with respect to one or more claimed uses if the Secretary makes a final determination that—

''(I) the information submitted in notifications under paragraph (2) for such uses does not demonstrate the clinical validity of the claimed uses; and

''(II) the test poses a risk of immediate harm to the public health with respect to such claimed uses.

''(ii) EFFECTIVE UPON RECEIPT.—An order under clause (i) shall be effective immediately upon receipt by the laboratory or test-offering entity.

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

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

"(5) ADMINISTRATIVE APPEAL.—If the Secretary makes a final determination under paragraph (4)(A) or (4)(C)(iii) that clinical validity has not been established, or issues an order under paragraph (4)(G), with respect to one or more clinical uses of a test, the laboratory or test-offering entity may, not later than 30 days after the date of the final determination or issuance of the order, bring an administrative appeal by selecting the procedures set forth in one (and only one) of the following subparagraphs:

"(A) DISPUTE RESOLUTION BY ADVISORY COMMITTEE.—

"(i) IN GENERAL.—The laboratory or test-offering entity may seek dispute resolution by referral to an advisory committee of non-governmental experts who are qualified by training and experience to make a recommendation regarding the clinical validity of the claimed uses of the test.

"(ii) PROCESS.—In the case of an appeal under this subparagraph, the committee shall hold a hearing to consider the

evidence of clinical validity, shall keep a written record of the hearing, and shall provide an opportunity for testimony from experts presented by both the appellant and the Secretary. The committee shall make a recommendation to the Secretary at the conclusion of the hearing. The Secretary shall consider the record and the recommendations of the committee and shall make a decision within 90 calendar days after the conclusion of the hearing.

''(iii) SELECTION OF COMMITTEE MEMBERS.—The members of an advisory committee under this subparagraph shall be selected by the Secretary from among individuals, including physicians, with demonstrated expertise in and experience with the analytical validity and clinical validity of laboratory-developed tests and the literature related to the validity of such tests.

''(B) REVIEW BY ADMINISTRATIVE LAW JUDGE.—The laboratory or test-offering entity may seek review by an administrative law judge pursuant to procedures established by the Secretary.

''(6) FINAL AGENCY ACTION.—

''(A) IN GENERAL.—Subject to judicial review under subsection (h), upon final agency action under paragraphs (4) and (5) determining that clinical validity of one or more claimed uses of a test has not been established or upon issuance of an order under paragraph (4)(G) for one or more claimed uses of a test, the laboratory or test-offering entity shall immediately—

''(i) cease offering the test for such uses; and

''(ii) cease reporting test results to health care providers or individuals for such uses.

''(B) REPORTING FOR CERTAIN SPECIMENS.—For specimens that have been received or tests that have been ordered but results not yet reported, the laboratory or test-offering entity shall notify the person who ordered the test that test results will not be reported because clinical validity for such clinical uses has not been established.

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

claimed use as a companion diagnostic test for purposes of specifying the use of a drug or biological product for therapeutic purposes. An LDT for use as a companion diagnostic test shall be reviewed exclusively pursuant to the requirements of this section and not under the Federal Food, Drug, and Cosmetic Act.

''(d) REGISTRATION BY TEST-OFFERING ENTITIES.—

''(1) REGISTRATION REQUIREMENT.—A test-offering entity may not offer or market a DTC DNA test unless the entity registers with the Secretary in accordance with this subsection and maintains such registration in effect.

''(2) TIMING.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), registration by a test-offering entity under this subsection shall occur before—

''(i) the entity offers or markets a DTC DNA test; or

''(ii) submits a premarket notification under subsection (c)(2)(A).

''(B) EXCEPTIONS.—

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

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

''(3) INAPPLICABILITY TO CERTIFIED LABORATORIES.—If a certified laboratory offers a DTC DNA test that is not offered or marketed by a test-offering entity, such laboratory—

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

''(B) shall not, because of offering such test, be regulated as a test-offering entity instead of a laboratory under section 353 or this section.

''(4) REGULATIONS.—

"(A) IN GENERAL.—In promulgating regulations under subsection (i)(1), the Secretary shall include regulations governing registration under this subsection.

"(B) INTERIM PROCEDURES.—The Secretary shall establish interim procedures governing registration under this subsection during the period beginning on the date of the enactment of this section and ending on the effective date of the regulations required by subparagraph (A). The Secretary shall establish such interim procedures not later than 90 calendar days after the date of the enactment of this section. The Secretary may establish such interim procedures by a guidance document or other means of public notification.

