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(Original Signature of Member)

118TH CONGRESS
1ST SESSION

H. R. _____

To amend the Federal Food, Drug, and Cosmetic Act with respect to in vitro clinical tests, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. BUCSHON introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to 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.

(a) SHORT TITLE.—This Act may be cited as the ''Verifying Accurate Leading-edge IVCT Development Act of 2023'' or the ''VALID Act of 2023''.

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 an article specified in subparagraph (2) that is 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—

''(A) identifying or diagnosing a disease or condition;

''(B) providing information for 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

''(C) selecting, monitoring, or informing therapy or treatment for a disease or condition.

''(2) An article specified in this subparagraph is—

''(A) a test kit;

''(B) a test system;

''(C) a test protocol or laboratory test protocol;

''(D) an instrument (as defined in section 587(11));

''(E) a specimen receptacle (as defined in section 587(17));

''(F) software, excluding software that is excluded by section 520(o) from the definition of a device under section 201(h), that—

''(i) is a component or part of another in vitro clinical test or analyzes, processes, or interprets a signal or pattern from another in vitro clinical test; and

''(ii) does not analyze, process, or interpret a signal, pattern, or medical image from a device; and

''(G) subject to subparagraph (3), a component or part of a test kit, a test system, a test protocol or laboratory test protocol, an instrument, a specimen receptacle, or software described in subparagraph (F), whether alone or in combination, including reagents, calibrators, and controls.

''(3) Notwithstanding subparagraph (2)(G), 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 acquisition, donation, or recovery of such article, including determination of donor eligibility, as applicable, until such time as the

article is released 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, a needle, or a lancet, except to the extent such article, needle, or lancet is an integral component of an article for holding, storing, or transporting a specimen.

''(C) General purpose laboratory equipment.'';

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

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

(3) in paragraph (h)(1), in the matter following clause (C), 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.''.

(c) IN VITRO CLINICAL TEST DEFINITION.—In this Act, the term ''in vitro clinical test'' has the meaning given such term in section 201(ss) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

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.—The term 'analytical validity' means, with respect to an in vitro clinical test, the ability of the in vitro clinical test, to identify, measure, detect, calculate, or analyze (or assist in such identification, measurement, detection, calculation, or analysis of) one or more analytes, biomarkers, substances, or other targets intended to be

identified, measured, detected, calculated, or analyzed by the test.

''(2) APPLICABLE STANDARD.—The term 'applicable standard', with respect to an in vitro clinical test, means a reasonable assurance of analytical and clinical validity for its indications for use, and a reasonable assurance of safety for individuals who come into contact with such in vitro clinical test, except that such term, with respect to specimen receptacles and test instruments, means a reasonable assurance of analytical validity for its indications for use and safety for individuals who come into contact with such specimen receptacle or test instrument.

''(3) CLINICAL USE.—The term 'clinical use' means the operation, application, or functioning of an in vitro clinical test for the purpose for which it is intended as described in section 201(ss)(1).

''(4) 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).

''(5) COMPONENT OR PART.—The term 'component or part' means a substance, piece, part, raw material, software, firmware, labeling, or assembly, including reagents, that is intended to be included as

an aspect of an in vitro clinical test described in section 201(ss)(1).

''(6) DEVELOP.—The term 'develop', with respect to an in vitro clinical test, means—

''(A) designing, validating, producing, manufacturing, remanufacturing, labeling, advertising, propagating, importing, or assembling an in vitro clinical test;

''(B) modifying an in vitro clinical test, including modifying the indications for use of the in vitro clinical test, or modifying an article to be an in vitro clinical test; or

''(C) establishing a test system as described or included in a test protocol developed by another entity unless such test protocol is listed as an in vitro clinical test in the comprehensive test information system established under section 587T by that other entity.

''(7) DEVELOPER.—The term 'developer' means a person who engages in development as described in paragraph (6), except the term does not include a laboratory that—

''(A) is certified by the Secretary under section 353 of the Public Health Service Act; and

''(B) assembles for use solely within that laboratory, without otherwise developing, an in vitro clinical test appropriately listed in the comprehensive test information system established under section 587T by a different person.

