[PRELIMINARY DISCUSSION DRAFT]

115TH CONGRESS
2D SESSION

H. R. __

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON (for himself and Ms. DEGETTE) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical 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 "Verifying Accurate Leading-edge IVCT Development Act of 2018" or the "VALID Act of 2018".

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

SEC. 2. DEFINITIONS.

(a) IN GENERAL.—Section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

(1) by adding at the end the following:

"(ss)(1) The term 'in vitro clinical test' means—

"(A) a test intended to be used in the collection, preparation, analysis, or in vitro clinical examination of specimens taken or derived from the human body for the purpose of—

"(i) identifying, diagnosing, screening, measuring, detecting, predicting, prognosing, analyzing, or monitoring a disease or condition, including by making a determination of an individual's state of health; or

"(ii) selecting, monitoring, or informing therapy or treatment for a disease or condition;

"(B) a test protocol intended to be used as described in clause (A);

"(C) a test platform (as defined in section 587) for use in or with a test described in clause (A);

"(D) an article for taking or deriving specimens from the human body for a purpose described in clause (A);

"(E) software for a purpose described in clause (A), excluding software that is excluded by section 520(o) from the definition of a device under section 201(h); or

"(F) subject to subparagraph (2), a component or part of a test, a test protocol, a test platform, an article, or software described in any of clause (A) through (E), whether alone or in combination, including reagents, calibrators, and controls.

"(2) Notwithstanding subparagraph (1)(F), an article intended to be used as a component or part of an in vitro clinical test described in subparagraph (1) is excluded from the definition in subparagraph (1) if the article consists of any of the following:

"(A) Blood, blood components, or human cells or tissues, from the time of donation or recovery of such article, including determination of donor eligibility, as applicable, until such time as the article is released into interstate commerce as a component or part of an in vitro clinical test by the establishment that collected such article.

"(B) An article used for invasive sampling.

"(C) General purpose laboratory equipment.

"(D) An article used solely for personal protection during the administering, conducting, or otherwise performing test activities.";

(2) by adding at the end of section 201(g) the following:

"(3) The term 'drug' does not include an in vitro clinical test."; and

(3) in section 201(h), by striking "section 520(o)" and inserting "section 520(o) or an in vitro clinical test".

(b) EXCLUSION FROM DEFINITION OF BIOLOGICAL PRODUCT.—Section 351(i)(1) of the Public Health Service Act (42 U.S.C. 262(i)(1)) is amended—

(1) by striking "(1) The term 'biological product' means" and inserting "(1)(A) The term 'biological product' means"; and

(2) by adding at the end the following:

"(B) The term 'biological product' does not include an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act.".

SEC. 3. REGULATION OF IN VITRO CLINICAL TESTS.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) by amending the heading of chapter V to read as follows: "**DRUGS, DEVICES, AND IN VITRO CLINICAL TESTS**"; and

(2) by adding at the end of chapter V the following:

"subchapter J—In Vitro Clinical Tests

"SEC. 587. DEFINITIONS.

"In this subchapter:

"(1) ANALYTICAL VALIDITY.—

"(A) The term 'analytical validity' means, with respect to an in vitro clinical test, the ability of the in vitro clinical test, to—

"(i) identify, measure, detect, calculate, or analyze one or more analytes, biomarkers, substances, or other targets intended to be identified, measured, detected, calculated, or analyzed by the test; or

"(ii) as applicable, assist in such identification, measurement, detection, calculation, or analysis.

"(B) For an article for taking or deriving specimens from the human body described in section 201(ss)(1)(DD), the term 'analytical validity' means that such article performs as intended and will support the analytical validity of an in vitro clinical test with which it is used.

"(2) CLINICAL USE.—The term 'clinical use' means the operation, application, or functioning of an in vitro clinical test in connection with human specimens, including patient, consumer, and donor specimens, for the purpose for which it is intended as described in section 201(ss)(1)(A).

"(3) CLINICAL VALIDITY.—The term 'clinical validity' means the ability of an in vitro clinical test to achieve the purpose for which it is intended as described in section 201(ss)(1)(A).

"(4) COMPREHENSIVE TEST INFORMATION SYSTEM.—The term 'comprehensive test information system' means an online database that the Secretary may use to store and provide information about in vitro clinical tests to developers and the general public, as described in section 587U.

"(5) CROSS-REFERENCED TEST.— The term 'cross-referenced test' means an in vitro clinical test that—

"(A) references in its labeling the trade name or intended use of another medical product that is not an in vitro clinical test; or

"(B) is referenced by trade name or intended use in the labeling of another medical product that is not an in vitro clinical test.

"(6) DEVELOPER.—The term 'developer' means a person who—

"(A) develops an in vitro clinical test, including by designing, validating, producing, manufacturing, remanufacturing, propagating, or assembling the kit of an in vitro clinical test;

"(B) imports an in vitro clinical test; or

"(C) modifies an in vitro clinical test initially developed by a different person in a manner that—

"(i) changes any of the notification elements specified in paragraph (11) that define a test group, performance claims, or, as applicable, the safety of such in vitro clinical test; or

"(ii) adversely affects the performance of the in vitro clinical test.

"(7) HIGH-RISK.—

"(A) Subject to subparagraph (B), the term 'high-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that an undetected inaccurate result from such test or category—

"(i) when used as intended, would likely cause serious or irreversible harm or death to a patient or patients, or would otherwise cause serious harm to the public health; and

"(ii) would pose a likelihood of adverse patient impact or adverse public health impact caused by such an inaccurate result that is not remote.

"(B) Such term does not include an in vitro clinical test if mitigating measures are established and applied to sufficiently

mitigate the risk of inaccurate results as described in subparagraph (A), taking into account—

"(i) the degree to which the technology for the intended use of the in vitro clinical test is well-characterized, and the criteria for performance of the test are well-established to be sufficient for the intended use; and

"(ii) the clinical circumstances (including clinical presentation) under which the in vitro clinical test is used, and the availability of other tests (such as confirmatory or adjunctive tests) or relevant material standards.

"(8) LOW-RISK.—

"(A) Subject to subparagraph (B), the term 'low-risk', with respect to an in vitro clinical test or category of in vitro clinical tests, means that an undetected inaccurate result from such in vitro clinical test, or such category of in vitro clinical tests, when used as intended—

"(i) would cause minimal or no harm or disability, or immediately reversible harm, or would lead to only a remote risk of adverse patient impact or adverse public health impact; or

"(ii) could cause non-life threatening injury or injury that is medically reversible, or delay necessary treatment.

"(B) Such term does not include an in vitro clinical test if mitigating measures are sufficient to prevent such inaccurate result, detect such inaccurate result prior to any adverse patient impact or adverse public health impact, or otherwise sufficiently mitigate the risk associated with such inaccurate result.

"(9) MITIGATING MEASURES.—The term 'mitigating measures'—

"(A) means requirements that the Secretary determines, based on available evidence, are necessary—

"(i) for an in vitro clinical test, or a category of in vitro clinical tests, to meet the relevant standard for its intended use as defined in paragraph (10); or

"(ii) to mitigate the risk of harm ensuing from a false result or misinterpretation of any result; and

"(B) includes applicable requirements regarding labeling, advertising, website posting of information, testing, clinical studies, postmarket surveillance, user comprehension studies, training, conformance to standards, and performance criteria.

"(10) RELEVANT STANDARD.— The term 'relevant standard', with respect to an in vitro clinical test, means a reasonable assurance of adequate analytical and clinical validity, except that such term—

"(A) with respect to test platforms, means a reasonable assurance of adequate analytical validity; and

"(B) with respect to articles for taking or deriving specimens from the human body for purposes described in clause (i) or (ii) of section 201(ss)(1)(A) means a reasonable assurance of adequate analytical validity and, where applicable, safety.

"(11) TEST GROUP.—The term 'test group' means one or more in vitro clinical tests that have all of the following notification elements in common:

"(A) Substance or substances measured by the in vitro clinical test, such as an analyte, protein, or pathogen.

"(B) Type or types of specimen or sample.

"(C) Test method.

"(D) Test purpose or purposes, as described in section 201(ss)(1)(A).

"(E) Diseases or conditions for which the in vitro clinical test is intended for use.

"(F) Intended patient populations.

"(G) Context of use, such as in a clinical laboratory, in a health care facility, prescription home use, over-the-counter use, or direct-to-consumer testing.

"(12) TEST PLATFORM.—The term 'test platform' means an in vitro clinical test that is hardware intended by the hardware's developer to be used with one or more in vitro clinical tests to generate a clinical test result, including software used to effectuate the hardware's functionality.

"(13) VALID SCIENTIFIC EVIDENCE.—

"(A) VALID SCIENTIFIC EVIDENCE.—The term 'valid scientific evidence' means, with respect to an in vitro clinical test, evidence—

"(i) which has been generated and evaluated by persons qualified by training or experience to do so, using procedures generally accepted by other persons so qualified; and

"(ii) from which it can be fairly and responsibly concluded by qualified experts whether the relevant standard has been met by the in vitro clinical test for its intended use.

"(B) VALID SCIENTIFIC EVIDENCE.—The term 'valid scientific evidence' may include evidence described in subparagraph (A) consisting of—

"(i) peer-reviewed literature;

"(ii) clinical guidelines;

"(iii) reports of significant human experience with an in vitro clinical test;

"(iv) bench studies;

"(v) case studies or histories;

"(vi) clinical data;

"(vii) consensus standards;

"(viii) reference standards;

"(ix) data registries;

"(x) postmarket data;

"(xi) clinical trials; and

"(xii) data collected in countries other than the United States if such data are demonstrated to be adequate for the purpose of making a regulatory determination under the relevant standard in the United States.

"(14) FIRST-OF-A-KIND.—The term 'first-of-a-kind' means, with respect to an in vitro clinical test, a test that has a combination of the notification elements specified in paragraph (11) that constitutes a test group that differs from the combination of any such elements in any test group that is legally available in the United States.

"(15) WELL-CHARACTERIZED.—The term 'well-characterized' means well-established and well-recognized by the scientific or clinical community, if adequately evidenced by one or more of the following:

"(A) Literature.

"(B) Practice guidelines.

"(C) Consensus standards.

"(D) Recognized standards of care.

"(E) Technology in use for many years.

"(F) Scientific publication by multiple sites.

"(G) Wide recognition or adoption by the scientific or clinical community.

"(H) Real world data.

"SEC. 587A. APPLICABILITY.

"(a) IN GENERAL.—

"(1) SCOPE.—An in vitro clinical test—

"(A) shall be subject to the requirements of this subchapter, except as set forth in this section;

"(B) that is offered for clinical use in the United States is deemed to be introduced into interstate commerce for purposes of enforcing the requirements of this Act; and

"(C) subject to any exemption or exclusion in this section, shall not be subject to any provision or requirement of this Act other than this subchapter unless such other provision or requirement—

"(i) applies expressly to in vitro clinical tests; or

"(ii) describes the authority of the Secretary when regulating such articles or subset of articles, with respect to—

"(I) all articles regulated by the Secretary pursuant to this Act; or

"(II) a subset of such articles that includes in vitro clinical tests.

"(2) LABORATORIES AND BLOOD AND TISSUE ESTABLISHMENTS.—

"(A) RELATION TO CLIA.—Nothing in this subchapter shall be construed to modify the authority of the Secretary with respect to laboratories or clinical laboratories under section 353 of the Public Health Service Act.

"(B) AVOIDING DUPLICATION.—In implementing this subchapter, the Secretary shall, to the greatest extent possible, unless necessary to protect public health, avoid issuing or enforcing regulations that are duplicative of regulations under section 353 of the Public Health Service Act.

"(C) BLOOD AND TISSUE.—Nothing in this subchapter shall be construed to modify the authority of the Secretary with respect to laboratories, establishments, or other facilities to the extent they are engaged in the propagation, manufacture, or preparation, including filling, testing, labeling, packaging, and storage, of blood, blood components, human cells, tissues, or tissue products under this Act or section 351 of the Public Health Service Act.

"(3) PRACTICE OF MEDICINE.—

"(A) IN GENERAL.—Nothing in this subchapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed in vitro clinical test for any condition or disease within a legitimate health care practitioner-patient relationship.

"(B) SALE, DISTRIBUTION, LABELING.—Nothing in this paragraph shall be construed to limit any authority of the Secretary to establish and enforce restrictions on the sale, distribution, or labeling of an in vitro clinical test under this Act.

"(C) PROMOTION OF UNAPPROVED USES.—Nothing in this paragraph shall be construed to alter any prohibition on the promotion of unapproved uses of legally marketed in vitro clinical tests.

"(4) SPECIAL RULE.—

"(A) PREMARKET REVIEW APPLICABLE.—Notwithstanding the exemptions from premarket review under section 587B set forth in subsections (b), (c), (d), (e), (f), (g), (h), and (k), an in vitro clinical test shall be subject to the requirements of section 587B if the Secretary determines, in accordance with subparagraph (B), that—

"(i) there is insufficient valid scientific evidence that an article for taking or deriving specimens from the human body for the purposes specified in section 201(ss)—

"(I) performs as intended;

"(II) will support the analytical validity of tests with which it is used; or

"(III) where applicable, is safe for use;

"(ii) there is insufficient valid scientific evidence to support the analytical validity or the clinical validity of such in vitro clinical test;

"(iii) such in vitro clinical test is being offered by its developer with materially deceptive or fraudulent analytical or clinical claims; or

"(iv) there is a reasonable potential that such in vitro clinical test will cause death or serious adverse health consequences, including by causing the absence, delay, or discontinuation of appropriate medical treatment.

"(B) PROCESS.—

"(i) REQUEST FOR INFORMATION.—If the Secretary has reason to believe that one or more of the criteria listed in subparagraph (A) apply to an in vitro clinical test, the Secretary may request that the developer of the test submit information—

"(I) pertaining to such criteria; and

"(II) establishing the basis for any claimed exemption from premarket review.

"(ii) DEADLINE FOR SUBMITTING INFORMATION.—Upon receiving a request for information under clause (i), the developer of an in vitro clinical test shall submit the information within 30 days of such receipt.

"(iii) REVIEW DEADLINE.—Upon receiving a submission under clause (ii), the Secretary shall—

"(I) review the submitted information within 30 days of such receipt; and

"(II) determine whether one of more of the criteria listed in subparagraph (A) apply to the in vitro clinical test.

"(iv) PREMARKET REVIEW REQUIRED.—If the Secretary finds one or more of the criteria listed in subparagraph (A) apply to the in vitro clinical test, the developer shall—

"(I) promptly, and not later than 90 days after the date of receipt of such information, submit an application for premarket review of the test under section 587B; or

"(II) cease to market the test.

"(v) CONTINUED MARKETING.—During the period beginning on the date of a submission under clause (ii) and ending on the date of the disposition of an application for premarket review of the in vitro clinical test under section 587B, the developer of the test may continue to market the test for clinical use, unless the Secretary issues an order to the developer under clause (vi) to immediately cease distribution of the test.

"(vi) ORDER TO CEASE DISTRIBUTION.—If the developer of an in vitro clinical test fails to submit an application for premarket review of the test by the deadline applicable under clause (iv), if the Secretary finds that one of more of the criteria listed in subparagraph (A) apply to an in vitro clinical test, or if the Secretary finds that it is in the best interest of the public health, the Secretary may issue an order requiring the developer of such in vitro clinical test, and any other appropriate person (including a distributor or retailer of the in vitro clinical test)—

"(I) to immediately cease distribution of the test pending approval of an application for premarket review of the test under section 587B; and

"(II) to immediately notify health professionals and other user facilities of the order and to instruct such professionals and facilities to cease use of such in vitro clinical test.

An order under this clause shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such in vitro clinical test. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(vii) AMENDMENT TO REQUIRE RECALL.—If the Secretary determines that an order issued under clause (vi) should be amended to include a recall of the in vitro clinical test with respect to which the order was issued, the Secretary shall amend the order to require a recall. In such amended order, the Secretary shall specify a timetable in which the in vitro clinical test recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

["(viii) EFFECT OF TEST APPROVAL.—**[**Any order issued under this paragraph with respect to an in vitro clinical test shall cease to be in effect if such test is granted approval under section 587B, provided that the in vitro clinical test is developed and offered for clinical use in accordance with such approval.**]]**

"(5) EMERGENCY USE.—

"(A) IN GENERAL.—The exemptions from premarket review under subsections (b), (c), (d), (e), (f), (g), (h), and (k) of section 587B shall not apply to any in vitro clinical test that is eligible for an emergency use authorization under section 564(a).

"(B) TESTS OFFERED FOR CLINICAL USE UNDER AN EXEMPTION PRIOR TO A DECLARATION.—

"(i) CONTINUED MARKETING.—If the Secretary makes a declaration under section 564(b) for an in vitro clinical test that was offered for clinical use under an exemption under subsection (b), (c), (d), (e), (f), (g), (h), or (k) of section 587B prior to the declaration, such test may continue to be offered for clinical use after such declaration only if—

"(I) the developer of the test submits to the Secretary, not later than 5 days after the date of issuance of the declaration, a request for an emergency use authorization for the test under section 564(a) and the request remains pending;

"(II) the Secretary grants an emergency use authorization for the test under section 564(a); or

"(III) the Secretary approves the test for marketing under section 587B.

"(ii) NECESSARY ACTIONS.—The Secretary, in collaboration with the developers of in vitro clinical tests and other affected entities, as appropriate, shall take such actions as the Secretary determines to be necessary actions to ensure such tests are no longer distributed or offered for clinical use until they receive the required approval or authorization.

"(b) COMPONENTS AND PARTS.—

"(1) EXEMPTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), an in vitro clinical test that is a component or part described in section 201(ss)(1)(F) is exempt from the requirements of this Act if it is intended for further development as described in paragraph (2).

"(B) INAPPLICABILITY TO OTHER TESTS.—Notwithstanding subparagraph (A), an in vitro clinical test that is described in

subparagraph (A), (B), (C), (D), or (E) of section 201(ss)(1) and that uses a component or part described in such subparagraph shall be subject to the requirements of this Act, including requirements relating to the establishment and use of supplier controls, unless the test is otherwise exempted under this section.

"(2) FURTHER DEVELOPMENT.—An in vitro clinical test that is a component or part (as described in paragraph (1)(A)) is intended for further development (for purposes of such paragraph) if—

"(A) it is intended solely for use in the development of another in vitro clinical test; and

"(B) if introduced or delivered for introduction into interstate commerce after the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018, the labeling of such test bears the following statement: 'This product is intended solely for further development of an in vitro clinical test and is exempt from FDA regulation. This product must be evaluated by the in vitro clinical test developer in accordance with supplier controls if it is used with or in the development of an in vitro clinical test.'.

"(c) GRANDFATHERED TESTS.—

"(1) EXEMPTION.—An in vitro clinical test that meets the criteria set forth in paragraph (2) is exempt from premarket review under section 587B, the quality system requirements under section 587J, and the labeling requirements under section 587K, and may be lawfully marketed subject to the other applicable requirements of this Act, if—

"(A) each test report template under section 587K for the test bears a statement of adequate prominence that reads as follows: "This in vitro clinical test was developed and first introduced prior to 90 days prior to date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018 and has not been reviewed by the Food and Drug Administration."; and

"(B) the developer of the test—

"(i) maintains documentation demonstrating that the test meets and continues to meet the criteria set forth in paragraph (2); and

"(ii) makes such documentation available to the Secretary upon request.