"(e) INFORMATION REGARDING TEST CAPABILITIES AND LIMITATIONS.—

"(1) INCLUSION OF INFORMATION.—A laboratory or test-offering entity that offers an LDT or a DTC DNA test shall include in its test result reports, directories of services, marketing materials, and advertising—

''(A) truthful, accurate, and nondeceptive information regarding the capabilities and limitations of the tests; and

''(B) a statement that the test has been validated by the laboratory performing the test in accordance with the requirements of the Clinical Laboratory Improvement Amendments (referred to in this section as 'CLIA').

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

''(f) REPORTING.—

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

''(A) the laboratory or entity shall promptly investigate the incident;

''(B) if the laboratory or entity determines that the LDT or DTC DNA test may have caused or contributed to a death or serious bodily injury, within 10 working days of making

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

''(C) the laboratory or entity shall provide such additional information regarding the incident or the test associated with the incident as the Secretary may request.

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

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

''(B) for any incident that was determined under paragraph (1)(B) not to meet the requirements for reporting to the Secretary, the basis for such determination.

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

''(g) SANCTIONS.—

''(1) APPLICABILITY OF SANCTIONS TO CLINICAL LABORATORIES.—

''(A) INTERMEDIATE SANCTIONS.—The reference in section 353(h)(1) to the 'requirements for the issuance of a certificate' is deemed to include the requirements of this section.

''(B) SUSPENSION, REVOCATION, AND LIMITATION OF CERTIFICATE.—

''(i) The reference in section 353(i)(1)(A) to 'misrepresentation in obtaining the certificate' is deemed to include any misrepresentation of information in a submission to the Secretary pursuant to this section.

''(ii) The reference in section 353(i)(1)(F) to 'any provisions of this section' is deemed to include any provisions of this section.

''(2) APPLICABILITY OF SANCTIONS TO TEST-OFFERING ENTITIES.—

''(A) INTERMEDIATE SANCTIONS.—

''(i) IN GENERAL.—If the Secretary determines that a test-offering entity registered under subsection (d) is no longer meeting the requirements of this section, the Secretary may impose intermediate

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

''(ii) TYPES OF SANCTIONS; PROCEDURES.—The provisions of paragraphs (2) and (3) of section 353(h) shall apply with respect to intermediate sanctions against a test-offering entity under clause (i) to the same extent and in the same manner as such provisions apply with respect to intermediate sanctions against a laboratory under section 353(h).

''(B) SUSPENSION, REVOCATION, AND LIMITATION OF REGISTRATION.—The registration of a test-offering entity under subsection (d) may be suspended, revoked, or limited if the Secretary finds, using the procedures applicable under section 353(i)(1) to suspension, revocation, or limitation of a laboratory's certificate, that the owner or operator or any employee of the test-offering entity—

''(i) has misrepresented information in a submission to the Secretary pursuant to this section;

''(ii) has failed to comply with the requirements of this section;

''(iii) has failed to comply with reasonable requests of the Secretary for—

''(I) any information or materials that the Secretary concludes are necessary to determine the test-offering entity's continued compliance with the requirements of this section; or

''(II) work on materials, that the Secretary concludes is necessary to determine the test-offering entity's continued compliance with the requirements of this section;

''(iv) has refused a reasonable request of the Secretary (or, if designated by the Secretary, any Federal officer, government employee, or a nongovernmental organization or an accreditation body designated under subsection (k)) for permission to inspect the test-offering entity and its operations and pertinent records during the hours the test-offering entity is in operation;

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

section or of any regulation promulgated thereunder; or

''(vi) has not complied with an intermediate sanction imposed under subparagraph (A).

''(C) ACTION BEFORE A HEARING.—If the Secretary determines that—

''(i) the failure of a test-offering entity to comply with the requirements of this section presents an imminent and serious risk to human health; or

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

the Secretary may suspend or limit the registration of the laboratory before holding a hearing under subparagraph (B) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this subparagraph shall stay in effect until the decision of the Secretary made after the hearing under subparagraph (B).

''(D) INJUNCTIONS.—If the Secretary has reason to believe the continuation of any activity by a test-offering entity would constitute a significant hazard to the public health, the Secretary may bring suit in any district court of the United States that has jurisdiction over such entity to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subparagraph shall be granted without bond by such court.

''(3) APPLICABILITY OF CRIMINAL SANCTIONS TO ALL PERSONS.—The reference in section 353(l) to 'any requirement of this section' is deemed to include any requirement of this section.

''(4) REPORTING.—In promulgating regulations under subsection (i)(1), the Secretary may include sanctions specific to violations of subsection (f) (regarding reporting), including the following:

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

''(B) Directed plans of correction.