''(8) FIRST-OF-A-KIND.—The term 'first-of-a-kind', with respect to an in vitro clinical test, means that such test has any novel combination of the elements specified in paragraph (10) that differs from in vitro clinical tests that already are legally available in the United States, except for such tests offered under section 587C(a)(3), 587C(a)(4), or 587G.

''(9) HIGH-RISK.—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 such category of tests, when used as intended—

''(A)(i) is reasonably likely to result in serious or irreversible harm or death to a patient or patients, or would otherwise cause serious harm to the public health; or

''(ii) is reasonably likely to result in the absence, significant delay, or discontinuation of

life-supporting or life-sustaining medical treatment; and

''(B) mitigating measures are not able to be established and applied to prevent, mitigate, or detect the inaccurate result, or otherwise sufficiently mitigate the risk resulting from an undetected inaccurate result described in subparagraph (A), such that the test would be moderate-risk or low-risk.

''(10) INDICATIONS FOR USE.—The term 'indications for use', with respect to an in vitro clinical test, means the following elements:

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

''(B) Test method.

''(C) Test purpose or purposes, as described in section 201(ss)(1).

''(D) Diseases or conditions for which the in vitro clinical test is intended for use, including intended patient populations.

''(E) 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.

''(11) INSTRUMENT.—

''(A) IN GENERAL.—The term 'instrument' means an analytical or pre-analytical instrument.

''(B) ANALYTIC INSTRUMENT.—The term 'analytic instrument' means an in vitro clinical test that is hardware intended by the developer to be used with one or more other in vitro clinical tests to generate a clinical test result, including software used to effectuate the functionality of the hardware.

''(C) PRE-ANALYTICAL INSTRUMENT.—The term 'pre-analytical instrument' means an in vitro clinical test that is hardware intended by the developer solely to generate an output for use exclusively with one or more analytical instruments as defined in subparagraph (B) and which does not itself generate a clinical test result. Such term may include software used to effectuate the hardware's functionality.

''(12) INSTRUMENT FAMILY.—The term 'instrument family' means more than one instrument developed by the same developer for which the developer demonstrates and documents, with respect to all such instruments, that all—

''(A) have the same basic architecture, design, and performance characteristics;

''(B) have the same indications for use and capabilities;

''(C) share the same measurement principles, detection methods, and reaction conditions, as applicable; and

''(D) produce the same or similar analytical results from samples of the same specimen type or types.

''(13) LABORATORY OPERATIONS.—The term 'laboratory operations'—

''(A) means the conduct of a laboratory examination or other laboratory procedure on materials derived from the human body, including the conduct of an in vitro clinical test and associated activities, that is—

''(i) regulated under section 353 of the Public Health Service Act; and

''(ii) not related to the design, analytical validation, or clinical validation of an in vitro clinical test; and

''(B) includes—

"(i) performing pre-analytical and post-analytical processes for an in vitro clinical test;

"(ii) standard operating procedures and the conduct thereof; and

"(iii) preparing reagents or other test materials that do not meet the criteria for being an in vitro clinical test for clinical use.

"(14) LOW-RISK.—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—

"(A) would cause only minimal or immediately reversible harm, and would lead to only a remote risk of adverse patient impact or adverse public health impact; or

"(B) sufficient mitigating measures are able to be established and applied such that the in vitro clinical test meets the standard described in subparagraph (A).

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

''(A) means controls, standards, and other requirements that the Secretary determines, based on evidence, are necessary—

''(i) for an in vitro clinical test, or a category of in vitro clinical tests, to meet the applicable standard; or

''(ii) to mitigate the risk of harm ensuing from an undetected inaccurate result or misinterpretation of a result; and

''(B) may include, as required by the Secretary, as appropriate, applicable requirements regarding labeling, conformance to performance standards and consensus standards, performance testing, submission of clinical data, advertising, website posting of information, clinical studies, postmarket surveillance, user comprehension studies, training, and confirmatory laboratory, clinical findings, the history of the developer, the role of a health professional in the testing process, such as integration of the testing laboratory into the direct medical care of the patient, including direct interaction between the testing laboratory and treating physician, or testing.