"(2) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as specified in paragraph (1) if the test—

"(A)(i) was first offered for clinical use or otherwise introduced or delivered for introduction into interstate commerce by such laboratory 90 days or more before the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018;

"(ii) was developed by a laboratory for which a certificate is in effect under section 353 of the Public Health Service Act that meets the requirements under section 353 for performing high-complexity testing for use only within that laboratory; and

"(iii) is performed in the same laboratory in which it was developed or by another such laboratory for which a certificate is in effect under section 353 within the same corporate organization and having common ownership by the same parent corporation;

"(B) does not have in effect an approval under section 515, a clearance under section 510(k), an authorization under section 513(f)(2), or an approval under section 520(m); and

"(C) is not modified on or after the date that is 90 days before the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018 by its initial developer (or another person) in a manner such that the test is a new in vitro clinical test under subsection (l).

"(3) MODIFICATIONS.—When a person modifies the person's own or another person's in vitro clinical test that is exempt as specified in paragraph (1) and determines that the modified test is not a new in vitro clinical test under subsection (l), such person shall—

"(A) document each such modification and the basis for such determination; and

"(B) provide such documentation to the Secretary upon request or inspection.

"(d) TESTS EXEMPT FROM SECTION 510(k).—

"(1) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully marketed subject to the other applicable requirements of this Act, if it meets the criteria described in paragraph (2).

"(2) CRITERIA FOR EXEMPTION.—The criteria described in this paragraph are that—

"(A) the in vitro clinical test—

"(i) was offered for clinical use prior to the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018; and

"(ii) was immediately prior to such date of enactment exempt pursuant to subsection (l) or (m)(2) of section 510 from the requirements for submission of a report under section 510(k); or

"(B) the test—

"(i) was not offered for clinical use prior to such date of enactment;

"(ii) is not a test platform (as defined in section 587); and

"(iii) falls within a category of tests that was exempt from the requirements for submission of a report under section 510(k) as of such date of enactment **[**(including class II 510(k)-exempt devices and excluding class I reserved devices)**]**.

"(3) EFFECT ON SPECIAL CONTROLS.—For any in vitro clinical test, or category of in vitro clinical tests, that is exempted from

premarket review based on the criteria in paragraph (2), any special control that applied to a device within a predecessor category immediately prior to the date of enactment of Verifying Accurate Leading-edge IVCT Development Act of 2018 shall be deemed a mitigating measure applicable under section 587E to an in vitro clinical test within the successor category, except to the extent such mitigating measure is withdrawn or changed in accordance with section 587E.

"(4) NEAR-PATIENT TESTING.—The Secretary shall issue guidance indicating categories of tests that shall be exempt from premarket review under section 587B when offered for near-patient testing (point of care), which were not exempt from submission of a report under section 510(k) pursuant to subsection (l) or (m)(2) of section 510 and regulations imposing limitations on exemption for in vitro devices intended for near-patient testing (point of care).

"(e) LOW-RISK TESTS.—

"(1) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully marketed subject to the other applicable requirements of this Act, if such test is included in, or falls within a category of tests that is included in, the list of low-risk in vitro clinical tests in effect under paragraph (2).

"(2) LIST OF LOW-RISK TESTS.—

"(A) IN GENERAL.—The Secretary shall maintain, and make publicly available on the website of the Food and Drug Administration, a list of in vitro clinical tests, and categories of in vitro clinical tests, that are low-risk in vitro clinical tests for purposes of the exemption under this subsection.

"(B) INCLUSION.—The list under subparagraph (A) shall consist of—

"(i) all in vitro clinical tests and categories of in vitro clinical tests that are exempt from premarket review pursuant to subsection (d)(1) or (d)(4); and

"(ii) all in vitro clinical tests and categories of in vitro clinical tests that are designated by the Secretary pursuant to subparagraph (C) as low-risk for purposes of this subsection.

"(C) DESIGNATION OF TESTS AND CATEGORIES.—Without regard to subchapter II of chapter 5 of title 5, United States Code, the Secretary may designate, in addition to the tests and categories described in subparagraph (B)(i), additional in vitro clinical tests, and categories of in vitro clinical tests, as low-risk in vitro clinical tests for purposes of the exemption under this subsection. The Secretary may make such a designation on the Secretary's own initiative or in response to a request by any person. In making such a designation for a test or category of tests, the Secretary shall consider—

"(i) whether the test, or category of tests, is low-risk (as defined in section 587); and

"(ii) such other factors as the Secretary deems to be relevant.

"(f) MANUAL TESTS.—

"(1) EXEMPTION.—An in vitro clinical test that is designed, manufactured, and used within a single laboratory for which a certificate is in effect under section 353 of the Public Health Service Act that meets the requirements under section 353 for performing high-complexity testing, is exempt from the requirements of this Act, if the test—

"(A) meets the criteria described in paragraph (2); and

"(B) is not intended—

"(i) for detecting human immunodeficiency virus (HIV) , or for measuring an analyte that serves as a surrogate marker for screening, diagnosis, monitoring, or monitoring therapy for acquired immunodeficiency syndrome (AIDS);

"(ii) for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products; or

"(iii) for testing maternal or fetal specimens for hemolytic disease of the fetus or newborn.

"(2) CRITERIA FOR EXEMPTION.—The criteria described in this paragraph are that—

"(A) the output of the in vitro clinical test is the result of manual interpretation (meaning direct observation) by a qualified laboratory professional, without the use of automated instrumentation or software for intermediate or final interpretation; and

"(B) the test—

"(i) is not a high-risk test; or

"(ii) is a high-risk test for which the Secretary publishes in the Federal Register a notice determining that the test is appropriate to be exempted pursuant to paragraph (1) and that the test meets at least one of the following conditions:

"(I) No component or part of such test, including any reagent, is introduced into interstate commerce under the exemption under subsection (b)(1) (relating to components or parts intended for further development), and **[**any article for taking or deriving specimens from the human body used in conjunction with the test remains subject to**]** the requirements of this Act.

"(II) The test has been developed in accordance with the quality system requirements under section 587J.

"(g) TESTS FOR RARE DISEASES.—

"(1) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully marketed subject to the other applicable requirements of this Act, if—

"(A) the test meets the criteria described in paragraph (2); and

"(B) the developer of the test—

"(i) maintains documentation (which may include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, governmental statistics publications, or, if no such studies or literature citations exist, credible conclusions from appropriate research or surveys) demonstrating that such test meets and continues to meet the criteria described in paragraph (2); and

"(ii) makes such documentation available to the Secretary upon request.

"(2) CRITERIA.—The criteria described in this paragraph are that—

"(A) fewer than 8,000 individuals per year in the United States would be subject to testing using the in vitro clinical test;

"(B) the test is not a cross-referenced test; and

"(C) the test is not for a communicable disease.

"(h) CUSTOM TESTS AND LOW-VOLUME TESTS.—

"(1) EXEMPTION.—An in vitro clinical test that meets the criteria described in paragraph (2) is exempt from premarket review under section 587B, the quality system requirements under section 587J, and the notification requirements under section 587I, and may be lawfully marketed subject to the other applicable requirements of this Act, if—

"(A) the developer of the test—

"(i) maintains documentation demonstrating that such test meets and continues to meet the applicable criteria described in paragraph (2); and

"(ii) makes such documentation available to the Secretary upon request; and

"(B) the developer of the test informs the Secretary, on an annual basis, in a manner prescribed by the Secretary by guidance, that such test was introduced into interstate commerce.

"(2) CRITERIA FOR EXEMPTION.—The criteria described in this paragraph are that the test—

"(A) is a low-volume test offered to no more than 5 patients per year; or

"(B) is a custom test to diagnose a unique pathology or physical condition of a specific patient named in an order of a physician, dentist, or other health professional (or any other specially qualified person designated under regulations promulgated by the Secretary for purposes of this subparagraph) for which no other in vitro clinical test is commercially available in the United States, and is—

"(i) not used for other patients;

"(ii) developed or modified to comply with such order; and

"(iii) not included in any test menu, template test report, or other promotional materials, and not otherwise advertised.

"(i) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

"(1) IN GENERAL.—The provisions of this subchapter shall not apply to a test intended to be used solely for public health surveillance.

"(2) DEFINITION.—In this subsection, the term 'public health surveillance' means ongoing systematic activities, including collection, analysis, and interpretation of health-related data, essential to planning, implementing, and evaluating public health practice.

"(3) EXCLUSION.—An in vitro clinical test that is either intended for use in making clinical decisions for individual patients or other purposes not described in paragraph (2) or whose individually identifiable results may be reported back to an individual patient or the patient's health care provider, even if also intended for public health

surveillance, is not intended solely for use in public health surveillance for purposes of this subsection.

"(j) LAW ENFORCEMENT.—An in vitro clinical test that is intended solely for use in forensic analysis or other law enforcement activity is exempt from the requirements of this Act. An in vitro clinical test that is intended for use in making clinical decisions for individual patients, or whose individually identifiable results may be reported back to an individual patient or the patient's health care provider, even if also intended for law enforcement purposes, is not intended solely for use in law enforcement for purposes of this subsection.

"(k) PRECERTIFIED TESTS.—**[**An in vitro clinical test that is subject to a precertification order, as described in section 587D(a)(2), is exempt from premarket review under section 587B.**]**

"(l) MODIFIED TESTS.—

"(1) IN GENERAL.—An in vitro clinical test that is modified, by the initial developer of the test or a different person, is a new in vitro clinical test subject to this Act if the modification—

"(A) changes any of the elements specified in section 587(11) that define a test group;

"(B) changes performance claims made with respect to the test;

"(C) causes the test to no longer comply with applicable mitigating measures or restrictions;

"(D) adversely affects performance of the test; or

"(E) as applicable, affects the safety of an article for taking or deriving specimens from the human body for a purpose described in section 201(ss)(1).

"(2) DOCUMENTATION.—When a person modifies an in vitro clinical test that was developed by another person, such modified test is exempt from the requirements of this Act provided that such person shall—

"(A) document the modification that was made and the basis for determining that the modification, considering the changes individually and collectively, was not a type of modification described in paragraph (1); and

"(B) provide such documentation to the Secretary upon request or inspection.

"(m) INVESTIGATIONAL USE.—An in vitro clinical test for investigational use is exempt from the requirements of this Act, except as provided in section 587R.

"(n) TRANSFER OR SALE OF AN IN VITRO CLINICAL TEST.—

"(1) TRANSFER AND ASSUMPTION OF REGULATORY OBLIGATIONS.—If ownership of an in vitro clinical test is sold or transferred in such manner that the developer transfers the regulatory submissions and obligations applicable under this subchapter with respect to the test, the transferee or purchaser becomes the developer of the test and shall have all regulatory obligations applicable to such a test under this subchapter. The transferee or purchaser shall update the registration and notification information under section 587I for the in vitro clinical test.

["(2) TRANSFER OR SALE OF PREMARKET APPROVAL.—

["(A) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells the approval of the in vitro clinical test, the transferor or seller shall—

["(i) submit a notice of the transfer or sale to the Secretary and update the registration and notification information under section 587I for the in vitro clinical test; and**]**

["(ii) submit a supplemental application if required under subsection (f).**]**

]

["(B) EFFECTIVE DATE OF APPROVAL TRANSFER.—A transfer or sale described in subparagraph (A) shall become

effective upon completion of a transfer or sale described in paragraph (1) or the approval of a supplemental application under subsection (f) if required, whichever is later. The transferee or purchaser shall update the registration and notification information under section 587I for the in vitro clinical test within 15 calendar days of the effective date of the transfer or sale.]

]

[“(3) TRANSFER OR SALE OF PRECERTIFICATION.—

[“(A) REQUIREMENTS FOR TRANSFER OR SALE OF PRECERTIFICATION.—A precertification can be transferred or sold if the transferee or purchaser—

[“(i) is an eligible person under section 587D(b)(1); and]

[“(ii) maintains, upon such transfer or sale, the site, quality system, processes and procedures, and scope of precertification identified in the applicable precertification submission.]

]

[“(B) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells an approved precertification, the transferor or seller shall submit a notice of the transfer or sale to the Secretary and shall update the registration and notification information under section 587I for all in vitro clinical tests covered by the precertification.]

[“(C) EFFECTIVE DATE OF PRECERTIFICATION TRANSFER.—The transfer of a precertification shall become effective upon completion of a transfer or sale described in subparagraph (A). The transferee or purchaser shall update the registration and notification information under section 587I for the in vitro clinical test within 30 calendar days of the effective date of the precertification transfer.]

[“(D) NEW PRECERTIFICATION REQUIRED.—If the requirements of subclause (A)(ii) are not met, then the approved precertification cannot be transferred and the transferee or purchaser of an in vitro clinical test must submit an application for precertification and obtain approval of such application prior to offering the test for clinical use.]

]

“(o) GENERAL EXEMPTION AUTHORITY.—The Secretary may, by order published in the Federal Register following notice and an opportunity for comment, exempt a class of persons from any section under this subchapter upon a finding that such exemption is appropriate in light of public health and other relevant considerations.

“(p) REGULATIONS.—The Secretary may issue regulations to implement this subchapter.

“SEC. 587B. PREMARKET REVIEW.

“(a) IN GENERAL.—No person shall introduce or deliver for introduction into interstate commerce any in vitro clinical test, unless—

“(1) an approval of an application filed pursuant to subsection (b) [or pursuant to priority review under section 587C] is effective with respect to test; or

“(2) the test is exempt under section 587A from premarket review under this section.

“(b) APPLICATION.—

“(1) FILING.—Any person may file with the Secretary an application for premarket approval of an in vitro clinical test.

“(2) CONTENTS.—An application submitted under paragraph (1) with respect to an in vitro clinical test shall include the following:

"(A) The information required in paragraphs (a), (b)(1), (b)(2), (b)(3)(iii), (b)(3)(iv), (b)(3)(v), (b)(3)(vi), (b) (8), (b)(10), and (b)(12) of section 814.20 of title 21 of the Code of Federal Regulations (or successor regulations) until such time as the Secretary promulgates final regulations requiring comparable information with respect to in vitro clinical tests and such regulations are in effect.

"(B) General information regarding the test, including—

"(i) a description of its intended use;

"(ii) an explanation regarding how the test functions and significant performance characteristics;

"(iii) a risk assessment of the test; and

"(iv) a statement attesting to the truthfulness and accuracy of the information submitted in the application.

"(C) Except for test platforms, collection articles, and **[**in vitro clinical tests eligible for precertification**]**, information regarding the methods used in, or the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality system requirements under section 587J.

"(D) Information demonstrating compliance with—

"(i) any applicable mitigating measures under section 587E; and

"(ii) standards established or recognized under section 514 prior to the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018, or, after applicable standards are established or recognized under section 587Q, with such standards.

"(E) Valid scientific evidence to support analytical and clinical validity of the test, which shall include—

"(i) summary information for all supporting validation studies performed; and

"(ii) raw data for—

"(I) tests that are high-risk, cross-referenced, or first-of-a-kind, unless the Secretary determines otherwise; and

"(II) all other types of in vitro clinical tests, available upon the Secretary's request;

"(iii) in the case of a test platform or article for taking or deriving specimens from the human body, information concerning a representative test or tests covering all intended test methodologies using the test platform or article;

"(iv) for nonclinical laboratory studies involving the test, a statement that studies were conducted in compliance with applicable good laboratory practices under part 58 of title 21 of the Code of Federal Regulations (or successor regulations) **[**which shall be interpreted to apply to in vitro clinical tests**]**; and

"(v) for investigations involving human subjects, statements that any clinical investigation involving human subjects was conducted in compliance with—

"(I) institutional review board regulations in part 56 of title 21 of the Code of Federal Regulations (or successor regulations)**[**, which shall be interpreted to apply to in vitro clinical tests**]**;

"(II) informed consent regulations in part 50 of title 21 of the Code of Federal Regulations (or successor regulations)**[**, which shall be interpreted to apply to in vitro clinical tests**]**; and

"(III) investigational use requirements in section 587R, as applicable.

"(F) To the extent the application seeks authorization to make modifications to the test within the scope of the approval, a change protocol that includes validation procedures and acceptance criteria for specific types of anticipated modifications that could be made to the test within the scope of the approval.

"(G) For an article for taking or deriving specimens from the human body, and for any in vitro clinical test that includes such article, safety information, as applicable, including biocompatibility, sterility, human factors, and user studies, and information regarding the types of tests that could be used with the article**[**; however, collection articles shall not be subject to premarket review of quality systems documentation or preapproval inspection, and the developer shall not be required to provide raw data by default**]**.

"(H) For a test platform that has not been previously approved by the Food and Drug Administration, and for any in vitro clinical test that includes such test platform, data, as applicable, to support software validation, electromagnetic compatibility, and electrical safety, or information demonstrating compliance with applicable recognized standards addressing these areas. **[**These platforms shall not be subject to premarket review of quality systems documentation and preapproval inspection, and the developer shall not be required to provide raw data by default.**]**

"(I) Proposed labeling, in accordance with the requirements of section 587K.

"(J) Such other information as the Secretary may require through guidance **[**or regulation**]**.

["(3) PRECERTIFICATION ELIGIBLE TESTS.—**[**For an in vitro clinical test eligible for precertification under section 587D, unless requested by the Secretary—**]**

["(A) an application under paragraph (2) need not include quality systems documentation or raw data; and**]**

[“(B) a preapproval inspection need not occur.]

]

“(4) REFERRAL TO PANEL.—Upon receipt of an application meeting the requirements set forth in paragraph (2) or (3), the Secretary may refer such application to [the appropriate panel under section 513] for study and for submission to the Secretary (within such period as the Secretary may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation. Such referral may be—

“(A) on the Secretary’s own initiative; or

“(B) on the request of an applicant [unless the Secretary finds that the information in the application requested to be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel under section 513].

“(5) DEFICIENT APPLICATION.—If, after [receipt] of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary shall provide to the applicant a description of such deficiencies and identify the information required to correct such deficiencies.

“(c) AMENDMENTS TO AN APPLICATION.—

“(1) IN GENERAL.—An applicant may amend or supplement an application under subsection (b).

“(2) REQUIRED AMENDMENT OR SUPPLEMENT.—An applicant shall amend or supplement an application under subsection (b) if the applicant becomes aware of information that—

“(A) could reasonably affect an evaluation of whether the relevant standard has been met; or

“(B) could reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the proposed labeling.

"(3) REQUEST FOR AMENDMENT OR SUPPLEMENT.—The Secretary may request that an applicant amend or supplement an application under subsection (b) with any information necessary for review under this section.

"(d) ACTION ON AN APPLICATION FOR PREMARKET APPROVAL.—

"(1) REVIEW.—

"(A) DISPOSITION.—As promptly as possible, but not later than **[___]** days after an application under subsection (b) is accepted for submission, unless the Secretary determines that an extension is necessary to review one or more major amendments to the application under subsection (c), the Secretary, after considering any applicable report and recommendation by a panel pursuant to subsection (b)(4), shall issue an order—

"(i) approving the application if the Secretary finds that all of the grounds for approval in paragraph (2) are met; or

"(ii) denying approval of the application if the Secretary finds that one or more grounds for approval in paragraph (2) are not met.