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

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

''(h) JUDICIAL REVIEW.—If a laboratory or test-offering entity is subject to a sanction or other action pursuant to subsection (g) or is adversely affected by final agency action under subsection (c), the laboratory or entity may appeal such sanction or action by filing a petition for judicial review with the United States court of appeals for the circuit where the laboratory or entity has its principal place of business. The provisions of section 353(k) applicable to judicial review of sanctions and actions under section 353 shall apply to judicial review of sanctions and actions under this section.

''(i) REGULATIONS.—

''(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this section, the Secretary shall promulgate final regulations to carry out this section.

''(2) RARE DISEASES AND CONDITIONS.—In carrying out paragraph (1), the Secretary shall include regulations specific to any LDT or DTC DNA test used in connection with a rare disease or condition (as such term is defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act). Such regulations—

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

"(B) shall contain standards of evidence for demonstrating the clinical validity of such test that takes into account special issues relating to studies in small populations;

"(C) shall take into account relevant technical standards and guidelines applicable to testing for such a rare disease and condition; and

"(D) may authorize the Secretary to waive any requirement of this section if the Secretary determines that application of such requirement would unreasonably delay or prevent access to such test.

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

that take into account special issues relating to infectious pathogens and public health threats.

''(4) EXTERNAL QUALITY ASSESSMENT.—In carrying out paragraph (1), the Secretary, in consultation with proficiency testing organizations approved under section 353(f)(C), shall include regulations establishing an external review process to evaluate the analytical validity of LDTs.

''(j) INSPECTIONS.—

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

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

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

''(2) TEST-OFFERING ENTITIES.—The Secretary—

''(A) shall have the same authority to conduct inspections of a test-offering entity for purposes of determining compliance with this section as the Secretary has under paragraph (1) and section 353(g)(1) to conduct inspec-

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

"(B) during an inspection under subparagraph (A), may require a test-offering entity to provide evidence of clinical validity for any claim made for a DTC DNA test offered or marketed by that entity.

"(3) PROPRIETARY OR CONFIDENTIAL INFORMATION.—The Secretary shall establish procedures to protect any proprietary or confidential information concerning an LDT or DTC DNA test that may be disclosed during an inspection under this subsection.

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

"(1) pursuant to agreement, designate a nongovernmental organization that has qualifications and expertise in the evaluation of laboratory testing and in evaluating the analytical and clinical validity of laboratory tests to assist in the review of premarket notifications and test registry data bank information and in the performance of inspections authorized under subsection (j); and

''(2) subject to the provisions of section 353(e), designate an accreditation organization to assist in the review of premarket notifications and test registry data bank information and in the performance of inspections authorized under subsection (j).

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

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

(a) DEVICE DEFINITION.—Section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)) is amended by adding at the end the following: ''The term 'device' does not include a laboratory-developed test or a direct-to-consumer DNA test as defined in section 353A of the Public Health Service Act.''.

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

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

(2) by inserting after paragraph (3) the following:

''(4) clinical laboratories certified under section 353 of the Public Health Service Act insofar as such laboratories—

''(A) use devices to perform laboratory tests; or

''(B) create and perform laboratory-developed tests as defined in section 353A of such Act;''.

SEC. 4. FEES.

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

(1) in paragraph (2), by adding at the end the following sentence: ''In the case of a laboratory or test-offering entity that is required to submit information under section 353A(b)(2)(A), the Secretary shall also require the payment of fees for reviews of premarket notifications and supplemental notifications submitted pursuant to subparagraph (A), (B), or (C) of section 353A(c)(2), registration of test-offering entities under section 353A(d), and inspections conducted pursuant to section 353A(j).'';

(2) in paragraph (3)(B)—

(A) by striking ''inspections and proficiency testing described in paragraph (2)'' and inserting ''inspections and proficiency testing

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

(B) by striking the period at the end and inserting ``, review of premarket notifications and supplemental notifications submitted pursuant to subparagraph (A), (B), or (C) of section 353A(c)(2), registration of test-offering entities under section 353A(d), and inspections conducted pursuant to section 353A(j)''; and

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

``(4) FISCAL REPORT.—By December 31, 2011, and by the end of each calendar year thereafter, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the amount of fees collected during the preceding fiscal year under this subsection and the amount of fees collected under this subsection available to support activities under this section and section 353A. Before increasing the amount of any fee required by this subsection, the Secretary shall include in a report under this paragraph an explanation of the need for such an increase, including the likely reve-

nues and expenses expected to be incurred. The effective date of any such increase shall not be sooner than the date that is 120 days after the submission of the report containing such explanation.''.

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