''(16) MODERATE-RISK.—The term 'moderate-risk', with respect to an in vitro clinical test or category of in vitro clinical tests—

''(A) means a test or category of tests that is not high-risk under the criteria under paragraph (9) or low-risk under the criteria under paragraph (14); and

''(B) may include a test or category of tests that, when used as intended, meet the criteria specified in paragraph (9)(A) for high-risk, but for which one or more mitigating measures are able to be established and applied to prevent, mitigate, or detect an inaccurate result or otherwise sufficiently mitigate the risk resulting from an undetected inaccurate result, but are not sufficient such that the test is low-risk under the criteria in paragraph (14).

''(17) SPECIMEN RECEPTACLE.—The term 'specimen receptacle' means an in vitro clinical test intended for taking, collecting, holding, storing, or transporting of specimens derived from the human body or for preparation, analysis, or in vitro clinical examination for purposes described in section 201(ss)(1).

''(18) TECHNOLOGY.—The term 'technology'—

''(A) means a set of control mechanisms, energy sources, or operating principles—

''(i) that do not differ significantly among multiple in vitro clinical tests; and

''(ii) for which design and development (including analytical and clinical validation, as applicable) of the tests would be addressed in a similar manner or through similar procedures; and

''(B) may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture, next generation sequencing, nephlometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

''(19) TEST.—The term 'test', unless otherwise provided, means an in vitro clinical test.

''(20) VALID SCIENTIFIC EVIDENCE.—The term 'valid scientific evidence'—

''(A) means, with respect to an in vitro clinical test, evidence that—

''(i) 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) forms an appropriate basis for concluding by qualified experts whether the applicable standard has been met by the in vitro clinical test; and

''(B) 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) real world data;

''(xii) clinical trials; and

''(xiii) data collected in countries other than the United States if such data are demonstrated to be appropriate for the purpose of making a regulatory determination under this subchapter.

''SEC. 587A. REGULATION OF IN VITRO CLINICAL TESTS.

''(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 (a) or (b) of section 587B is effective with respect to such in vitro clinical test;

''(2) the in vitro clinical test is offered under a technology certification order under section 587D(b)(1); or

''(3) the test is exempt under sections 587C or 587G from the requirements of section 587B.

''(b) TRANSFER OR SALE OF IN VITRO CLINICAL TESTS.—

''(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 listing information under section 587J 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 listing information under section 587J for the in vitro clinical test; and

''(ii) submit a supplement to an application if required under section 587B(h).

''(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 supplement to an application under section 587B(h) if required, whichever is later. The transferee or

purchaser shall update the registration and listing information under section 587J for the in vitro clinical test within 15 calendar days of the effective date of the transfer or sale.

''(3) TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—

''(A) REQUIREMENTS FOR TRANSFER OR SALE OF TECHNOLOGY CERTIFICATION.—An unexpired technology certification can be transferred or sold if the transferee or purchaser—

''(i) is an eligible person under section 587D(a)(2); and

''(ii) maintains, upon such transfer or sale, test design and quality requirements, processes and procedures under the scope of technology certification, and scope of the technology certification identified in the applicable technology certification order.

''(B) NOTICE REQUIRED.—If a developer of an in vitro clinical test transfers or sells a technology certification order that has not expired, the transferor or seller shall submit a notice of the transfer or sale to the Secretary and shall update the registration and listing information under section 587J for all in vitro clin-

ical tests covered by the technology certification.

''(C) EFFECTIVE DATE OF TECHNOLOGY CERTIFICATION TRANSFER.—The transfer of a technology certification shall become effective upon completion of a transfer or sale described in subparagraph (A). The transferee or purchaser shall update the registration and listing information under section 587J for the in vitro clinical test within 30 calendar days of the effective date of the technology certification transfer.

''(D) NEW TECHNOLOGY CERTIFICATION REQUIRED.—If the requirements of subparagraph (A)(ii) are not met, the technology certification order may not be transferred and the transferee or purchaser of an in vitro clinical test is required to submit an application for technology certification and obtain a technology certification order prior to offering the test for clinical use.

''(c) REGULATIONS.—The Secretary may issue regulations to implement this subchapter.

''SEC. 587B. PREMARKET REVIEW.

''(a) APPLICATION.—

''(1) FILING.—Any developer may file with the Secretary an application for premarket approval of an in vitro clinical test under this subsection.