"(B) RELIANCE ON PROPOSED LABELING.—In determinating whether to approve or deny an application under paragraph (1), the Secretary shall rely on the intended use included in the proposed labeling, if such labeling is not false or misleading based on a fair evaluation of all material facts.

"(2) APPROVAL OR DENIAL OF AN APPLICATION.—

"(A) IN GENERAL.—The Secretary shall approve an application submitted under subsection (b) with respect to an in vitro clinical test if the Secretary finds that there has been an adequate showing that—

"(i) the relevant standard is met;

"(ii) the applicant is in compliance with applicable quality system requirements in section 587J [or as otherwise specified in a condition of approval];

"(iii) the application does not contain a false statement of material fact;

"(iv) based on a fair evaluation of all material facts, the proposed labeling is truthful and non-misleading and complies with the requirements of section 587K;

"(v) the applicant [permits/permitted, if requested,] authorized employees of the Food and Drug Administration and persons accredited under section 587P an opportunity—

> "(I) to inspect at a reasonable time and in a reasonable manner the facilities and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, including all things (including records, files, papers, and controls) bearing on whether an in vitro clinical test is adulterated, misbranded, or otherwise in violation of this Act; and
>
> "(II) to view and to copy and verify all records pertinent to the application and the in vitro clinical test;

"(vi) the test conforms in all respects with any applicable performance standards under section 587Q and any applicable mitigating measures under section 587E;

"(vii) all nonclinical laboratory studies that are described in the application, and that are essential to show, with respect to the test, analytical validity and clinical validity, were conducted in compliance with the good laboratory practice regulations in part 58 of title 21 of the Code of Federal Regulations (or successor regulations) [which shall be interpreted to apply to in vitro clinical tests];

"(viii) all clinical investigations involving human subjects described in the application subject to the institutional review

board regulations in part 56 of title 21 of the Code of Federal Regulations and informed consent regulations in part 50 of title 21 of the Code of Federal Regulations (or successor regulations) [each of which shall be interpreted to apply to in vitro clinical tests,] were conducted in compliance with those regulations; and

"(ix) such other showings as the Secretary may require.

"(B) CONDITIONS OF APPROVAL.—An order approving an application pursuant to this paragraph may require conditions of approval for the in vitro clinical test, including conformance with performance standards under section 587Q and restrictions under section 587N.

"(C) FIRST-OF-A-KIND TEST.—For a first-of-a-kind in vitro clinical test, an order approving an application pursuant to this paragraph—

"(i) may impose requirements for the test group, including conformance with performance standards under section 587Q, restrictions under section 587N, and mitigating measures under section 587E; and

"(ii) shall indicate whether subsequent in vitro clinical tests in that test group may meet an exemption set forth in section 587A.

"(D) PUBLICATION.—The Secretary shall publish each order approving an application pursuant to this paragraph on the public website of the Food and Drug Administration and make publicly available a summary of the data used to grant the approval, except to the extent that such order or data is restricted from disclosure pursuant to statutory provisions other than this section.

"(3) REVIEW OF DENIALS.—[An applicant whose application submitted under subsection (b) has been denied approval may, by petition filed not more than [__ days] after the date on which the applicant receives notice of such denial, obtain review of the denial in

accordance with section 587O, and any interested person may obtain review, in accordance with section 587O**]**.

"(e) BREAKTHROUGH.—**[***to be supplied***]**

"(f) SUPPLEMENTS TO AN APPLICATION.—

"(1) RISK ANALYSIS.—Prior to implementing any modification to an in vitro clinical test, the holder of the application approved under subsection (d) for such test shall perform a risk analysis in accordance with section 587J.

"(2) SUPPLEMENT REQUIREMENT.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), or otherwise specified by the Secretary, the holder of the application approved under subsection (d) for an in vitro clinical test shall submit to the Secretary and receive approval of a supplement before implementing a modification to the test.

"(B) EXCEPTIONS.—Subject to subparagraphs (C) and (D), and so long as the holder of an application approved under subsection (d) for an in vitro clinical test does not add a manufacturing site, or change activities at an existing manufacturing site, with respect to the test, the holder may, without prior approval of a supplement, implement the following modifications to the test:

"(i) Modifications included in and implemented in accordance with an approved change protocol.

"(ii) Modifications that—

"(I) do not change any of the elements listed in section 587(11) with respect to the test group involved;

"(II) do not change performance claims for the test;

"(III) do not change, as applicable, the safety of the test;

"(IV) do not adversely affect the performance of the test; and

"(V) do not cause the test to no longer comply with applicable mitigating measures under section 587E or restrictions under section 587N.

"(iii) Labeling changes that are appropriate to address a safety concern.

"(C) REPORTING FOR FIRST CATEGORIES OF EXCEPTIONS.—The holder of the application approved under subsection (d) for an in vitro clinical test shall—

"(i) report any modification to the test described in clause (i) or (ii) of subparagraph (B) in the next annual report for the test under subsection (h) following the date on which the test, with the modification, is introduced into interstate commerce; and

"(ii) include in such report—

"(I) a description of the modification; and

"(II) as applicable, a summary of the analytical validity and clinical validity of the test, as modified, and acceptance criteria.

"(D) REPORTING FOR OTHER CATEGORY OF EXCEPTIONS.—The holder of the application approved under subsection (d) for an in vitro clinical test shall—

"(i) report to the Secretary any modification to the test described in clause (iii) of subparagraph (B) not more than 30 days after the date on which the test, with the modification, is introduced into interstate commerce; and

"(ii) include in the report—

"(I) a summary of the relevant change or changes;

"(II) the rationale for implementing such change or changes; and

"(III) a description of how the change or changes were evaluated.

Upon review of such report and a finding that the relevant modification is inconsistent with the standard specified under clause (iii) of subparagraph (B), the Secretary may require a supplement under subparagraph (A).

"(3) CONTENTS OF SUPPLEMENT.—Unless otherwise specified by the Secretary, a supplement under this subsection shall include—

"(A) for modifications other than manufacturing site changes—

"(i) a description of the modification;

"(ii) summary or raw data, as applicable, to demonstrate that the relevant standard is met;

"(iii) acceptance criteria; and

"(iv) any revised labeling; and

"(B) for manufacturing site changes—

"(i) the matter listed in subparagraph (A); and

"(ii) information regarding the methods used in, or the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality system requirements under section 587J.

"(4) APPROVAL.—The Secretary shall approve a supplement under this subsection if—

"(A) the data, if applicable, demonstrate that the modified in vitro clinical test meets the relevant standard; and

"(B) the holder of the application approved under subsection (d) for the test has demonstrated compliance with applicable quality system and inspection requirements, where appropriate.

"(5) ADDITIONAL DATA.—The Secretary may require, when necessary, data to evaluate a modification to an in vitro clinical test that is in addition to the data otherwise required under the preceding paragraphs.

"(6) CONDITIONS OF APPROVAL.—In an order approving a supplement under this subsection, the Secretary may require conditions of approval for the in vitro clinical test, including conformance with performance standards under section 587Q and compliance with restrictions under section 587N.

"(7) PUBLICATION.—The Secretary shall publish on the public website of the Food and Drug Administration notice of any order approving a supplement under this subsection.

"(8) REVIEW OF DENIAL.—An applicant whose supplement under this subsection has been denied approval may, by petition filed on or before the **[**__**]** day after the date upon which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587O, **[**and any interested person may obtain review, in accordance with section 587O, of an order of the Secretary approving a supplement**]**.

"(g) WITHDRAWAL AND TEMPORARY SUSPENSION OF APPROVAL.—

"(1) ORDER WITHDRAWING APPROVAL.—

"(A) IN GENERAL.—The Secretary may, after providing due notice and an opportunity for an informal hearing to the holder of an approved application for an in vitro clinical test under this section, issue an order withdrawing approval of the application if the Secretary finds that—

"(i) the grounds for approval in subsection (d)(2) are no longer met; or

"(ii) there is a reasonable likelihood that the test would cause death or serious adverse health consequences, including by causing the absence, delay, or discontinuation of appropriate medical treatment.

"(B) CONTENTS.—An order under subparagraph (A) withdrawing approval of an application shall state each ground for withdrawal and shall notify the holder of such application.

"(C) PUBLICATION.—The Secretary shall publish any order under subparagraph (A) on the public website of the Food and Drug Administration.

"(2) ORDER OF TEMPORARY SUSPENSION.—If, after providing due notice and an opportunity for an informal hearing to the holder of an approved application for an in vitro clinical test under this section, the Secretary determines there is a reasonable likelihood that the in vitro clinical test would cause death or serious adverse health consequences, including by causing the absence, delay, or discontinuation of appropriate medical treatment, the Secretary shall by order temporarily suspend the approval of the application. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw approval of such application.

"(h) LEAST BURDENSOME REQUIREMENTS.—

["(1) IN GENERAL.—In carrying out this subchapter, the Secretary shall consider the **[**least burdensome**]** appropriate means necessary to demonstrate that an in vitro clinical test has met the relevant standard and other regulatory requirements.**]**

["(2) NECESSARY DEFINED.—For purposes of paragraph (1) and paragraph (3), the term 'necessary' means the minimum required information that would support a determination by the Secretary that the relevant standard or other regulatory requirement has been met.**]**

["(3) CONSIDERATION OF ROLE OF POSTMARKET INFORMATION.—For purposes of this subsection, the Secretary shall

consider the role of postmarket information in determining the [least burdensome] appropriate means necessary to demonstrate that the relevant standard and other regulatory requirements have been met.]

[“(4) RULE OF CONSTRUCTION.—Nothing in this subsection alters the relevant standard as defined in section 587.]

“(i) ANNUAL REPORT.—

“(1) IN GENERAL.—Unless the Secretary specifies otherwise, the holder of an approved application under this section shall submit an annual report each year at a time designated by the Secretary in the approval order. Such report shall—

“(A) identify all modifications that an approved application holder has made to any test that is covered by the approval order, including any modification that requires a supplement under subsection (f); and

“(B) include any other information required by the Secretary.

“(2) EXCEPTION.—This annual reporting requirement in paragraph (1) shall not apply to in vitro clinical tests that are deemed to have a premarket approval based on a prior clearance under section 510(k) or prior authorization under section 513(f).

“(j) SERVICE OF ORDERS.—Orders of the Secretary under this section with respect to applications under subsection (b) or supplements under subsection (f) shall be served—

“(1) in person by any officer or employee of the Department of Health and Human Services designated by the Secretary; or

“(2) by mailing the order by registered mail or certified mail or electronic equivalent addressed to the applicant at the last known address in the records of the Secretary.

“SEC. 587C. PRIORITY REVIEW.

"(a) IN GENERAL.—

[**[**"(1) An in vitro clinical test that is otherwise required to have approval under section 587B may be designated by the Secretary for priority review in accordance with this section. An application for in vitro clinical test that has been so designated may be granted approval under subsection (f), in accordance with the requirements of this section.**]**

[**[**"(2) An in vitro clinical test for which approval has been granted under this section, and for which such approval is in effect, is exempt from the requirement to obtain premarket approval under section 587B.**]**

"(b) ELIGIBILITY.—An in vitro clinical test is eligible for designation, review, or approval under this section if—

[**[**"(1) the test provides or enables more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions compared to existing approved or precertified alternatives; and**]**

[**[**"(2) it is a test—

[**[**"(A) that represents a breakthrough technology;**]**

[**[**"(B) for which no approved or precertified alternative exists;**]**

[**[**"(C) that offers a clinically meaningful advantage over existing approved or precertified alternatives, including the potential, compared to existing approved or precertified alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or**]**

[**[**"(D) the availability of which is in the best interest of patients or public health.**]**

]

"(c) DESIGNATION.—

["(1) REQUEST.—Except as provided in section 587(e), to receive breakthrough approval or approval under this section, an applicant must first request that the Secretary designate the in vitro clinical test for priority review. Such a request shall include information demonstrating that the test is eligible for designation under subsection (b).]

["(2) DETERMINATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), and prior to acceptance of an application for approval, the Secretary shall determine whether the in vitro clinical test that is the subject of the request meets the criteria described in subsection (b). If the Secretary determines that the test meets the criteria, the Secretary shall designate the test for priority review.]

["(3) REVIEW.—Review of a request under paragraph (1) shall be undertaken by a team that is composed of experienced staff and senior managers of the Food and Drug Administration.]

["(4) WITHDRAWAL.—

["(A) The designation of an in vitro clinical test under this subsection is deemed to be withdrawn, and such in vitro clinical test shall no longer be eligible for review and approval under this section, if an application for approval under subsection (f) for the test is denied.]

["(B) The Secretary may not withdraw a designation granted under this subsection based on the subsequent approval or [precertification] of another test that—

["(i) is designated under this section; or]

["(ii) was given priority review under section 515C.]

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]

"(d) EXPEDITED DEVELOPMENT AND PRIORITY REVIEW.—

["(1) For purposes of expediting the development and review of in vitro clinical tests under this section, the Secretary may take the actions and additional actions set forth in section 515B(e) when reviewing such tests under subsection (e) or (f).**]**

["(2) Any reference or authorization in section 515B(e) with respect to a device shall be deemed a reference or authorization with respect to an in vitro clinical test for purposes of this section.**]**

"(e) BREAKTHROUGH IN VITRO CLINICAL TESTS.—**[***To be supplied***]**

"(f) ANNUAL REPORT.—Unless otherwise specified by the Secretary, section 587B, requiring annual reports applies to in vitro clinical tests approved under this subsection.

"(g) SERVICE OF ORDERS.—Orders of the Secretary under this section shall be served—

["(1) in person by any officer or employee of the Department of Health and Human Services designated by the Secretary; or**]**

["(2) by mailing the order by registered mail or certified mail or electronic equivalent addressed to the applicant at his last known address in the records of the Secretary.**]**

"SEC. 587D. PRECERTIFICATION.

"(a) IN GENERAL.—

["(1) Any eligible person may seek precertification in accordance with this section.**]**

[“(2) An in vitro clinical test is exempt from premarket review under section 587A if its developer is eligible under this section and the in vitro clinical test—

[“(A) is an eligible in vitro clinical test under subsection (b)(2); and]

[“(B) falls within the scope of a precertification order issued under this section, and such order is in effect.]

]

“(b) ELIGIBILITY.—

[“(1) ELIGIBLE PERSON.—As used in this section, the term ‘eligible person’ means an in vitro clinical test developer unless, at the time such person seeks or would seek precertification, the person—

[“(A) has been found to have committed a significant violation of this Act or the Public Health Service Act, except that this subparagraph shall not apply if—

[“(i) such violation occurred more than 5 years prior to the date on which such precertification is or would be sought;]

[“(ii) such violation has been resolved; or]

[“(iii) such violation is not pertinent to any in vitro clinical test within the scope of the precertification that such person seeks or would seek; or]

]

[“(B) has been disqualified by the Secretary on the basis of actions or omissions that raise serious questions regarding whether the eligibility of such person would be in the interest of public health, such as—

[“(i) making false or misleading statements about matters relevant under this subchapter;]

[“(ii) failing to maintain required certifications under section 353 of the Public Health Service Act (42 U.S.C. 263a); or]

[“(iii) violating any requirement of this Act or the Public Health Service Act, where such violation exposes persons to serious risk of illness, injury, or death.]

]
]

[“(2) ELIGIBLE IN VITRO CLINICAL TEST.—An in vitro clinical test is eligible under subsection (a)(2) for exemption from premarket review under section 587A except as provided in this paragraph.

[“(A) An in vitro clinical test is not eligible under subsection (a)(2)for an exemption from premarket review if it is—

[“(i) a component or part of an in vitro clinical test as described under section 201(ss)(1)(E);]

[“(ii) a test platform under section 201(ss)(1)(B);]

[“(iii) an article for taking or deriving specimens from the human body under section 201(ss)(1)(C);]

[“(iv) software under section 201(ss)(1)(D), unless such software itself identifies, diagnoses, screens, measures, detects, predicts, prognoses, analyzes, or monitors a disease or condition, including a determination of the state of health, or itself selects, monitors, or informs therapy or treatment for a disease or condition; or]

[“(v) an in vitro clinical test, including reagents used in such tests, intended for use—

[“(I) in the collection, manufacture, or use of blood and blood components intended for transfusion or further manufacturing use or the recovery, manufacture, or use of human cells, tissues, and cellular and tissue-based products intended for implantation, transplantation, infusion, or transfer into a human recipient, including tests intended for use in determination of donor eligibility, donation suitability, and compatibility between donor and recipient;]

[“(II) in the diagnosis, monitoring, or treatment of hemolytic disease of the newborn, including tests intended for use in determination of compatibility between mother and newborn; or]

[“(III) in the diagnosis or monitoring of human retroviruses or human retrovirus infection.]

]
]

[“(B) An in vitro clinical test that is a first-of-a-kind in vitro clinical test, test system for home use, high risk in vitro clinical test, cross-referenced in vitro clinical test, or a direct-to-consumer in vitro clinical test is not eligible under subsection (a)(2) for an exemption from premarket review unless the Secretary makes a determination pursuant to section 587F.]

]

“(c) APPLICATION FOR PRECERTIFICATION.—

[“(1) IN GENERAL.—A person seeking precertification shall submit an application under this subsection, which shall contain the information specified under paragraph (2).]

[“(2) CONTENTS OF APPLICATION.—An application for precertification shall contain—

[“(A) a statement identifying the scope of the proposed precertification, which shall be no broader than a single technology (i.e., test method) and shall specify medical subspecialties (such as would be described by the combination of a test purpose and disease or condition) intended to be offered under the application, consistent with the procedures for analytical validation and clinical validation included in the application;]

[“(B) information showing that the person seeking precertification is an eligible person under subsection (b)(1);]

[“(C) information showing that the methods used in, and the facilities and controls used for, the development of all eligible in vitro clinical tests within the proposed scope of precertification conform to the quality system requirements of section 587J;]

[“(D) procedures for analytical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a reasonable assurance of analytical validity of all eligible in vitro clinical tests within the proposed scope of precertification;]

[“(E) procedures for clinical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a reasonable assurance of clinical validity of all eligible in vitro clinical tests within the proposed scope of precertification;]

[“(F) a notification under section 587I for each in vitro clinical test that would be precertified under the application for precertification and would be introduced or delivered for introduction into interstate commerce upon the issuance of the precertification order;]

[“(G) information concerning one or more representative in vitro clinical tests, including—

[“(i) the highest complexity test to validate and run within the developer’s stated scope, and a rationale for such selection;]

[“(ii) the information specified in section 587B(b) for the representative in vitro clinical test or tests, except that raw data shall be provided for any such in vitro clinical test unless the Secretary determines otherwise;]

[“(iii) an explanation of how the representative in vitro clinical test or tests adequately represent the range of procedures included in the application under subparagraphs (C), (D), (E), and (F); and]

[“(iv) a narrative description of how the procedures included in the application under subparagraphs (C), (D), (E), and (F) have been applied to the representative in vitro clinical test or tests;]

]

[“(H) such other information relevant to the subject matter of the application as the Secretary may require; and]

[“(I) a certification, in the opinion of the developer and to the best of his knowledge, that all information submitted in the application is truthful and accurate and that no material fact has been omitted.]

]

“(d) ACTION ON AN APPLICATION FOR PRECERTIFICATION.—

[“(1) As promptly as possible, but no later than [X days] after receipt of an application under subsection (c), the Secretary shall—

[“(A) issue a precertification order granting the application, which shall specify the scope of the precertification, if the Secretary finds that all of the grounds in paragraph (3) are met; or]

["(B) deny the application if the Secretary finds (and sets forth the basis of such finding as part of or accompanying such denial) that one or more grounds for granting the application specified in paragraph (3) are not met.**]**

]

["(2) If, after receipt of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary shall provide to the applicant a description of such deficiencies and identify the information required to correct such deficiencies.**]**

["(3) The Secretary shall grant an application under this section if, on the basis of the information submitted to the Secretary as part of the application and any other information before him or her with respect to such applicant, the Secretary finds that—

["(A) there is a showing of reasonable assurance of adequate analytical validity for all eligible in vitro clinical tests within the proposed scope of the precertification, as evidenced by the procedures for analytical validation;**]**

["(B) there is a showing of reasonable assurance of adequate clinical validity for all eligible in vitro clinical tests within the proposed scope of the precertification, as evidenced by the procedures for clinical validation;**]**

["(C) the methods used in, or the facilities or controls used for, the development of all eligible in vitro clinical tests within the proposed scope of the precertification conform to the requirements of section 587J;**]**

["(D) based on a fair evaluation of all material facts, the applicant's labeling and advertising is not false or misleading in any particular;**]**

["(E) the application does not contain a false statement of material fact;**]**

[“(F) there is a showing that the representative in vitro clinical test or tests—

[“(i) meets the standard for approval under section 587B; and]

[“(ii) adequately represent the range of procedures for analytical validation and clinical validation included in the application; and]

]

[“(G) the applicant permits authorized employees of the Food and Drug Administration or persons accredited under this Act an opportunity to inspect at a reasonable time and in a reasonable manner the facilities and all pertinent equipment, finished and unfinished materials, containers, and labeling therein, including all things (including records, files, papers, and controls) bearing on whether an in vitro clinical test is adulterated, misbranded, or otherwise in violation of this Act, and permits such authorized employees or persons accredited under this Act to view and to copy and verify all records pertinent to the application and the in vitro clinical test.]

]

[“(4) An applicant whose application has been denied may, by petition filed on or before the date that is 30 calendar days after the date upon which such applicant receives notice of such denial, obtain review thereof in accordance with section 587O.]

“(e) DURATION; SUBSEQUENT SUBMISSIONS.—

[“(1) ORDER DURATION.—A precertification order under subsection (d)(1)(A) shall remain in effect until the earliest of—

[“(A) the expiration of such precertification order under paragraph (2); or]

[“(B) the withdrawal of such precertification order under subsection (h).]

]

[“(2) EXPIRATION.—An initial precertification order under subsection (d)(1)(A) shall expire on the date that is two years after the date that such order is issued, except that if an application for renewal under paragraph (3) has been received not later than 30 days prior to the expiration of such order under this paragraph, such order shall expire on the date on which the Secretary has granted or denied the application for renewal. Any such subsequent renewal of precertification shall expire on the date that is four years after the date that such precertification order is issued.]

[“(3) RENEWAL.—[(A) Any person with a precertification order in effect with respect to development of in vitro clinical tests may seek renewal of such order provided that—

[“(i) such person is an eligible person under subsection (b)(1); and]

[“(ii) none of the information specified in subsection (c)(2) has changed.]

]

[“(B) An application for renewal under this paragraph shall include information concerning one or more representative in vitro clinical tests in accordance with subsection (c)(2)(G), except that such representative test or tests shall be different from the representative test or tests included in any prior application and shall represent a medical subspeciality that has not yet been reviewed, if applicable.]

[“(C) The Secretary’s action on an application for renewal of precertification under this paragraph shall be conducted in accordance with subsection (d), and any order resulting from such application shall be treated as a precertification order for purposes of this subchapter.]

]

[“(4) SUPPLEMENTS; REPORTS.—

[“(A) SUPPLEMENTS.—Except as provided in subparagraph (B), any person with a precertification order in effect may seek a supplement to such order upon a change or changes to the information provided in the application for precertification under subparagraphs (C), (D), and (E) of subsection (c)(2), provided that such person is an eligible person under subsection (b)(1) and that such change does not expand the scope of the precertification. A supplement may contain only information relevant to the change or changes. The Secretary’s action on a supplement shall be in accordance with subsection (d), and any order resulting from such supplement shall be treated as an amendment to a precertification order that is in effect.]

[“(B) REPORTS.—If a change or changes described in subparagraph (A) is made in order to address a potential risk to public health by adding a new specification or test method, the person may immediately implement such change or changes and shall report such changes or changes to the Secretary within 30 days.

[“(i) Any report to the Secretary under this subparagraph shall include—

[“(I) a summary of the relevant change or changes;]

[“(II) the rationale for implementing such change or changes; and]

[“(III) a description of how the change or changes were evaluated.]

]

[“(ii) Upon review of such report and a finding that the relevant change or changes are inconsistent with the standard

specified under this subparagraph, the Secretary may require a supplement under subparagraph (A).**]**

]
]

"(f) MAINTENANCE REQUIREMENTS.—For the duration of a precertification under subsection (e)(1), a holder of a precertification order shall—

["(1) use the procedures included in the relevant application, supplement, or report under subsections (b) and (e);**]**

["(2) ensure compliance with any applicable mitigating measures;**]**

["(3) maintain, and provide to the Secretary upon request, records related to any in vitro clinical test offered without premarket review under the precertification order, where those records are necessary to demonstrate compliance with applicable provisions of this Act; and**]**

["(4) comply with the notification requirements under section 587I for each in vitro clinical test offered without premarket review under the precertification order.**]**

"(g) TEMPORARY HOLD.—

["(1) IN GENERAL.—Upon one or more findings under paragraph (3), the Secretary may issue a temporary hold prohibiting any holder of a precertification order from introducing into interstate commerce an in vitro clinical test that was not previously the subject of a notification under section 587I. The temporary hold must identify the grounds for the temporary hold under paragraph (3) and the rationale for such finding.**]**

["(2) WRITTEN REQUESTS.—Any written request to the Secretary from the holder of a precertification order that a temporary hold under paragraph (1) be removed shall receive a decision, in writing and specifying the reasons therefore, within **[**180**]** days after receipt of such request. Any such request shall include information to support the removal of the temporary hold.**]**

["(3) GROUNDS FOR TEMPORARY HOLD.—A temporary hold under this subsection may be instated upon a finding or findings that the holder of a precertification order—

["(A) is not in compliance with any maintenance requirements under subsection (f);**]**

["(B) labels or advertises one or more in vitro clinical tests with false or misleading claims; or**]**

["(C) is no longer an eligible person under subsection (b)(1).**]**

]

"(h) WITHDRAWAL.—**[**(1) The Secretary may, after due notice and opportunity for informal hearing, issue an order withdrawing a precertification order if the Secretary finds that—

["(A) the application, supplement, or report under subsections (b) or (e) contains false or misleading information or fails to reveal a material fact; or**]**

["(B) such holder fails to correct false or misleading labeling or advertising upon the request of the Secretary;**]**

["(C) in connection with a precertification, the holder provides false or misleading information to the Secretary; or**]**

["(D) the holder of such precertification order fails to correct the grounds for temporary hold within a timeframe specified in the temporary hold order.**]**

]

["(2) Paragraph (1) shall not apply to any person who violates the requirements of subsections (b) or (e) unless such violation constitutes—

[“(A) a significant or knowing departure, as defined in parts 17.3 (A)(1) and (2) of title 21 of the Code of Federal Regulations, from such requirements; or]

[“(B) a risk to public health.]

]

“(i) REPORTS TO CONGRESS.—

[“(1) Not later than one year after the effective date, and annually thereafter, for a total of five years, 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, and make publicly available, including through posting on the Internet website of the Food and Drug Administration, a report containing the information required under paragraph (2).]

[“(2) The report shall at a minimum address—

[“(A) the number and type of applications for precertification filed, granted, withdrawn or denied;]

[“(B) the number of precertifications put on temporary hold under subsection (g) and the number of precertifications withdrawn under subsection (h);]

[“(C) the technologies and medical subspecialties for which precertification orders were granted;]

[“(D) the number of high-risk in vitro clinical tests offered without premarket review pursuant to precertification orders according to technology and medical subspecialty; or]

[“(E) the number of laboratories and manufacturers with precertification orders in effect.]

]

[“(3) No later than [two months] after submission of the fourth report under subsection (i)(1), the Secretary of Health and Human Services shall convene a public meeting on the program being conducted under this section. The Secretary shall invite to such meeting representatives from the in vitro clinical test industry and organizations representing patients and consumers. The public meeting shall be assigned a docket number by the Commissioner of Food and Drugs and made available for the submission of public comments.]

[“(4) The fifth report submitted under subsection (i)(1) shall include a summary of, and responses to, comments raised in the meeting and docket described in subsection (i)(3).]

“SEC. 587E. MITIGATING MEASURES.

“(a) ESTABLISHMENT OF MITIGATING MEASURES.—

“(1) ESTABLISHING, CHANGING, OR WITHDRAWING.—

“(A) ESTABLISHMENT.—If the Secretary determines that the establishment of mitigating measures is necessary for any of the reasons identified in section 587(9)(A) for any test group or test groups, the Secretary may require that in vitro clinical tests in such group or groups comply with such mitigating measures.

“(B) PROCESS.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may establish, change, or withdraw a requirement for compliance with mitigating measures under subparagraph (A) by—

“(i) publishing a proposed administrative order in the Federal Register;

“(ii) providing an opportunity for public comments; and

“(iii) after consideration of such comments, publishing a final administrative order in the Federal Register.

"(2) IN VITRO CLINICAL TESTS PREVIOUSLY REGULATED AS DEVICES.—

"(A) IN GENERAL.—Any special controls or restrictions applicable to an in vitro clinical test or test group based on prior regulation as a device, including any such special controls or restrictions established during the period beginning on the date of enactment of the Verifying Accurate Leading-edge IVCT Development Act of 2018 and ending on the effective date of such Act (as described in section 5(b) of such Act)—

"(i) shall continue to apply to such test or test group after such effective date; and

"(ii) are deemed to be mitigating measures as of such effective date.

"(B) CHANGES.—The Secretary may establish, change, or withdraw mitigating measures for such a test or test group using the procedures under paragraph (1).

"(b) DOCUMENTATION.—

"(1) TESTS SUBJECT TO PREMARKET REVIEW.—The developer of an in vitro clinical test subject to premarket review under section 587B and to which mitigating measures apply shall—

"(A) in accordance with section 587B(b)(2)(D), submit documentation to the Secretary as part of the application for the test under section 587B(b) demonstrating that such mitigating measures have been met;

"(B) if such application is approved, maintain documentation demonstrating that such mitigating measures continue to be met; and

"(C) make such documentation available to the Secretary upon request or inspection.

"(2) OTHER TESTS.—The developer of an in vitro clinical test that is marketed within the scope of a [precertification] or other exemption from premarket review under section 587B and to which mitigating measures apply shall—

"(A) maintain documentation in accordance with the quality systems requirements in section 587J demonstrating that such mitigating measures continue to be met;

"(B) make such documentation available to the Secretary upon request or inspection; and

"(C) include in the performance summary for such test a description of how such mitigating measures are met, if applicable.

"SEC. 587F. REGULATORY PATHWAY DESIGNATION.

"(a) IN GENERAL.—Based on new information, including the establishment of mitigating measures under section 587E, and after considering all available evidence respecting a test group, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person—

"(1) revoke any exemption or requirement in effect under this subchapter with respect to such test group; or

"(2) determine that the test group is subject to premarket review under section 587B, is eligible for [precertification in accordance with section 587D(b)(2)(B)], or is exempt from premarket review under section 587B or other requirements of this subchapter.

"(b) PROCESS.—Any action under subsection (a), including any revocation, shall be made by publication of a [notice] of such proposed action in the Federal Register, consideration of comments to a public docket on such proposal, and publication of a final [notice] in the Federal Register, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

"SEC. 587G. ADVISORY COMMITTEES.

"(a) IN GENERAL.—The Secretary may establish advisory committees to make recommendations to the Secretary regarding in vitro clinical tests for the purposes of—

"(1) determining whether to approve an application for an in vitro clinical test submitted under this subchapter, including for evaluating the analytical validity, clinical validity, and as applicable safety, of in vitro clinical tests;

"(2) evaluating the potential effectiveness of mitigating measures for a determination on the applicable regulatory pathway under section 587 or risk evaluation for an in vitro clinical test or test group;

"(3) establishing quality system requirements under section 587J or applying such requirements to in vitro clinical tests developed or imported by developers; and

"(4) such other purposes as the Secretary determines appropriate.

"(b) APPOINTMENTS.—

"(1) VOTING MEMBERS.—The Secretary shall appoint to each committee established under subsection (a), as voting members, individuals who are qualified by training and experience to evaluate in vitro clinical tests for the purposes specified in subsection (a), including individuals with knowledge of in vitro clinical tests, laboratory operations, and the use of in vitro clinical tests. The Secretary shall designate one member of each committee to serve as chair thereof.

"(2) NONVOTING MEMBERS.—In addition to the individuals appointed pursuant to paragraph (1), the Secretary shall appoint to each committee established under subsection (a), as nonvoting members—

"(A) a representative of consumer interests; and

"(B) a representative of interests of the in vitro clinical test industry.

"(3) LIMITATION.—No individual who is in the regular full-time employ of the United States and engaged in the administration of this

Act may be a member of any advisory committee established under subsection (a).

"(4) COMPENSATION.—Members of an advisory committee established under subsection (a), while attending meetings or conferences or otherwise engaged in the business of the advisory committee—

"(A) shall receive compensation **[**at rates to be fixed by the Secretary**]**; and

"(B) may be allowed travel expenses as authorized by section 5703 of title 5, United States Code, for employees serving intermittently in the Government service.

"(c) GUIDANCE.—The Secretary may issue guidance on the policies and procedures governing advisory committees established under subsection (a).

"SEC. 587H. REQUEST FOR INFORMAL FEEDBACK.

"Before submitting a premarket application or **[**precertification package**]** for an in vitro clinical test—

"(1) the developer of the test may submit to the Secretary a written request for a meeting or conference to discuss and provide information relating to—

"(A) the submission process and the type and amount of evidence expected to demonstrate the relevant standard;

"(B) **[**which regulatory pathway is appropriate for an in vitro clinical test; or**]**

"(C) **[**an investigation plan for an in vitro clinical test, including a clinical protocol; and**]**

"(2) upon receipt of such a request, the Secretary shall—

"(A) within [X] calendar days after such receipt, or within such time period as may be agreed to by the developer, meet or confer with the developer submitting the request; and

"(B) within [X] calendar days after such meeting or conference, provide to the developer a written record or response describing the issues discussed and conclusions reached in the meeting or conference.

"SEC. 587I. REGISTRATION AND NOTIFICATION.

"(a) REGISTRATION OF ESTABLISHMENTS FOR IN VITRO CLINICAL TESTS"..—.

"(1) Each person who is an in vitro clinical test developer— or a contract manufacturer (including contract packaging), contract sterilizer, repackager, relabeler, distributor, or a person who introduces or proposes to begin the introduction or delivery for introduction into interstate commerce any in vitro clinical test shall—

"(A) During the period beginning on October 1 and ending on December 31 of each year, register with the Secretary the name of such person, places of business of such person, all establishments engaged in the activities specified under this paragraph, the unique facility identifier of each such establishment, and a point of contact for each such establishment, including an electronic point of contact; and

"(B) Submit an initial registration containing the information required under subparagraph (A) not later than—

"(i) the date of implementation of this section if such establishment is engaged in any activity described in this paragraph on the date of enactment of this section, unless the Secretary establishes by guidance a date later than such implementation date for all or a category of such establishments; or

"(ii) 30 days prior to engaging in any activity described in this paragraph after enactment of this section, if such establishment is not engaged in any activity described in this paragraph on the date of enactment of this section.

"(2) The Secretary may assign a registration number or unique facility identifier to any person or any establishment registered in accordance with this section. Registration information shall be made publicly available by publication on the website maintained by the Food and Drug Administration.

"(3) Every person or establishment that is required to be registered with the Secretary under this section shall be subject to inspection pursuant to section 704.

"(b) NOTIFICATION INFORMATION FOR IN VITRO CLINICAL TESTS.—

"(1) Each developer of an in vitro clinical test shall submit a notification to the Secretary containing the information described in this subsection in accordance with the applicable schedule described under subsection (c). Such notification shall be prepared in such form and manner as the Secretary may specify in guidance. Notification information shall be submitted to the comprehensive test information system in accordance with section 587U.

"(2) Each developer shall electronically submit to the comprehensive test information system the following information for each in vitro clinical test for which such person is a developer in the form and manner prescribed by the Secretary:

"(A) name of the establishment and its unique facility identifier;

"(B) contact information for the official correspondent for the notification;

"(C) name (common name and trade name, if applicable) of the in vitro clinical test; and its test notification number (when available).

"(D) CLIA certificate number for any laboratory certified by the Secretary under section 263a of title 42 that meets the requirements for performing high-complexity testing that is the developer of the in vitro clinical test, and CLIA certificate number for any laboratory under common ownership that is performing the test developed by such test developer;

"(E) the appropriate category under this subchapter under which the in vitro clinical test is offered, introduced or marketed, such as — **[**precertification**]**, low-risk exemption, premarket approval, grandfathering, or another specified category;

"(F) brief narrative description of the in vitro clinical test;

"(G) substance or substances measured by the in vitro clinical test, such as analyte, protein, or pathogen;

"(H) type or types of specimen or sample;

"(I) test method;

"(J) test purpose, as described in section 201(ss)(1)(A), such as screening, predicting, or monitoring;

"(K) disease or condition for which the in vitro clinical test is intended for use;

"(L) intended patient population;

"(M) context of use, such as in a clinical laboratory, in a health care facility, prescription home use, over-the-counter use, or direct-to-consumer testing.

"(N) summary of in vitro clinical test analytical performance and clinical performance, and as applicable lot release criteria;

"(O) statement describing conformance with applicable mitigating measures, restrictions, and standards;

"(P) representative labeling for the in vitro clinical test; and

"(Q) a certification that the information submitted is truthful and accurate.

"(3) The Secretary may assign a test notification number to each in vitro clinical test that is the subject of a notification under this section. The process for assigning test notification numbers may be established through guidance, and may include the recognition of standards, formats, or conventions developed by a third-party organization.

"(4) A person who is not a developer but is otherwise required to register pursuant to subsection (a) shall submit an abbreviated notification to the Secretary containing the information described in subparagraphs (A) through (C) of paragraph (2), the name of the developer, and any other information described in paragraph (2) as may be specified by the Secretary in guidance, as applicable to the activities of each class of persons required to register. The information shall be submitted in accordance with the applicable schedule described under subsection (c). Such abbreviated notification shall be prepared in such form and manner as the Secretary may specify in guidance. Notification information shall be submitted to the comprehensive test information system in accordance with section 587U.