''(2) TRANSPARENCY AND PREDICTABILITY.—If a developer files a premarket application under this section and provides any additional documentation required under section 587D, the in vitro clinical test that is the subject of the premarket application may be utilized as the representative in vitro clinical test reviewed by the Secretary to support a technology certification order under section 587D.

''(3) APPLICATION CONTENT.—An application submitted under paragraph (1) shall include the following, in such format as the Secretary specifies:

''(A) General information regarding the in vitro clinical test, including—

''(i) the name and address of the applicant;

''(ii) the table of contents for the application and the identification of the information the applicant claims as trade secret or confidential commercial or financial information;

''(iii) a description of the test's design and intended use, including the indications for use; and

''(iv) a description regarding test function and performance characteristics.

''(B) A summary of the data and information in the application for the in vitro clinical test, including—

''(i) a brief description of the foreign and domestic marketing history of the test, if any, including a list of all countries in which the test has been marketed and a list of all countries in which the test has been withdrawn from the market for any reason related to the ability of the in vitro clinical test to meet the applicable standard, if known by the applicant;

''(ii) a description of benefit and risk considerations related to the in vitro clinical test, including a description of any applicable adverse effects of the test on health and how such adverse effects have been, or will be, mitigated;

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

''(iv) a description of how the data and information in the application constitute valid scientific evidence and support a showing that the test meets the applicable standard under section 587(2).

''(C) The signature of the developer filing the premarket application or an authorized representative.

''(D) A bibliography of applicable published reports and a description of any studies conducted, including any unpublished studies related to such test, that are known or that should reasonably be known to the applicant, and a description of data and information relevant to the evaluation of whether the test meets the applicable standard.

''(E) Applicable information regarding the methods used in, and the facilities or controls used for, the development of the test to demonstrate compliance with the applicable quality requirements under section 587K.

''(F) Information demonstrating compliance with any relevant and applicable—

''(i) mitigating measures under section 587E; and

''(ii) standards established or recognized under section 514 prior to the date of enactment of the VALID Act of 2023, or, after applicable standards are established or recognized under section 587R, with such standards.

''(G) Valid scientific evidence to support that the test meets the applicable standard, which shall include—

''(i) summary information for all supporting validation studies performed, including a description of the objective of the study, a description of the experimental design of the study, a description of any limitations of the study, a brief description of how the data were collected and analyzed, a brief description of the results of each study, and conclusions drawn from each study;

''(ii) raw data for each study, which may include, as applicable, tabulations of data and results; and

''(iii) for nonclinical laboratory studies involving the test, if applicable, a statement that studies were conducted in com-

pliance with applicable good laboratory practices.

''(H) To the extent the application seeks authorization to make modifications to the test within the scope of the approval that are not otherwise permitted without premarket review under this subchapter, a proposed change protocol that includes validation procedures and acceptance criteria for anticipated modifications that could be made to the test within the scope of the approval.

''(I) Proposed labeling, in accordance with the requirements of section 587L.

''(J) Such other data or information as the Secretary may require in accordance with the least burdensome requirements under section 587AA(c).

''(4) REGULATION FOR PREMARKET AND ABBREVIATED PREMARKET APPLICATIONS.—Not later than 3 years after the date of enactment of the VALID Act of 2023, the Secretary shall promulgate final regulations detailing the information to be provided in a premarket application and abbreviated premarket application under this section.

''(5) REFUSE TO FILE A PREMARKET OR ABBREVIATED PREMARKET APPLICATION.—The Secretary may refuse to file an application under this section only for lack of completeness or legibility of the application. If, after receipt of an application under this section, the Secretary refuses to file such an application, the Secretary shall provide to the developer, within 45 calendar days of receipt of such application submitted under this subsection or within 30 calendar days of receipt of an application submitted under subsection (b), a description of the reason for such refusal, and identify the information required, if any, to allow for the filing of the application.

''(6) SUBSTANTIVE REVIEW FOR DEFICIENT APPLICATION.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is materially deficient, the Secretary shall provide to the applicant a description of such material deficiencies and the information required to resolve such deficiencies.