"(c) TIMELINES FOR SUBMISSION.—

"(1) For an in vitro clinical test that was listed as a device under section 510(j) prior to the date of enactment of this section, a person shall maintain a device listing under section 510 until such time as the system for submitting the notification information required under subsection (b) becomes available to in vitro clinical test developers, and thereafter shall submit the notification information no later than **[**X**]**.

"(2) For an in vitro clinical test that is subject to the grandfathering provisions of section 587A(c), a person shall submit the notification information required under subsection (b) no later than **[**X**]** months after the system for submitting the notification becomes available.

"(3) For an in vitro clinical test that is not subject to paragraph (1) or (2), a person shall submit the required notification information prior to offering, introducing, or marketing the in vitro clinical test as follows:

"(A) For an in vitro clinical test that is not exempt from premarket approval, a person shall submit the required notification information no later than ten business days after the date of approval of the premarket approval application.

"(B) For an in vitro clinical test that is exempt from premarket approval, a person shall submit the required notification information at least ten business days prior to offering the in vitro test for clinical use or otherwise introducing the in vitro clinical test into interstate commerce.

"(4) Each person required to submit notification information under this section shall update such information within ten business days of any change that causes any previously notified information to be inaccurate or incomplete.

"(5) Each person required to submit notification information under this section shall update its information annually during the period beginning on October 1 and ending on December 31 of each year and certify that the information contained in such notification is truthful and accurate, and shall pay the annual notification fee prescribed in section 587W.

"(d) PUBLIC AVAILABILITY OF NOTIFICATION INFORMATION.—

"(1) Notification information submitted pursuant to this section shall be made publicly available by publication on the website of the Food and Drug Administration after the in vitro clinical test developer has certified the information as truthful and accurate.

"(2) Notification information for an in vitro clinical test that is subject to premarket approval or **[**precertification**]** shall remain confidential until such date as the in vitro clinical test receives the applicable premarket approval or **[**precertification**]**.

"(3) The registration and notification information requirements described in subsections (a) and (b) shall not apply to the extent the Secretary determines that such information is restricted from disclosure pursuant to another statute, including information relating to national security or countermeasures.

"SEC. 587J. QUALITY SYSTEM REQUIREMENTS.

"(a) APPLICABILITY.—

"(1) Each developer and each other person required to register under section 587I(a)(1) shall establish and maintain a quality system in accordance with the applicable requirements set forth in subsection (b), except as provided in section 587A.

"(2) A developer that operates its own clinical laboratory certified by the Secretary under section 263a of title 42 of the United States Code that meets the requirements for performing high-complexity testing and develops its own in vitro clinical test or tests or modifies another developer's in vitro clinical test in that certified laboratory in a manner described in section 587(6), where such in vitro clinical test or in vitro clinical tests are for use only within that certified laboratory, shall establish and maintain with respect to such test or tests a quality system that complies with the requirements set forth in subsection (b)(2). The applicable requirements set forth in subsection (b)(1) shall apply to any test platform, article for taking or deriving specimens from the human body, component or part that is developed for use by a clinical laboratory to which the first sentence of this paragraph applies.

"(3) A clinical laboratory certified by the Secretary under section 263a of title 42 of the United States Code that meets the requirements for performing high-complexity testing must comply with the applicable quality system requirements under subsection (b) no later than the date of implementation of this subchapter.

"(4) As necessary, the Secretary shall amend part 820 of title 21 of the Code of Federal Regulations, or successor regulations, to implement the provisions of this **[**section**]**. In considering such amendment, the Secretary shall consider whether and to what extent international harmonization might be appropriate. Until such amendment takes effect, such regulations shall be interpreted to apply to in vitro clinical tests and developers.

"(5) The Secretary may establish such other regulations under this section as are necessary to assure the analytical and clinical validity of

in vitro clinical tests, or the safety of articles for taking or deriving specimens from the human body.

"(6) In implementing quality system requirements for test developers under this section, the Secretary shall—

"(A) for purposes of facilitating international harmonization, take into account whether the developer participates in an audit program in which the United States participates or the United States recognizes or conforms with standards recognized by the Secretary; and

"(B) ensure a **[**least burdensome**]** approach by leveraging, to the extent applicable, the quality assurance requirements applicable to developers certified by the Secretary under section 263a of title 42 of the United States Code.

"(b) QUALITY SYSTEM REQUIREMENTS.—

"(1) IN GENERAL.—The quality system requirements applicable under this section shall, including applying or amending part 820 of title 21 of the Code of Federal Regulations as provided in subsection (a)(4)—

"(A) apply only with respect to the design, development, validation, production, manufacture, preparation, propagation, or assembly of an in vitro clinical test, offered under this subchapter;

"(B) not apply with respect to laboratory operations; and

"(C) shall include each of the following, subject to paragraphs (2) and (3):

"(i) Management responsibility.

"(ii) Quality audit.

"(iii) Personnel.

"(iv) Design controls.

"(v) Document controls.

"(vi) Purchasing controls, including supplier controls.

"(vii) Identification and Traceability.

"(viii) Production and process controls.

"(ix) Acceptance activities.

"(x) Nonconforming product.

"(xi) Corrective and preventive action.

"(xii) Labeling and packaging controls.

"(xiii) Handling, storage, distribution, and installation.

"(xiv) Records.

"(xv) Servicing.

"(xvi) Statistical techniques.

"(2) QUALITY SYSTEM REQUIREMENTS FOR CERTAIN LABORATORIES.—With regard to establishing quality system requirements under this Act, including applying or amending part 820 of title 21 of the Code of Federal Regulations as provided in subsection (a)(4), quality system requirements applicable to the in vitro clinical tests and developers described in subsection (a)(2) shall consist of the following:

"(A) Design controls.

"(B) Purchasing controls, including supplier controls.

"(C) Acceptance activities.

"(D) Corrective and preventative action.

"(E) Records.

"(3) QUALITY SYSTEM REQUIREMENTS FOR CERTAIN LABORATORIES DISTRIBUTING PROTOCOLS.—

"(A) With regard to establishing quality system requirements under this Act, including applying or amending part 820 of title 21 of the Code of Federal Regulations as provided in subsection (a)(4), quality system requirements applicable to the developer and in vitro clinical test distributed under subparagraph (B) shall consist of the following provided that the conditions of subparagraph (B) are met:

"(i) The requirements in paragraph (2).

"(ii) The labeling requirements in subparagraph (1)(L).

"(iii) The requirement to maintain records of the laboratories to which the test protocol is distributed.

"(B) To be eligible for subparagraph (A), the following conditions must be met—

"(i) the laboratory distributing the protocol is certified by the Secretary under section 263a of title 42 of the United States Code and meets the requirements for performing high-complexity testing;

"(ii) the laboratory develops its own in vitro clinical test or modifies another developer's in vitro clinical test in a manner described in section 587(6); and

"(iii) the laboratory distributes the test protocol for such test only to another laboratory that—

"(I) is certified by the Secretary under section 263a of title 42 of the United States Code and meets the requirements for performing high-complexity testing; and

"(II) is within the same corporate organization and having common ownership by the same parent corporation; or as applicable, is within the Laboratory

Response Network of the Centers for Disease Control and Prevention.

"SEC. 587K. LABELING REQUIREMENTS.

"(a) IN GENERAL.—An in vitro clinical test shall bear or be accompanied by labeling, and a label as applicable, that meet the requirements set forth in subsections (b) and (c), and any other requirements established by the Secretary by regulations, unless such test is exempt as specified in subsection (d) or (e).

"(b) LABELS.—

"(1) The label of an in vitro clinical test shall meet the requirements set forth in paragraph (2), except this requirement shall not apply to an in vitro clinical test that consists solely of a test protocol, or that is designed, manufactured, and used solely within a single laboratory certified by the Secretary under section 263a of title 42 that meets the requirements for performing high-complexity testing.

"(2) The label of an in vitro clinical test shall state the name and place of business of its developer and meet the requirements set forth in section 809.10(a) of title 21 of the Code of Federal Regulations, or any successor regulation. The Secretary shall amend such regulation, as necessary, to ensure its applicability to in vitro clinical tests. Until such amendment takes effect, such regulations shall be interpreted to apply to in vitro clinical tests.

"(c) LABELING.—

"(1) Labeling accompanying an in vitro clinical test, including labeling in the form of a package insert, standalone laboratory reference document, or other similar document except the labeling specified in paragraph (2), shall include adequate directions for use and shall meet the requirements set forth in section 809.10(b) and (g) of title 21 of the Code of Federal Regulations, or any successor regulation, except as provided in subsection (d). Labeling in the form of a package insert shall also include the information in paragraph (2)(A) through (C). The Secretary shall amend such regulation, as necessary, to ensure its applicability to in vitro clinical tests. Until such amendment takes

effect, such regulation shall be interpreted to apply to in vitro clinical tests.

"(2) Labeling accompanying an in vitro clinical test that is in the form of a test report template or ordering information shall include—

"(A) the test notification number that was provided to the developer at the time of notification;

"(B) instructions for how and where to report an adverse event under section 587L;

"(C) instructions for how and where to access the performance summary data displayed in the notification database for the test;

"(D) the intended use of the in vitro clinical test;

"(E) any warnings;

"(F) contraindications; and

"(G) limitations.

"(3) Labeling for an in vitro clinical test used for immunohematology testing shall meet the following additional requirements set forth in part 660 of the Code of Federal Regulations (or any successor regulation), as they appear on the date of enactment of this subchapter if to the extent such test fell within the scope of such regulations immediately prior to such date of enactment:

"(A) Section 660.28 (a)(1)(i); (a)(1)(ii)(A) and (F); (a)(2)(i) and (xiv); and (a)(4);

"(B) Section 660.35 (a)(1)(ii); (a)(2) - (4); (a)(6) - (9); and

"(C) Section 660.55 (a)(1)(i); (a)(1)(ii)(A) and (H).

The Secretary shall amend such regulations, as necessary, to ensure their applicability to in vitro clinical tests. Until such amendment takes effect, such regulations shall be interpreted to apply to in vitro clinical tests.

"(d) EXEMPTIONS AND ALTERNATIVE REQUIREMENTS.—

"(1) IN GENERAL.—For an in vitro clinical test that is designed, manufactured, and used solely within a single high complexity laboratory certified by the Secretary under section 353 of the Public Health Service Act, and owned and operated by the developer of such in vitro clinical test, the requirement in section 809.10(b) of title 21 of the Code of Federal Regulations that the labeling 'state in one place' all of the required information may be satisfied by the laboratory posting such required information on its website or in multiple documents, if such documents are maintained and accessible in one place.

"(2) LABELING.—The labeling for a test platform, when such platform is not committed to specific diagnostic procedures or systems, is not required to bear the information indicated in paragraphs (3), (4), (5), (7), (8), (9), (10), (11), (12), and (13) of section 809.10(b) of title 21 of the Code of Federal Regulations, as it appears on the date of enactment of this subchapter and amended thereafter.

"(3) REAGENT LABELING.—For purposes of compliance with subsection (c)(1), the labeling for a reagent intended for use as a replacement in a diagnostic system may be limited to that information necessary to identify the reagent adequately and to describe its proper use in the system.

"(4) LAB RESEARCH OR INVESTIGATIONAL USE.—A shipment or other delivery of an in vitro diagnostic test shall be exempt from the requirements of subsection (b) and (c)(1) and from any standard promulgated under part 861 of title 21 of the Code of Federal Regulations, or any successor regulation, provided that the conditions set forth in 809.10(c) of such title, as it appears on the date of enactment of this subchapter and amended thereafter are met. The Secretary shall amend such regulations, as necessary, to ensure their applicability to in vitro clinical tests. Until such amendment takes effect, such regulations shall be interpreted to apply to in vitro clinical tests.

"(5) GENERAL PURPOSE LABORATORY REAGENTS.—The labeling of general purpose laboratory reagents, such as hydrochloric acid, whose uses are generally known by persons trained in their use need not bear the directions for use required by subsection (b) and subsection (c)(1).

"(6) ANALYTE SPECIFIC REAGENTS.—The labeling of analyte specific reagents, such as monoclonal antibodies, deoxyribonucleic acid probes, viral antigens, ligands and other similar items, shall bear the information set forth in part 809.10(e)(1) through (2) of title 21 of the Code of Federal Regulations as it appears on the date of enactment of this subchapter and amended thereafter and shall bear the following statement: 'This product is intended solely for further development of an in vitro clinical test and is exempt from most FDA regulation. This product must be evaluated by the in vitro clinical test developer in accordance with supplier controls if it is used with or in the development of an in vitro clinical test.'. If the labeling of an analyte specific reagent bears the information set forth in this paragraph, it need not bear the information required by subsection (c)(1).

"(7) OVER-THE-COUNTER TEST SAMPLE COLLECTION SYSTEMS LABELING.—The labeling for over-the-counter (OTC) test sample collection systems for drugs of abuse testing shall bear the name and place of business of the developer and the information specified in part 809.10(f) of title 21 of the Code of Federal Regulations as it appears on the date of enactment of this subchapter and amended thereafter, in language appropriate for the intended users. If the labeling of such OTC test sample collection system bears the information set forth in this paragraph (4)(G), it need not bear the information required by subsection (c)(1).

"(e) TESTS IN THE STRATEGIC NATIONAL STOCKPILE.—

"(1) The Secretary may grant an exception or alternative to any provision listed in this section, unless explicitly required by a statutory provision outside this section, for specified lots, batches, or other units of an in vitro clinical test, if the Secretary determines that compliance with such labeling requirement could adversely affect the safety, effectiveness, or availability of such products that are or will be included in the Strategic National Stockpile.

"(2) The Secretary may issue regulations amending section 809.11 of title 21 of the Code of Federal Regulations or any successor regulation to apply in full or in part to in vitro clinical tests and in vitro clinical test developers.

"(f) GUIDANCE.—The Secretary may, in collaboration with developers, issue guidance on standardized, general content and format for in vitro clinical test labeling to help ensure compliance with applicable requirements in this subsection.

"SEC. 587L. ADVERSE EVENT REPORTING.

"(a) APPLICABILITY.—

"(1) Each in vitro clinical test developer shall establish, maintain, and implement a system for reporting adverse events in accordance with subsection (b), except as provided in section 587A.

"(2) The Secretary shall amend part 803 of title 21 of the Code of Federal Regulations (or any successor regulations) to apply to in vitro clinical tests. Until such amendment takes effect, such part shall be interpreted to apply to in vitro clinical tests.

"(3) The Secretary may by regulation require reporting of such other adverse events as determined by the Secretary to be necessary to be reported to assure the analytical and clinical validity of in vitro clinical tests, and in addition, the safety of articles for taking or deriving specimens from the human body.

"(b) ADVERSE EVENT REPORTING REQUIREMENTS.—

"(1) Each in vitro clinical test developer shall report to the Secretary whenever the developer receives or otherwise becomes aware of information that reasonably suggests that one of its in vitro clinical tests—

"(A) may have caused or contributed to a death or serious injury;

"(B) has malfunctioned and the in vitro clinical test, or a similar in vitro clinical test developed or marketed by the in vitro clinical test developer, would be likely to cause or contribute to a death or serious injury if the malfunction were to recur; and

"(C) such adverse event cannot be directly attributed to laboratory error.

"(2) For purposes of this section, the term 'serious injury' shall mean—

"(A) a critical delay in diagnosis or causing the absence, delay, or discontinuation of appropriate medical treatment; or

"(B) an injury that—

"(i) is life threatening;

"(ii) results in permanent impairment of a body function or permanent damage to a body structure; or

"(iii) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

"(3) Reports required under this section shall be submitted as follows:

"(A) An individual adverse event reports shall be submitted for the following events not later than—

"(i) 5 calendar days after an in vitro clinical test developer receives or otherwise becomes aware of information that reasonably suggests the adverse event involves a patient death; or

"(ii) 5 calendar days after an in vitro clinical test developer receives or otherwise becomes aware of information that reasonably suggests the event presents an imminent threat to public health.

"(B) Quarterly reports shall be submitted for all other adverse events and no later than the end of the quarter following the quarter in which the adverse event information was received by the in vitro clinical test developer.

"SEC. 587M. CORRECTIONS AND REMOVALS.

"(a) APPLICABILITY.—

"(1) The Secretary shall amend part 806 of title 21 of the Code of Federal Regulations (or any successor regulations) to apply to in vitro clinical tests. Until such amendment takes effect, such part shall be interpreted to apply to in vitro clinical tests.

"(2) The Secretary may by regulation require reporting of such corrections and removals as determined by the Secretary to be necessary to be reported to assure the analytical and clinical validity of in vitro clinical tests, and in addition, the safety of articles for taking or deriving specimens from the human body.

"(b) REPORTS OF REMOVALS AND CORRECTIONS.—Each in vitro clinical test developer or importer shall report to the Secretary any correction or removal of an in vitro clinical test undertaken by such developer or importer if the removal or correction was undertaken—

"(1) to reduce the risk to health posed by the in vitro clinical test;

"(2) to remedy a violation of this Act caused by the in vitro clinical test which may present a risk to health;

"(3) the developer or importer shall submit any report required under this subsection to the Secretary within 10 business days of initiating such correction or removal; or

"(4) a developer or importer of an in vitro clinical test who undertakes a correction or removal of an in vitro clinical test which is not required to be reported under this subsection shall keep a record of such correction or removal.

"(c) DEFINITIONS.—For purposes of this section, the terms 'correction' and 'removal' do not include routine servicing.

"SEC. 587N. RESTRICTED IN VITRO CLINICAL TESTS.

"(a) APPLICABILITY.—

"(1) IN GENERAL.—The Secretary, in issuing an approval **[**or precertification**]** of an in vitro clinical test of a category described in paragraph (3) may require that such test be restricted to sale, distribution, or use upon such conditions as the Secretary may prescribe under paragraph (2).

"(2) CONDITIONS PRESCRIBED BY THE SECRETARY.—The conditions prescribed by the Secretary under this paragraph, with respect to an in vitro clinical test described in paragraph (3), are those conditions which the Secretary determines due to the potentiality for harmful effect of such test (including any resulting absence, delay, or discontinuation of appropriate medical treatment), are necessary to assure the analytical or clinical validity of the test, or the safety of an article for taking or deriving specimens from the human body.

"(3) IN VITRO CLINICAL TESTS SUBJECT TO RESTRICTIONS.—The restrictions authorized under this section may be applied by the Secretary to any high-risk in vitro clinical test, prescription home-use in vitro clinical test, direct-to-consumer in vitro clinical test, or over-the-counter in vitro clinical test.

"(4) PROMULGATION OF REGULATIONS.—In addition to imposing restrictions under paragraph (1), the Secretary may promulgate regulations restricting the sale, distribution, or use of any in vitro clinical test described in paragraph (3), based on such conditions as may be prescribed by the Secretary under paragraph (2) with respect to such test.

"(b) LABELING AND ADVERTISING OF A RESTRICTED IN VITRO CLINICAL TEST.—**[***To be supplied***]**

"(c) REQUIREMENTS PRIOR TO ENACTMENT.—An in vitro clinical test that was offered, sold, or distributed as a restricted device prior to the enactment date of this subchapter shall continue to comply with the applicable restrictions imposed under section 515 or section 520(e) until the effective date of restrictions issued under subsection (a).

"SEC. 587O. APPEALS.

"(a) IN GENERAL.—The Secretary shall establish by guidance an appeals process for the review of determinations made by the Secretary under this subchapter, within **[**X**]** months after the effective date of **[**this subchapter**]**.

"(b) TIMING FOR CERTAIN APPEALS.—With respect to a premarket determination approving or disapproving an application under sections 587B, 587D, 587R, or 587S the applicant may, by petition filed on or before the day that is 30 days after the date on which the Secretary issues the order approving or disapproving such application, obtain review of such determination under the appeals process established pursuant to subsection (a).

"(c) FINAL ACTION FOR JUDICIAL REVIEW.—The process established under subsection (a) shall provide for a decision constituting final agency action not later than 180 calendar days after the date on which the appeal is first submitted.

"(d) ADVISORY PANELS.—The process established under subsection (a) shall permit the appellant to request review by an advisory committee established under section 587G.

"SEC. 587P. ACCREDITED PERSONS.

"(a) IN GENERAL.—

["(1) REVIEW OF APPLICATIONS.—

["(A) The Secretary may accredit persons for the purpose of reviewing applications for **[**precertification**]** and applications for premarket approval of an in vitro clinical test, and making recommendations to the Secretary with respect to such applications, subject to the requirements of this section.**]**

["(B) The Secretary shall issue guidance on the factors that the Secretary will use in determining whether a test group or a scope of **[**precertification**]** is eligible for review by an accredited person.**]**

[“(C) In making a recommendation to the Secretary under this paragraph, an accredited person shall notify the Secretary in writing of the reasons for the recommendation concerning the application.]

[“(D) Not later than [X] days after the date on which the Secretary is notified of a recommendation under subparagraph (C) by an accredited person with respect to an application, the Secretary shall make a determination with respect to such application.]

]

“(2) INSPECTIONS.—

“(A) The Secretary may accredit persons for the purpose of conducting inspections under section 704 of in vitro clinical test developers and other persons required to register pursuant to section 587I, subject to the requirements of this section.

“(B) The Secretary shall issue guidance on the factors that the Secretary will use in determining whether an in vitro clinical test developer or other registered person is eligible for inspection by an accredited person.

“(C) Persons accredited to conduct inspections, when conducting such inspections, shall record in writing their specific observations and shall present their observations to the establishment’s designated representative. Additionally, such accredited person shall prepare and submit to the Secretary an inspection report in a form and manner designated by the Secretary for conducting inspections, taking into consideration the goals of international harmonization of quality systems standards. Any official classification of the inspection shall be determined by the Secretary.

“(D) Any statement or representation made by an employee or agent of an establishment to a person accredited to conduct inspections shall be subject to section 1001 of title 18, United States Code.

"(E) Nothing in this section affects the authority of the Secretary to inspect any in vitro clinical test developer or other person registered under section 587I.

"(b) ACCREDITATION.—

"(1) ACCREDITATION PROGRAM.—

"(A) The Secretary may provide for accreditation of persons to perform the duties specified under **[**subsection (a)**]** for some or all eligible in vitro clinical tests through programs administered by the Food and Drug Administration, by other non-Federal government agencies, or by qualified nongovernmental organizations.

"(B) The Secretary shall issue guidance on the criteria that the Secretary will use to accredit or deny accreditation to a person who requests to perform any of the duties specified under **[**subsection (a)**]**.

"(C) The Secretary shall not accredit or maintain accreditation for a person unless such person meets the minimum qualifications required under subsection (c).

"(D) The Secretary shall publish on the website of the Food and Drug Administration a list of persons who are accredited under this section. Such list shall be updated on at least a monthly basis. The list shall specify the particular activity or activities under this section for which the person is accredited.

"(2) ACCREDITATION PROCESS.—

"(A) The Secretary shall issue guidance specifying the process for submitting a request for accreditation and reaccreditation under this section, including the form and content of information to be submitted in such a request.

"(B) The Secretary shall respond to a request for accreditation or reaccreditation within 90 days of the receipt of the request. The Secretary's response may be to accredit or reaccredit the person, to

deny accreditation, or to request additional information in support of the request.

"(C) The accreditation of a person shall specify the particular activity or activities under [subsection (a)] for which such person is accredited, including if the activity is limited to certain eligible in vitro clinical tests.

"(D) The Secretary may audit the performance of persons accredited under this section for purposes of assuring that they continue to meet the published criteria for accreditation, and may modify the scope or particular activities for which a person is accredited if the Secretary determines that such person fails to meet one or more criteria for accreditation.

"(E) The Secretary may suspend or withdraw accreditation of any person accredited under this section, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or the published criteria for accreditation, or poses a threat to public health, or fails to act in a manner that is consistent with the purposes of this section.

"(F) Accredited persons must be reaccredited at least every 2 years.

"(c) QUALIFICATIONS OF ACCREDITED PERSONS.—

"(1) An accredited person shall, at a minimum, meet the following requirements:

"(A) Such person may not be an employee of the Federal Government.

"(B) Such person shall not engage in the development of in vitro clinical tests and shall not be a person required to register under section 587I.

"(C) Such person shall not be owned or controlled by, and shall have no organizational, material or financial affiliation with,

an in vitro clinical test developer or other person required to register under section 587I.

"(D) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

"(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices.

"(F) Such person shall include in its request for accreditation a commitment to, at the time of accreditation and at any time it is performing activities pursuant to this section—

"(i) certify that the information reported to the Secretary accurately reflects the data or operations reviewed;

"(ii) limit work to that for which competence and capacity are available;

"(iii) treat information received or learned, records, reports, and recommendations as proprietary information of the person submitting such information; and

"(iv) in conducting the activities for which the person is accredited in respect to a particular in vitro clinical test, protect against the use of any employee or consultant who has a financial conflict of interest regarding that in vitro clinical test.

"(2) The Secretary may waive any requirements in subparagraphs (1)(A), (1)(B), or (1)(C) upon making a determination that such person has implemented other appropriate controls sufficient to ensure a competent and impartial review.

"(d) COMPENSATION OF ACCREDITED PERSONS.—

["(1) **[**Compensation of an accredited person who reviews an application for **[**precertification**]** or an application for premarket approval shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.**]]**

"(2) Compensation of an accredited person who is conducting an inspection under section 704 shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

"(e) COOPERATIVE AGREEMENTS.—The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether in vitro clinical tests intended for use in the United States by a person whose facility is located outside the United States shall be refused admission on any of the grounds set forth in section 801(a).

"SEC. 587Q. STANDARDS.

"(a) IN GENERAL.—The Secretary may by order establish performance standards for an in vitro clinical test or test group to provide reasonable assurance of the analytical validity, clinical validity, or as applicable safety, of that in vitro clinical test or test group.

"(b) CONSENSUS STANDARDS.—In establishing performance standards under subsection (a), the Secretary may recognize and adopt, in whole or in part, consensus standards developed by national or international standards development organizations. The Secretary shall issue guidance establishing the criteria and process for such recognition and adoption.

"(c) ORDER PROCESS.—In establishing a standard under this section, the Secretary shall issue a draft order proposing to establish a performance standard and shall provide for a comment period of not less than 60 days. The Secretary in his discretion, at his own initiative or in response to a petition by any interested person, may choose to seek the recommendation of an advisory committee concerning a proposed standard either prior to or after issuance of a proposed order. After considering the comments, the Secretary shall issue a final order adopting the proposed standard, adopting a modification of the proposed standard, or terminating the proceeding.

"(d) AMENDMENT PROCESS.—The procedures established in this section or in guidance issued under this section shall apply to amendment of an existing performance standard.

"SEC. 587R. INVESTIGATIONAL USE.

"(a) IN GENERAL.—Except as provided in subsection (c), an in vitro clinical test for investigational use shall be exempt from the requirements of this subchapter other than sections 587A, 587O, and 587V.

"(b) AMENDMENTS.—The Secretary shall amend part 812 of title 21 of the Code of Federal Regulations, or successor regulations, to apply as the Secretary deems appropriate to in vitro clinical tests and to implement the requirements in subsection (c). The Secretary shall amend parts 50, 54, and 56 of title 21 of the Code of Federal Regulations, or successor regulations, to apply as the Secretary deems appropriate to in vitro clinical tests. Until each such amendment takes effect, each such regulation shall be interpreted to apply to in vitro clinical tests.

"(c) APPLICATION FOR AN EXEMPTION.—

"(1) IN GENERAL.—

"(A) In the case of an in vitro clinical test the investigational use of which poses a significant risk, a sponsor of an investigation of such a test seeking an investigational use exemption shall submit to the Secretary an investigational use application with respect to the test in accordance with paragraphs (2) and (3). For purposes of this subparagraph, the term 'significant risk' means, with respect to an in vitro clinical test that is the subject of an investigational use application, that the use of the test—

"(i) is a use of substantial importance in performing an activity or activities described in subsection (ss)(1)(A) for, a serious or life-threatening disease or condition without confirmation of the diagnosis by a medically established means;

"(ii) requires an invasive sampling procedure; or

"(iii) otherwise presents a reasonably foreseeable serious risk to the health of a human subject.

"(B) In the case of an in vitro clinical test, the investigational use of which does not pose a significant risk—

"(i) the sponsor of such investigation shall comply with—

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

"(II) such other requirements as the Secretary may determine to be necessary for the protection of the public health and safety, including the monitoring of investigations conducted with such test, the establishment and maintenance of records, or the submission to the Secretary of reports of data obtained as a result of the investigational use of the in vitro clinical test during the period covered by the exemption; and

"(ii) the sponsor may rely on any exception or exemption identified in paragraph (5)(B) or as established by the Secretary in regulations issued under subsection (b).

"(2) APPLICATION CONTENTS.—An investigational use application shall be submitted in such time and manner and contain such information as the Secretary may require in regulation, and shall include assurances to the satisfaction of the Secretary that the sponsor involved shall, with respect to the in vitro clinical test that is the subject of the application—

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

"(B) submit to the Secretary reports of data obtained as a result of the investigational use of the in vitro clinical test during the period covered by the exemption that the Secretary reasonably determines will enable the Secretary—

"(i) to ensure compliance with the conditions for approval specified in paragraph (3);

"(ii) to review the progress of the investigation involved; and

"(iii) to evaluate the analytical validity and clinical validity of such test.

"(3) CONDITIONS OF APPROVAL.—An investigational use application with respect to an in vitro clinical test shall only be approved if each of the following conditions is met:

"(A) The Secretary finds that the risks to the subjects of the in vitro clinical test are outweighed by the anticipated benefits to the subjects and the importance of the knowledge to be gained, informed consent is adequate or waived, the investigation is scientifically sound, and there is no reason to believe that the in vitro clinical test as used is ineffective.

"(B) The proposed labeling for the in vitro clinical test involved clearly and conspicuously states 'For investigational use'.

"(C) The sponsor submitting such application complies with the requirements of this section and such other requirements as the Secretary determines to be necessary for the protection of the public health and safety and requires in regulation.

"(4) COORDINATION WITH INVESTIGATIONAL NEW DRUG APPLICATIONS.—Any requirement for the submission of a report to the Secretary pursuant to an investigational new drug application involving an in vitro clinical test shall supersede the reporting requirement in paragraph (2)(B), but only to the extent the requirement with respect to the investigational new drug application is duplicative of the reporting requirement under such paragraph.

"(5) INVESTIGATION PLAN REQUIREMENTS.—

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

"(i) in the case of such a plan submitted to an institutional review committee, promptly notify the Secretary of the approval or the suspension or termination of the approval of such plan by an institutional review committee;

"(ii) in the case of an in vitro clinical test to be distributed or otherwise made available to investigators for clinical testing, obtain, and submit to the Secretary, signed agreements from each of the individuals carrying out the investigation that is the subject of such plan that—

"(I) any testing under such plan involving human subjects will be under the supervision of such individual;

"(II) any testing under such plan will be conducted in compliance with the investigational plan and applicable regulations;

"(III) the individual will ensure that informed consent is obtained from each such human subject, except in cases specifically exempted pursuant to this section; and

"(IV) the individual will comply with additional investigator obligations as set forth in the final rule issued pursuant to subsection (b); and

"(iii) submit an assurance to the Secretary that informed consent will be obtained from each human subject (or the representative of such subject) of proposed clinical testing involving such in vitro clinical test, except in the following cases, for which informed consent is not required, subject to such other conditions as the Secretary may prescribe—

"(I) the proposed clinical testing poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of the human subject; or

"(II) the investigator conducting or supervising the proposed clinical testing determines (subject to subparagraph (B)(ii), with the concurrence of a licensed physician who is not involved in the testing of the human subject) in writing that—

"(aa) there exists a life-threatening situation involving the human subject of such testing which necessitates the use of such in vitro clinical test;

"(bb) it is not feasible to obtain informed consent from the subject; and

"(cc) there is not sufficient time to obtain such consent from a representative of such subject.

"(B) EXCEPTIONS.—

"(i) SIGNED AGREEMENTS NOT REQUIRED.—Subparagraph (A)(iii) shall not apply to the distribution of or other arrangements by a sponsor to make available an in vitro clinical test to an investigator that is employed by the sponsor.

"(ii) CONCURRENCE OF PHYSICIAN NOT REQUIRED.—The requirement to obtain the concurrence of a licensed physician or informed consent from the human subject's representative with respect to a determination under subparagraph (A)(iii)(II) shall not apply if—

"(I) immediate use of the in vitro clinical test in the investigation involved is required to save the life of the human subject; and

"(II) there is not sufficient time to obtain such concurrence.

"(iii) INFORMED CONSENT NOT REQUIRED WITH RESPECT TO CERTAIN SPECIMENS.—Notwithstanding subparagraph (A)(iii)(II), the informed consent of human subjects shall not be required with respect to clinical testing conducted as part of an investigation, if—

"(I) the clinical testing uses remnants of specimens collected for routine clinical care or analysis that would have been discarded, leftover specimens that were

previously collected for other research purposes, or specimens obtained from specimen repositories;

"(II) the identity of the subject of the specimen is not known to, and may not readily be ascertained by, the investigator or any other individual associated with the investigation, including the sponsor;

"(III) any clinical information that accompanies the specimens does not make the specimen source identifiable to the investigator or any other individual associated with the investigation, including the sponsor;

"(IV) the individuals caring for the human subjects as patients are different from, and do not share information about the patient with, the individuals conducting the investigation; and

"(V) the specimens are provided to the investigators without personally identifiable information and the supplier of the specimens has established policies and procedures to prevent the release of personally identifiable information.

"(6) VARIATION.—The requirements imposed under this subsection with respect to an investigational use application may vary based on—

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

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

"(C) the need to permit changes to be made in the in vitro clinical test involved during testing conducted in accordance with a plan required under paragraph (3)(B); or

"(D) whether the clinical testing of such in vitro clinical test is for the purpose of developing data to obtain approval to offer such test.

"(d) REVIEW OF APPLICATIONS.—

"(1) IN GENERAL.—The Secretary may issue an order approving an investigation as proposed, approving it with conditions or modifications, or disapproving it.

"(2) FAILURE TO ACT.—Unless the Secretary, not later than the date that is 30 calendar days after the date of the submission of an investigational use application that meets the requirements of subsection (c)(2), issues an order under subsection (d)(1) and notifies the sponsor submitting the application, the application shall be treated as approved as of such date without further action by the Secretary.

"(3) DISAPPROVAL.—The Secretary may disapprove an investigational use application submitted under this subsection if the Secretary determines that the investigation with respect to which the application is submitted does not conform to the requirements of subsection (c)(3). A notification of such disapproval submitted to the sponsor with respect to such an application shall contain the order of disapproval and a complete statement of the reasons for the Secretary's disapproval of the application.

"(e) WITHDRAWAL OF APPROVAL.—

"(1) IN GENERAL.—The Secretary may, by administrative order, withdraw the approval of an exemption granted under this subsection with respect to an in vitro clinical test, including an exemption granted based on the Secretary's failure to act pursuant to subsection (d)(2), if the Secretary determines that the test does not meet the applicable conditions under subsection (c)(3) for such approval.

"(2) OPPORTUNITY TO BE HEARD.—

"(A) IN GENERAL.—Subject to subparagraph (B), an order withdrawing the approval of an exemption granted under this subsection may be issued only after the Secretary provides the applicant or sponsor of the test with an opportunity for an informal hearing.

"(B) EXCEPTION.—An order referred to in subparagraph (A) with respect to an exemption granted under this subsection may be issued on a preliminary basis before the provision of an opportunity for an informal hearing if the Secretary determines that the continuation of testing under the exemption will result in an unreasonable risk to the public health. The Secretary will provide an opportunity for an informal hearing promptly following any preliminary action under this subparagraph.

"(f) CHANGES.—

"(1) IN GENERAL.—The amended regulations under subsection (b) shall provide, with respect to an in vitro clinical test for which an exemption under this subsection is in effect, procedures and conditions under which the changes to the test are allowed without the additional approval of an application for an exemption or the approval of a supplement to such an application. Such regulations shall provide that such a change may be made if—

"(A) the sponsor or applicant determines, on the basis of credible information (as defined by the Secretary) that the change meets the conditions specified in paragraph (2); and

"(B) the sponsor or applicant submits to the Secretary, not later than 5 calendar days after making the change, a notice of the change.

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

"(A) in the case of developmental changes to an in vitro clinical test (including manufacturing changes), the changes—

"(i) do not constitute a significant change in design or in basic principles of operation;

"(ii) do not affect the rights, safety, or welfare of the human subjects (if any) involved in the investigation; and

"(iii) are made in response to information gathered during the course of an investigation; and

"(B) in the case of changes to clinical protocols applicable to the test, the changes do not affect—

"(i) the validity of data or information resulting from the completion of an approved clinical protocol;

"(ii) the scientific soundness of a plan submitted under subsection (cc)(3)(B); or

"(iii) the rights, safety, or welfare of the human subjects (if any) involved in the investigation.

"(g) CLINICAL HOLD.—

"(1) IN GENERAL.—At any time, the Secretary may impose a clinical hold with respect to an investigation of an in vitro clinical test if the Secretary makes a determination described in paragraph (2). The Secretary shall, in imposing such clinical hold, specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing. The applicant or sponsor may immediately appeal any such determination pursuant to section 587O.

"(2) DETERMINATION.—For purposes of paragraph (1), a determination described in this subparagraph with respect to a clinical hold is a determination that—

"(A) the in vitro clinical test involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the in vitro clinical test, the design of the clinical investigation, the condition for which the in vitro clinical test is to be investigated, and the health status of the subjects involved;

"(B) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish: or

"(C) any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30

days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

"SEC. 587S. EMERGENCY USE AUTHORIZATION.

"An in vitro clinical test may be authorized for use in emergency, and used, held, and developed for such use, pursuant to sections 564, 564A, 564B, and 564C.

"SEC. 587T. COLLABORATIVE COMMUNITIES FOR IN VITRO CLINICAL TESTS.