''(7) INSPECTIONS.—With respect to an application under paragraph (1), preapproval inspections authorized by an employee of the Food and Drug Administration or a person accredited under section

587Q need not occur unless requested by the Secretary.

''(b) ABBREVIATED PREMARKET REVIEW.—

''(1) IN GENERAL.—Any developer may file with the Secretary an application for abbreviated premarket approval for—

''(A) an instrument;

''(B) a specimen receptacle;

''(C) an in vitro clinical test that is moderate-risk; or

''(D) an in vitro clinical test that is determined by the Secretary to be eligible for abbreviated premarket review under section 587F(a)(1)(B).

''(2) APPLICATION CONTENT.—An application under paragraph (1) shall include—

''(A) the information required for applications submitted under subsection (a)(3), except that applications under paragraph (1) need not include—

''(i) quality requirement information; or

''(ii) raw data, unless requested in writing by the Secretary, in accordance with the least burdensome requirements

under section 587AA(c), and with supervisory review and concurrence prior to issuance of such request; and

''(B) data, as applicable, to support software validation, electromagnetic compatibility, and electrical safety, and information demonstrating compliance with maintaining quality systems documentation.

''(3) SAFETY INFORMATION.—The developer of an in vitro clinical test specimen receptacle reviewed under this subsection shall maintain safety information for such specimen receptacle.

''(4) INSPECTIONS.—With respect to an application under paragraph (1), preapproval inspections shall not be required unless requested in writing by the Secretary, after supervisory review and concurrence, because such inspection is considered necessary to complete the review.

''(c) INSTRUMENTS AND INSTRUMENT FAMILIES.—

''(1) IN GENERAL.—A developer of an instrument family shall file with the Secretary an application for premarket approval of one version of an instrument under this subsection. Any modified versions of the instrument that generate a new instrument within the same instrument family shall be

exempt from premarket review requirements of this section, provided that the developer of such instrument or instrument family—

"(A) maintains documentation that the new instrument is part of the instrument family, as defined in section 587;

"(B) performs, documents, and maintains a risk assessment (as described in subsection (a)(3)(B)(iii)) of the new instrument compared to the instrument approved under subsection (b) and no new risks are identified;

"(C) performs, documents, and maintains validation and verification activities for the new instrument;

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

"(E) registers and lists the new instrument in accordance with section 587J.

"(2) TEST KITS AND TEST PROTOCOLS.—With regard to a test kit or test protocol that is approved under this section for use on an approved instrument or an instrument exempt from premarket review, including an instrument within an instrument family under this section, a submission under this section shall not be required for such test kit or test

protocol in order for it to be used on a new instrument within its instrument family, provided that—

''(A) use of the test kit or test protocol with the new instrument does not—

''(i) change the claims for the test kit or test protocol, except as applicable, claims regarding an instrument or instruments that can be used with such test kit or test protocol;

''(ii) adversely affect performance of the test kit or test protocol; or

''(iii) cause the test kit or test protocol to no longer conform with performance standards required under section 587R or comply with any applicable mitigating measures under section 587E, conditions of approval under subsection (e)(2)(B), or restrictions under section 587O;

''(B) the test developer does not identify any new risks for the test kit or test protocol when using the new instrument after conducting a risk assessment;

''(C) the test developer validates the use of the new instrument with the test kit or test

protocol and maintains validation documentation;

''(D) the test kit or test protocol is not intended for use—

''(i) in settings for which a certificate of waiver is in effect under section 353 of the Public Health Service Act;

''(ii) without a prescription;

''(iii) at home; or

''(iv) in testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products;

''(E) the test developer makes the documentation described under subparagraph (C) available to the Secretary upon request; and

''(F) the test developer updates the listing information for the test kit or test protocol, as applicable.

''(d) AMENDMENTS TO AN APPLICATION.—An applicant shall amend an application submitted under subsection (a), (b), or (f) if the applicant becomes aware of information that could reasonably affect an evaluation under subsection (e) of whether the approval standard has been met.