"(a) IN GENERAL.—

"(1) The Secretary may initiate, establish and participate in collaborative communities of public and private participants that may provide recommendations and other advice to the Secretary on the development and regulation of in vitro clinical tests.

"(2) A collaborative community under this section shall have broad representation of interested private and public-sector stakeholder communities and may include patients, care partners, academics, healthcare professionals, healthcare systems, payers, Federal and State agencies, international regulatory bodies, industry, or other interested entities or communities.

"(b) RECOMMENDATIONS.—A collaborative community may make recommendations to the Secretary on matters including—

"(1) mitigating measures for in vitro clinical tests;

"(2) standards development activities and performance standards for in vitro clinical tests;

"(3) scientific and clinical evidence to support new claims for in vitro clinical tests;

"(4) new technologies and methodologies for in vitro clinical tests;

"(5) stakeholder engagement;

"(6) new approaches and solutions to multifaceted problems involving diverse stakeholders; and

"(7) development of effective policies and processes.

"(c) USE BY SECRETARY.—The Secretary may adopt one or more recommendations made under subsection (b), or otherwise incorporate the feedback from collaborative communities, in its application of its authorities under this subchapter to one or more in vitro clinical tests or a group of in vitro clinical tests, as appropriate.

"(d) TRANSPARENCY.—The Secretary shall—

"(1) publish on the internet website of the Food and Drug Administration matters for which it is seeking comments or recommendations;

"(2) maintain a list of Collaborative Communities recognized by the Secretary and make this list available on the internet website of the Food and Drug Administration; and

"(3) post on the internet website of the Food and Drug Administration at least once every year a report on the recommendations it has adopted from Collaborative Communities.

"(e) EXCEPTION.—The Federal Advisory Committee Act in the appendix to title 5 shall not apply to collaborative communities established and used in accordance with this section.

"SEC. 587U. COMPREHENSIVE TEST INFORMATION SYSTEM.

"**[**placeholder**]**

"SEC. 587V. PREEMPTION.

"(a) IN GENERAL.—No State, tribal, or local government (or political subdivision thereof) may establish or continue in effect any requirement related to the development, manufacture, labeling, distribution, sale, or use of an in vitro clinical test that is different from, or in addition to, the requirements of this subchapter.

"(b) EXCEPTIONS.—Subsection (a) shall not be construed to affect the authority of a State, tribal, or local government—

["(1) to license laboratory personnel, health care practitioners, or health care facilities or to regulate any aspect of a health care practitioner-patient relationship; or**]**

["(2) to enforce laws of general applicability, such as zoning laws, environmental laws, labor laws, and general business laws.**]**

"(c) CLARIFICATION.—This section shall not be construed to shift liability to health care practitioners or other users.

"SEC. 587W. ADULTERATION.

"An in vitro clinical test shall be deemed to be adulterated:

"(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

"(2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

"(3) if its package is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

"(4) if it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 721(a).

"(5) If its analytical or clinical validity, or if applicable its safety, or its strength, purity, or quality, differs from or falls below that which it purports or is represented to possess.

"(6) If it is required to be, declared to be, purports to be, or is represented as being, in conformity with any standard established or recognized under section 587Q unless such in vitro clinical test is in all respects in conformity with such standard.

"(7) If it is required to be in conformity with a mitigating measure established under section 587E unless such in vitro clinical test is in all respects in conformity with such mitigating measure.

"(8) If it fails to have an approved premarket application under section 587B unless such in vitro clinical test can be lawfully offered—

"(A) for clinical use pursuant to an exemption under section 587A, [precertification] under section 587D;

"(B) for emergency use pursuant to an authorization under section 587S; or

"(C) for investigational use pursuant to section 587R.

"(9) If it is not in conformity with any condition of approval established under section 587B, 587D, or 587S.

"(10) If it purports to be an in vitro clinical test that is offered for clinical use or introduced into interstate commerce subject to an exemption under section 587A and it fails to meet or maintain any requirement of such exemption.

"(11) If it has been granted an exemption under section 587R for investigational use, and the person granted such exemption or any investigator who uses such in vitro clinical test under such exemption fails to comply with a requirement prescribed by or under such section.

"(12) If it fails to meet the quality system requirements prescribed in or established under section 587J, or the methods used in, or facilities or controls used for, its manufacture, packing, storage, or

installation are not in conformity with applicable requirements established under such section.

"(13) If it has been manufactured, processed, packed or held in any establishment, factory, or warehouse and the owner, operator or agent of such establishment, factory, or warehouse delays, denies, or limits an inspection, or refuses to permit entry or inspection.

"(14) If it is not in compliance with any restriction established under section 587N.

"(15) If it is a banned in vitro clinical test.

"SEC. 587X. MISBRANDING.

" An in vitro clinical test shall be deemed to be misbranded:

"(1) If its labeling is false or misleading in any particular.

"(2) If in a package form unless it bears a label containing—

"(A) the name and place of business of the test developer, manufacturer, packer, or distributor; and

"(B) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count, subject to the authority of the Secretary to issue guidance to establish exemptions from the requirements of this subparagraph with respect to small packages.

"(3) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling, including a test report, is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

"(4) If it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name

prominently printed in type at least half as large as that used thereon for any proprietary name or designation for such in vitro clinical test; provided, that the Secretary may issue guidance regarding exemptions to the extent compliance with this requirement is impracticable or unnecessary. The term 'established name' means the applicable official name established by the Secretary pursuant to regulation or the official name or title recognized in an official compendium, or if neither of these apply, then the common or usual name of such in vitro clinical test.

"(5) Unless its labeling bears adequate directions for use and such adequate warnings as are necessary for the protection of users of the in vitro clinical test and recipients of the results of such in vitro clinical test, including patients, consumers, donors, and related health care professionals. Required labeling for in vitro clinical tests intended for use in health care facilities or by a health care professional may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the test developer, manufacturer, or distributor affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost.

"(6) If it is dangerous to health, including through absence, delay, or discontinuation in diagnosis or treatment, when used in the manner prescribed, recommended, or suggested in the labeling thereof.

"(7) If it was developed, manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 587I or it was not included in a notification under section 587I.

"(8) In the case of any in vitro clinical test subject to restrictions established under section 587N, (1) if its advertising is false or misleading in any particular, (2) if it is offered for clinical use, sold, distributed, or used in violation of such restrictions, or (3) unless the test developer, manufacturer, or distributor includes in all advertisements and other descriptive printed matter that such person issues or causes to be issued, a brief statement of the intended uses of the in vitro clinical test and relevant warnings, precautions, side effects,

and contraindications. This subsection shall not be applicable to any printed matter that the Secretary determines to be labeling as defined in section 201(m) or section 587K.

"(9) If it was subject to a mitigating measure established under section 587E, unless it bears such labeling as may be prescribed in such mitigating measure.

"(10) If it was subject to a standard established under section 587Q, unless it bears such labeling as may be prescribed in such standard.

"(11) Unless it bears such labeling as may be prescribed by or established under an applicable labeling requirement under this Act.

"(12) If there was a failure or refusal to comply with any requirement prescribed under section 587I, or to comply with a requirement under section 587Y, or to provide any report, material, or information required under sections 587B, 587C, 587D, 587F, 587L, 587M, 587R, or 587S.

"SEC. 587Y. POSTMARKET SURVEILLANCE.

"(a) IN GENERAL.—

"(1) In addition to other applicable requirements under this Act, the Secretary may require a developer to conduct postmarket surveillance of an in vitro clinical test (A) as a condition of approval under section 587B or by order at any time thereafter, or (B) as a mitigating measure established under section 587E.

"(2) The Secretary may order postmarket surveillance when he determines it necessary to assure that an in vitro clinical test will meet the relevant standard for its intended use or to mitigate a risk of patient harm from use of the in vitro clinical test.

"(b) SURVEILLANCE APPROVAL.—

"(1) Each developer required to conduct a surveillance of an in vitro clinical test shall submit, within 30 days of receiving an order

from the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has the appropriate qualifications and experience to undertake such surveillance and if the plan will result in useful data that can reveal unforeseen adverse events or other information necessary to protect the health of patients or the public.

"(2) The developer shall commence surveillance under this section not later than 15 months after the day on which the Secretary orders such postmarket surveillance.

"(3) The Secretary may order a prospective surveillance period of up to 36 months, except that the Secretary may require a longer period of prospective surveillance when necessary to assure the clinical validity or, as applicable, safety of an in vitro clinical test or test group.

"SEC. 587Z. ELECTRONIC FORMAT FOR SUBMISSIONS.

"(a) IN GENERAL.—All presubmissions and submissions to FDA for an in vitro clinical test shall include an electronic copy of such presubmission or submission.

"(b) ELECTRONIC FORMAT.—Beginning on such date as the Secretary specifies in final guidance issued under subsection (c), presubmissions and submissions for in vitro clinical tests (and any appeals of action taken by the Secretary with respect to such presubmissions and submissions) shall be submitted solely in such electronic format as specified by the Secretary in such guidance.

"(c) GUIDANCE.—The Secretary shall issue guidance implementing this section. In such guidance, the Secretary may—

"(1) provide standards for the electronic copy required under subsection (a) or the submission in electronic format required under subsection (b);

"(2) set forth criteria for waivers of or exemptions from the requirements of subsections (a) or (b); and

"(3) provide any other information for the efficient implementation and enforcement of this section.

"SEC. 587AA. POSTMARKET REMEDIES.

"(a) SAFETY NOTICE.—

"(1) If the Secretary determines that an in vitro clinical test presents an unreasonable risk of substantial harm to the public health, and notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this Act (other than this section) to eliminate the risk, the Secretary may issue such order as may be necessary to assure that adequate safety notice is provided in an appropriate form, by the persons and means best suited under the circumstances, to all health professionals who prescribe, order, or use the in vitro clinical test and to any other person (including developers, manufacturers, importers, distributors, retailers, and users) who should properly receive such notice.

"(2) An order under this subsection shall require that the individuals subject to the risk with respect to which the order is to be issued be included in the persons to be notified of the risk unless the Secretary determines that notice to such individuals would present a greater danger to the health of such individuals than no such notice. If the Secretary makes such a determination with respect to such individuals, the order shall require that the health professionals who prescribed, ordered, or used the in vitro clinical test provide notice to the individuals for whom the health professionals prescribed, ordered, or used such test, of the risk presented by such in vitro clinical test and of any action which may be taken by or on behalf of such individuals to eliminate or reduce such risk.

"(b) REPAIR, REPLACEMENT, OR REFUND.—

"(1)(A) If, after affording opportunity for an informal hearing, the Secretary determines that—

"(i) an in vitro clinical test presents an unreasonable risk of substantial harm to the public health,

"(ii) there are reasonable grounds to believe that the in vitro clinical test was not properly designed or manufactured with reference to the state of the art as it existed at the time of its design or manufacture,

"(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a developer, manufacturer, importer, distributor, or retailer of the in vitro clinical test to exercise due care in the installation, maintenance, repair, or use of the in vitro clinical test, and

"(iv) the notice authorized by subsection (a) would not by itself be sufficient to eliminate the unreasonable risk and action described in paragraph (2) of this subsection is necessary to eliminate such risk,

the Secretary may order the developer, manufacturer, importer, or any distributor of such in vitro clinical test, or any combination of such persons, to submit to him within a reasonable time a plan for taking one or more of the actions described in paragraph (2). An order issued under the preceding sentence which is directed to more than one person shall specify which person may decide which action shall be taken under such plan and the person specified shall be the person who the Secretary determines bears the principal, ultimate financial responsibility for action taken under the plan unless the Secretary cannot determine who bears such responsibility or the Secretary determines that the protection of the public health requires that such decision be made by a person (including a health professional or user of the in vitro clinical test) other than the person he determines bears such responsibility.

"(B) The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless he determines (after affording opportunity for an informal hearing) that the action or actions to be taken under the plan or the manner in which such action or actions are to be taken under the plan will not assure that the unreasonable risk with respect to which such order was issued will be eliminated. If the Secretary disapproves a plan, he shall order a revised plan to be submitted to him within a reasonable time. If the Secretary determines

(after affording opportunity for an informal hearing) that the revised plan is unsatisfactory or if no revised plan or no initial plan has been submitted to the Secretary within the prescribed time, the Secretary shall (i) prescribe a plan to be carried out by the person or persons to whom the order issued under subparagraph (A) was directed, or (ii) after affording an opportunity for an informal hearing, by order prescribe a plan to be carried out by a person who is a manufacturer, importer, distributor, or retailer of the in vitro clinical test with respect to which the order was issued but to whom the order under subparagraph (A) was not directed.

"(2) The actions which may be taken under a plan submitted under an order issued under paragraph (1) are as follows:

"(A) To repair the in vitro clinical test so that it does not present the unreasonable risk of substantial harm with respect to which the order under paragraph (1) was issued.

"(B) To replace the in vitro clinical test with a like or equivalent test which is in conformity with all applicable requirements of this Act.

"(C) To refund the purchase price of the in vitro clinical test (less a reasonable allowance for use if such in vitro clinical test has been in the possession of the user for one year or more at the time of notice ordered under subsection (a), or at the time the user receives actual notice of the unreasonable risk with respect to which the order was issued under paragraph (1), whichever occurs first).

"(3) No charge shall be made to any person (other than a developer, manufacturer, importer, distributor or retailer) for availing himself of any remedy, described in paragraph (2) and provided under an order issued under paragraph (1), and the person subject to the order shall reimburse each person (other than a developer, manufacturer, importer, distributor, or retailer) who is entitled to such a remedy for any reasonable and foreseeable expenses actually incurred by such person in availing himself of such remedy.

"(c) REIMBURSEMENT.—An order issued under subsection (b) of this section with respect to an in vitro clinical test may require any person who is a developer,

manufacturer, importer, distributor, or retailer of the in vitro clinical test to reimburse any other person who is a developer, manufacturer, importer, distributor, or retailer of such in vitro clinical test for such other person's expenses actually incurred in connection with carrying out the order if the Secretary determines such reimbursement is required for the protection of the public health. Any such requirement shall not affect any rights or obligations under any contract to which the person receiving reimbursement or the person making such reimbursement is a party.

"(d) RECALL AUTHORITY.—

"(1) If the Secretary finds that there is a reasonable probability that an in vitro clinical test would cause serious, adverse health consequences or death, including by the absence, delay, or discontinuation of diagnosis or treatment, the Secretary shall issue an order requiring the appropriate person (including the developers, manufacturers, importers, distributors, or retailers of the in vitro clinical test)—

"(A) to immediately cease distribution of such in vitro clinical test, and

"(B) to immediately notify health professionals and user facilities of the order and to instruct such professionals and facilities to cease use of such in vitro clinical test.

"(2) The order issued under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such in vitro clinical test. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(3)(A) If, after providing an opportunity for an informal hearing under paragraph (2), the Secretary determines that the order should be amended to include a recall of the in vitro clinical test with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the recall will occur and

shall require periodic reports to the Secretary describing the progress of the recall.

"(B) An amended order under subparagraph (A)—

"(i) shall—

"(I) not include recall of the in vitro clinical test from individuals, and

"(II) not include recall of an in vitro clinical test from device user facilities if the Secretary determines that the risk of recalling such in vitro clinical test from the facilities presents a greater health risk than the health risk of not recalling the in vitro clinical test from use, and

"(ii) shall provide for notice to individuals subject to the risks associated with the use of such in vitro clinical test. In providing the notice required by this clause, the Secretary may use the assistance of health professionals who prescribed, ordered, or used such an in vitro clinical test for individuals.

"(4) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

"(e) BANNING AUTHORITY.—

"(1) Whenever the Secretary finds, based on all available data and information, that an in vitro clinical test presents substantial deception or an unreasonable and substantial risk of illness or injury, the Secretary may initiate a proceeding to issue an order to make such an in vitro clinical test a banned in vitro clinical test.

"(2) The order issued under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

"(3) If the Secretary determines to issue a final order banning the in vitro clinical test, the order may be made immediately effective.

"(f) EFFECT ON OTHER LIABILITY.—Compliance with an order issued under this section shall not relieve any person from liability under federal or state law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.".

SEC. 4. PROHIBITED ACTS, ENFORCEMENT, AND OTHER PROVISIONS.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended—

(1) in paragraphs (a), (b), (c), (g), (k), (q), (r), and (y), by inserting "in vitro clinical test," after "device," each place it appears; and—

(A) by adding at the end, the following:

"(fff)(1) The introduction or delivery for introduction into interstate commerce of an in vitro clinical test in violation of section 587B(a).

"(2) The false, fraudulent, or deceptive claiming for an in vitro clinical test of an exemption from the premarket review required under section 587B.

"(3) When claiming an exemption under section 587A from the premarket review required under section 587B, the failure to maintain complete and accurate documentation for the exemption as required under section 587A or the failure to provide labeling required under section 587A.

"(4) With respect to an in vitro clinical test, the submission of any report that is required by or under this Act that is false or misleading in any material respect.

"(5) The making of a false, fraudulent, or materially deceptive analytical or clinical claim for an in vitro clinical test—

"(A) in any application, report, or notification submitted to the Secretary under this Act; or

"(B) in the labeling or advertising of an in vitro clinical test.

"(6) The failure to comply with a condition of approval, performance standard, mitigating measure, or restriction established in an order approving an application or supplement under section 587B or 587C; the failure to perform a risk analysis required by section 587B(f)(1); the failure to submit an annual report required under section 587B(j) or 587C(f); or the failure to complete postmarket studies required under section 587Y.

"(7) The marketing of an in vitro clinical test in violation of—

"(A) an order issued by the Secretary under section 587(a)(4); or

"(B) any requirement under section 587(a)(5).

"(8) **[**With respect to precertification under section 587D, the refusal to permit, or unreasonable delay in permitting, an inspection authorized under section 587D(d)(3); the failure to comply with applicable requirements to submit an application or report under section 587D(e); or the failure to comply with applicable maintenance requirements under section 587D(f).**]**

"(9) The failure to comply with an applicable mitigating measure established under section 587E or to maintain the documentation required under section 587E(c); or the failure to comply with a performance standard established under section 587Q.

"(10) The failure to register in accordance with section 587I, the failure to provide information required under section 587I(b), or the failure to maintain or submit information required under section 587I(c).

"(11) The failure to submit a report required under section 587L or 587M; the failure to comply with a restriction imposed under section 587N; or the failure to comply with labeling and advertising requirements under section 587N(b).

"(12) The failure to comply with the requirements of section 587P (relating to accredited persons).

"(13) The failure to comply with any requirement prescribed or established under section 587R; the failure to furnish any notification, information, material, or report required under section 587R; or the failure to comply with an order issued under section 587R.".

(b) PENALTIES.—Section 303(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)) is amended—

(1) in subparagraph (A), by inserting "or in vitro clinical tests" after "devices"; and

(2) in subparagraph (B)(i)—

(A) by inserting ", or 587J or 587L," after "520(f)"; and

(B) by inserting ", or who violates section 587M(b) with respect to a correction report" after "risk to public health".

(c) SEIZURE.—Section 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 334) is amended—

(1) in subsection (a)(2)—

(A) by striking "and" before "(E) Any"; and

(B) by inserting ", and (F) Any adulterated or misbranded in vitro clinical test" after "tobacco product";

(2) in subsection (d)(1), by inserting "in vitro clinical test," after "device,"; and

(3) in subsection (g)—

(A) in paragraph (1), by inserting ", in vitro clinical test," after "device" each place it appears; and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ", in vitro clinical test," after "device"; and

(ii) in subparagraph (B), by inserting "or in vitro clinical test" after "device" each place it appears.

(d) DEBARMENT, TEMPORARY DENIAL OF APPROVAL, AND SUSPENSION.—Section 306 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 335a) is amended by adding at the end the following:

"(n) IN VITRO CLINICAL TESTS; MANDATORY DEBARMENT REGARDING THIRD-PARTY INSPECTIONS AND REVIEWS.—

"(1) IN GENERAL.—If the Secretary finds that a person has been convicted of a felony under section 301(gg), 301(fff)(2), 301(fff)(5), or 301(fff)(8), the Secretary shall debar such person from being accredited under section 587P and from carrying out activities under an agreement described in section 803(b).

"(2) DEBARMENT PERIOD.—The Secretary shall debar a person under paragraph (1) for the following periods:

"(A) The period of debarment of a person (other than an individual) shall not be less than 1 year or more than 10 years, but if an act leading to a subsequent debarment under such paragraph occurs within 10 years after such person has been debarred under such paragraph, the period of debarment shall be permanent.

"(B) The debarment of an individual shall be permanent.

"(3) TERMINATION OF DEBARMENT; JUDICIAL REVIEW; OTHER MATTERS.—Subsections (c)(3), (d), (e), (i), (j), and (l)(1) apply with respect to a person (other than an individual) or an individual who is debarred under paragraph (1) to the same extent and in the same manner as such subsections apply with respect to a person who is debarred under subsection (a)(1), or an individual who is debarred under subsection (a)(2), respectively.".

(e) JUDICIAL REVIEW.—Section 517(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)) is amended—

(1) in paragraph (8), by striking "or" at the end;

(2) in paragraph (9), by inserting "or" after the comma at the end; and

(3) before the matter that follows paragraph (9), by inserting the following:

"(10) an order issued pursuant to sections 587B, 587D, 587R, or 587S,".

(f) AGENCY DOCUMENTATION AND REVIEW OF SIGNIFICANT DECISIONS REGARDING DEVICES.—Section 517A(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g–1(a)(1)) is amended by striking "section 515C, or" and inserting "section 515C, an application under section 587B, an application for exemption under section 587R, or".

(g) EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.—Section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) is amended—

(1) in subsections (a) through (d)—

(A) by striking "or investigational devices" each place it appears and inserting ", investigational devices, or investigational in vitro clinical tests"; and

(B) by striking "or investigational device" each place it appears (other than the second such place in paragraph (3)(A)) and inserting ", investigational device, or investigational in vitro clinical test";

(2) in subsection (c)—

(A) by amending the subsection heading to read: "TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS, TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS, AND TREATMENT INVESTIGATIONAL IN VITRO CLINICAL TEST EXEMPTIONS";

(B) in paragraph (3)(A), by striking "or investigational device exemption in effect under section 520(g)" and inserting ", investigational device exemption in effect under section 520(g), or investigational in vitro clinical test exemption"; and

(C) by striking "or treatment investigational device exemption" each place it appears and inserting ", treatment investigational device exemption, or treatment investigational in vitro clinical test exemption"; and

(3) by amending subsection (e) to read as follows:

"(e) DEFINITIONS.—In this section, the terms 'investigational drug', 'investigational device', 'investigational in vitro clinical test', 'treatment investigational new drug application', 'treatment investigational device exemption', and 'treatment investigational in vitro clinical test exemption' shall have the meanings given the terms in regulations prescribed by the Secretary.".

(h) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a(b)) is amended by inserting "an in vitro clinical test, as defined in subsection (ss) of such section," before "or a biological product".

(i) PATIENT PARTICIPATION IN MEDICAL PRODUCT DISCUSSION.—The heading of subsection (a) of section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) is amended by striking "DRUGS AND DEVICES" and inserting "DRUGS, DEVICES, AND IN VITRO CLINICAL TESTS".

(j) REGULATIONS AND HEARINGS.—Section 701(h)(1)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)(ii)) is amended by inserting " and in vitro clinical tests" after "devices".

(k) FACTORY INSPECTION.—Section 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 374) (other than subsection (g)) is amended—

(1) by striking "drugs or devices" each place it appears and inserting "drugs, devices, or in vitro clinical tests";

(2) in subsection (a)(2)(B)—

(A) by inserting "or in vitro clinical tests" after "prescribe or use devices"; and

(B) by inserting "or in vitro clinical tests" after "process devices";

(3) by inserting "in vitro clinical test," after "device," each place it appears;

(4) after making the amendments in paragraphs (1) and (2), by inserting "in vitro clinical tests," after "devices," each place it appears;

(5) in subsection (e), by inserting ", or section 587L, 587M, or 587R," after "section 519 or 520(g)"; and

(6) in subsection (f)(3)—

(A) in subparagraph (A), by striking "or" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; or"; and

(C) after subparagraph (B), by inserting the following:

"(C) is accredited under section 587P.".

(l) PUBLICITY.—Section 705(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 375(b)) is amended by inserting "in vitro clinical tests," after "devices,".

(m) PRESUMPTION.—Section 709 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379a) is amended by inserting "in vitro clinical test," after "device,".

(n) IMPORTS AND EXPORTS.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381) is amended—

(1) in subsection (a)—

(A) by inserting "in vitro clinical tests," after "devices," each place it appears;

(B) by inserting "in the case of an in vitro clinical test, the test does not conform to the requirements of section 587J, or" after "requirements of section 520(f), or" ;

(2) in subsection (d)(3)—

(A) in subparagraph (A)—

(i) in the matter preceding clause (i), by inserting "and no component of an in vitro clinical test or other article of in vitro clinical test that requires further processing," after "health-related purposes";

(ii) in clause (i), by striking "drug or device" and inserting "drug, device, or in vitro clinical test"; and

(iii) in clause (i)(I), by inserting "in vitro clinical test," after "device,"; and

(B) in subparagraph (B), by inserting "in vitro clinical test," after "device,"; and

(3) in subsection (e)(1), by inserting "in vitro clinical test," after "device,".

(o) OFFICE OF INTERNATIONAL RELATIONS.—Section 803 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383) is amended—

(1) in subsection (b)—

(A) in the matter preceding paragraph (1), by inserting "and in vitro clinical tests" after "devices"; and

(B) in paragraph (1), by inserting "quality system requirements established under section 587J; and" at the end; and

(2) in subsection (c)—

(A) in paragraph (2), by inserting "in vitro clinical tests," after "devices,"; and

(B) in paragraph (4), by inserting "or in vitro clinical tests" after "devices".

(p) RECOGNITION OF FOREIGN GOVERNMENT INSPECTIONS.—Section 809(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 384e(a)(1)) is amended by inserting ", or section 587I" after "510(h)".

(q) FOOD AND DRUG ADMINISTRATION.—Section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)) is amended—

(1) in subparagraph (D), by striking "and" at the end;

(2) in subparagraph (E), by striking the semicolon at the end and inserting "; and"; and

(3) by adding at the end the following:

"(F) in vitro clinical tests are analytically and clinically valid;".

(r) OFFICE OF WOMEN'S HEALTH.—Section 1011(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 399b(b)) is amended—

(1) in paragraph (1), by inserting "in vitro clinical tests," after "devices,"; and

(2) in paragraph (4), by inserting "in vitro clinical test developers," before "health professionals".

SEC. 5. TRANSITION.

(a) FUNDING.—For the purposes of carrying out this Act and the amendments made by this Act, there is authorized to be appropriated **[**$X MILLION**]** for **[**fiscal year X**]**.

(b) IMPLEMENTATION.—The amendments made by this Act apply beginning on **[**DATE X**]** (in this section and in subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, referred to in this Act and the amendments made by this Act as the effective date of this Act), except that the Secretary of Health and Human Services (in this section referred to as the "Secretary") may take such actions, and expend such funds, as the Secretary deems necessary to ensure an orderly transition.

(c) APPLICATION OF DEVICE AUTHORITIES TO IN VITRO CLINICAL TESTS UNTIL AND AFTER EFFECTIVE DATE OF THIS ACT.—Except as provided in subsection (d), for any product or test that is an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, the following authorities shall apply:

(1) Any such product or test that was offered, sold, or distributed prior to the enactment date of this Act, except for those addressed in subsection (d), shall continue to comply with the applicable device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) until the effective date of this Act.

(2) Before any product or test that is an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, is first offered, sold, or distributed after the date of enactment of this Act, but prior to the effective date of this Act, such product or test shall comply with the applicable device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.), except that a product or test described in subsection (d) shall likewise be subject to the provisions of that subsection.

(3) For any product or test that is an in vitro clinical test as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, for which a submission for marketing authorization under section 515, clearance under section 510(k), authorization under section 513(f)(2), approval under section 520(m), or emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k), 360c(f)(2), 360j(m), 360bbb–3) or approval under the Public Health Service Act (42 U.S.C. 201 et seq.) is pending on the effective date of this Act, the Secretary may review and take action on such submission after the effective date of this Act according to the statutory provision under which such submission was submitted.

(d) APPLICATION OF AUTHORITIES TO TRANSITIONAL AND GRANDFATHERED IN VITRO CLINICAL TESTS.—

(1) TRANSITIONAL TESTS.—

(A) DEFINITION.—For purposes of this paragraph, the term "transitional in vitro clinical test" means an in vitro clinical test, as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, that—

(i) was developed by a laboratory certified by the Secretary under section 353 of the Public Health Service Act (42 U.S.C. 263a) that meets the requirements for performing high-complexity testing for use only within that certified laboratory;

(ii) does not have an approval under section 515, a clearance under section 510(k), an authorization under 513(f)(2), an approval under section 520(m), or an emergency use authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e, 360(k), 360c(f)(2), 360j(m), 360bbb–3) or approval under the Public Health Service Act (42 U.S.C. 201 et seq.); and

(iii) is first offered for clinical use during the period beginning on the date that is 90 days before the date of enactment of this Act and ending on the date of applicability described in subsection (b).

(B) CONTINUED OFFERING.—Notwithstanding subsection (c), a transitional in vitro clinical test may continue to be offered for clinical use until the effective date of this Act, except that the Secretary retains authority to enforce the device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) for any specific transitional in vitro clinical test, or any type of transitional in vitro clinical test, as the Secretary determines necessary to protect the public from a serious risk to health.

(C) PREMARKET REVIEW OR PRECERTIFICATION.—A transitional in vitro clinical test that is the subject of an application for premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act **[**or precertification application under section 587C of such Act**]**, as added by this Act, that is submitted on or within **[__]** days of the effective date of this Act may continue to be offered, sold, or distributed until completion of the Secretary's review of the premarket application **[**or precertification application**]**.

(2) GRANDFATHERED TESTS.—An in vitro clinical test that meets the criteria for a grandfathered test as set forth in section 587A(c)(2) of the Federal Food, Drug, and Cosmetic Act, as added by this Act, may continue to be offered for clinical use until the effective date of this Act, except that the Secretary retains authority to enforce the device provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301

et seq.) and the Public Health Service Act (42 U.S.C. 201 et seq.) for any specific product or test or any type of product or test as the Secretary determines necessary to protect the public from a serious risk to health.

(e) CONVERSION.—

(1) DEEMED PREMARKET APPROVAL.—Any in vitro clinical test (as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act) with a premarket approval under section 515, a clearance under section 510(k), an authorization under section 513(f), or a licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) is deemed to have an approved application under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by this Act, after the effective date of this Act.

(2) DEEMED INVESTIGATIONAL USE APPROVAL.—Any in vitro clinical test (as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by this Act) that has an approved investigational device exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is deemed to have an approved investigational use under section 587Q of such Act, as added by this Act, after the effective date of this Act.

(f) PLATFORMS.—A test platform (as defined in section 587 of the Federal Food, Drug, and Cosmetic Act, as added by this Act) that was purchased prior to the date of enactment of this Act and was not cleared, authorized, or approved by the Food and Drug Administration at the time of purchase may continue to be used by the purchaser to develop and introduce into interstate commerce an in vitro clinical test during the period beginning on the date of enactment of this Act and ending **[**5 years**]** after such date of enactment. Beginning at the end of such period, any new in vitro clinical test that is developed and introduced into interstate commerce shall be based on a test platform that complies with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended by this Act.

(g) RELATION TO IN VITRO CLINICAL TEST PROVISION.—This section applies notwithstanding section 587A(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act, as added by this Act.

SEC. 6. ANTIMICROBIAL SUSCEPTIBILITY TESTS.

Section 511A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360a-2) is amended—

(1) in subsection (a)(1)(C)—

(A) by inserting "and clear, approve, or exempt under subchapter J," before "antimicrobial susceptibility"; and

(B) by striking "testing devices" and inserting "tests";

(2) in subsection (c)(5), by striking "drug or device" each place it appears and inserting "drug, device, or in vitro clinical test";

(3) in subsection (e)—

(A) by striking "and 515," and inserting "515, and section 587B";

(B) by striking "antimicrobial susceptibility testing device" and inserting "antimicrobial susceptibility in vitro clinical test";

(C) in the heading of subsection (e), by striking "TESTING DEVICES" and inserting "IN VITRO CLINICAL TESTS";

(D) in the heading of subsection (e)(2), by striking "TESTING DEVICES" and inserting "IN VITRO CLINICAL TESTS";

(E) after making the amendments in subparagraphs (B), (C), and (D), by striking "device" each place it appears and inserting "in vitro clinical test"; and

(F) in paragraph (2), by amending subparagraph (C) to read as follows:

"(C) The antimicrobial susceptibility in vitro clinical test meets all other requirements to be approved under section 587B **[**or exempted from premarket review under section 587D.";**]**

(4) in subsection (f), by amending paragraph (1) to read as follows:

"(1) The term 'antimicrobial susceptibility in vitro clinical test' means an in vitro clinical test that utilizes susceptibility test interpretive criteria to determine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).";

(5) in subsection (g)(2), by amending the matter preceding subparagraph (A) to read as follows:

"(2) with respect to approving in vitro clinical tests under section 587B **[**or exempting in vitro clinical tests from premarket review under section 587D**]**—"; and

(6) in subsection (g)(2)(A)—

(A) by striking "device" and inserting "in vitro clinical test"; and

(B) by striking "antimicrobial susceptibility testing device" and inserting "antimicrobial susceptibility in vitro clinical test".

SEC. 7. COMBINATION PRODUCTS.

(a) IN GENERAL.—Section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(g)) is amended—

(1) in paragraph (1)(A)—

(A) by inserting "(except for a combination product constituted of a device and an in vitro clinical test)" after "agency center,"; and

(B) by inserting "in vitro clinical test," before "or biological product";

(2) in paragraph (1)(D), by striking "If the Secretary determines" and inserting "Except for a combination product constituted of a device and an in vitro clinical test. For other combination products, if the Secretary determines";

(3) in paragraph (1)(D)(ii)—

(A) by inserting “or in vitro clinical test” after “device”; and

(B) by inserting “and in vitro clinical tests” before “shall”;

(4) in paragraph (3), by striking “safety and effectiveness or substantial equivalence” and inserting “safety and effectiveness, substantial equivalence, or analytical validity and clinical validity” before “for the approved constituent part”;

(5) in paragraph (4)(A), by striking “or 513(f)(2) (submitted in accordance with paragraph (5))” and inserting “, 513(f)(2) (submitted in accordance with paragraph (5)), or 587B”; and

(6) in paragraph (4)(B), by inserting “or 587B” after “section 515”;

(7) in paragraph (5)(A), by striking “or 510(k)” and inserting “, 510(k), or 587(b)”;

(8) in paragraph (7), by striking “or substantial equivalence” and inserting “, substantial equivalence, or analytical validity and clinical validity”;

(9) in paragraph (8), by inserting “This paragraph shall not apply to a combination product constituted of a device and an in vitro clinical test”;

(10) in paragraph (9)(C)(i), by striking “or” before “520(g)” and inserting “or 587B ” at the end; and

(11) in paragraph (9)(D), by striking “or” before “520” and inserting “or 587B” before “of this Act…”.

(b) CLASSIFICATION OF PRODUCTS.—Section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) is amended—

(1) in subsection (a), by inserting “in vitro clinical test,” after “device,” and by inserting “, except for a combination product constituted of a device and an in vitro clinical test,” before “respecting the component”;

(2) in subsection (b), by inserting "except for a combination product constituted of a device and an in vitro clinical test" before "the component of the"; and

(3) in subsection (c), by inserting "except for a combination product constituted of a device and an in vitro clinical test" before "the component of the".

SEC. 8. USER FEES.

(a) FINDINGS.— The Congress finds that—

(1) the establishment of a regulatory framework for in vitro clinical tests is critical to the improvement of the public health so that patients have confidence in the ability of in vitro clinical tests to identify, screen, measure, detect, predict, prognose, analyze, or monitor a disease or a condition, and will advance innovation that will benefit public health;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for the review of in vitro clinical tests and the assurance of in vitro clinical test analytical validity and clinical validity; and,

(3) the fees authorized by this section will be dedicated to meeting the goals identified in the letters from the Secretary of Health and Human Services to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate, as set forth in the Congressional Record.

(b) ESTABLISHMENT OF USER FEE PROGRAM.—

(1) DEVELOPMENT OF USER FEES FOR IN VITRO CLINICAL TESTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2019, the Secretary of Health and Human Services (in this section

referred to as the "Secretary") shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of in vitro clinical test applications submitted under subchapter J of chapter V of the Federal Food Drug, and Cosmetic Act, as added by this Act, for the first **[**3**]** fiscal years after **[**fiscal year 2020**]**. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Energy and Commerce of the House of Representatives;

(ii) the Committee on Health, Education, Labor, and Pensions of the Senate;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than June 1, 2020, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Congress that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), the Congress should authorize a program, effective on the **[**effective date of_____**]**, for the collection of user fees relating to the submission of in vitro clinical test applications submitted under subchapter J of chapter V of the Federal Food Drug, and Cosmetic Act, as added by this Act.

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR CERTAIN IN VITRO CLINICAL TESTS.—A submission for approval or clearance made by a manufacturer pursuant to section 5 of this Act shall be subject to a user fee pursuant to section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j).

(4) AUDIT.—

(A) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to submission of an in vitro clinical test application submitted under subchapter J of chapter V of the Federal Food Drug, and Cosmetic Act, as added by this Act, and on a biennial basis thereafter until October 1, 2027, the Secretary shall perform an audit of the costs of reviewing such applications under such subchapter J. Such an audit shall compare the costs of reviewing such applications under such subchapter J to the amount of the user fee applicable to such applications.

(B) ALTERATION OF USER FEE.—If the audit performed under paragraph (1) indicates that the user fees applicable to applications submitted under such subchapter J exceed **[**__**]** percent of the costs of reviewing such applications, then the Secretary shall alter the user fees applicable to applications submitted under such subchapter J such that the user fees do not exceed such percentage.

(C) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under paragraph (1) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.