''(e) ACTION ON AN APPLICATION FOR PREMARKET APPROVAL.—

''(1) REVIEW.—

''(A) DISPOSITION.—As promptly as possible, but not later than 90 calendar days after an application under subsection (a) is accepted for submission (unless the Secretary determines that an extension is necessary to review one or more major amendments to the application), or not later than 60 calendar days after an application under subsection (b) is accepted for submission or a supplemental application under subsection (f) is accepted for submission, the Secretary, after considering any applicable report and recommendations pursuant to advisory committees under section 587H, shall issue an order approving the application, unless the Secretary finds that the grounds for approval in paragraph (2) are not met.

''(B) RELIANCE ON PROPOSED LABELING.—In determining whether to approve or deny an application under paragraph (1), the Secretary shall rely on the indications for use included in the proposed labeling, provided that

such labeling is not false or misleading based on a fair evaluation of all material facts.

''(2) APPROVAL OF AN APPLICATION.—

''(A) IN GENERAL.—The Secretary shall approve an application submitted under subsection (a) or (b) with respect to an in vitro clinical test if the Secretary finds that the applicable standard is met, and—

''(i) the applicant is in compliance with applicable quality requirements in section 587K;

''(ii) the application does not contain a false statement or misrepresentation of material fact;

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

''(iv) the applicant permits, if requested, authorized employees of the Food and Drug Administration and persons accredited under section 587Q an opportunity to inspect pursuant to section 704;

''(v) the test conforms with any applicable performance standards required

under section 587R and any applicable mitigating measures under section 587E;

''(vi) all nonclinical laboratory studies and clinical investigations involving human subjects that are described in the application were conducted in a manner that meets the applicable requirements of this subchapter; and

''(vii) other data and information the Secretary may require under subsection (a)(3)(J) support approval.

''(B) CONDITIONS OF APPROVAL.—An order approving an application pursuant to this section may require reasonable conditions of approval for the in vitro clinical test, which may include conformance with applicable mitigating measures under section 587E, restrictions under section 587O, and performance standards under section 587R.

''(C) PUBLICATION.—The Secretary shall publish an order for each application approved 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 approve such application. In mak-

ing the order and summary publicly available, the Secretary shall not disclose any information that—

''(i) is confidential commercial information or trade secret information subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; or

''(ii) could compromise national security.

''(3) REVIEW OF DENIALS.—An applicant whose application submitted under this section has been denied approval under this subsection may, by petition filed not more than 60 calendar days after the date on which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587P.

''(f) SUPPLEMENTS TO AN APPROVED APPLICATION.—

''(1) RISK ANALYSIS.—Prior to implementing any modification to an in vitro clinical test, the holder of the application approved under subsection (e) for such test shall perform risk analyses in accordance with this subsection, unless such modification is included in the change protocol submitted by the ap-

plicant and approved under this section or exempt under section 587C.

''(2) SUPPLEMENT REQUIREMENT.—

''(A) IN GENERAL.—If the holder of an application of an approved in vitro clinical test makes a modification to such in vitro clinical test, except as provided in subparagraph (C), or otherwise specified by the Secretary, the holder of the application approved under subsection (e) for an in vitro clinical test shall submit a supplemental application to the Secretary. The holder of the application may not implement such modification to the in vitro clinical test until such supplemental application is approved. The information required in a supplemental application is limited to what is needed to support the change.

''(B) CHANGE PROTOCOLS.—The holder of an approved application may submit under this paragraph a supplemental application to modify the change protocol for a test or to request a change protocol for a test.

''(C) EXCEPTIONS.—Notwithstanding subparagraphs (A) and (B), and so long as the holder of an approved application submitted

under subsection (a) or (b) 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 of an approved application may, without submission of a supplemental application, implement the following modifications to the test:

''(i) Modifications in accordance with an approved change protocol under subsection (a)(3)(H).

''(ii) Modifications that are exempt under section 587C(a)(6).

''(iii) Labeling changes that are appropriate to address a safety concern, except such labeling changes that include any of the following remain subject to subparagraph (A):

''(I) A change to the indications for use of the test.

''(II) A change to the performance claims made with respect to the test.

''(III) A change that adversely affects performance of the test.

''(D) REPORTING FOR CERTAIN MODIFICATIONS MADE PURSUANT TO A CHANGE PROTOCOL.—The holder of an application approved under subsection (e), with an approved change protocol under subsection (a)(2)(H) for such in vitro clinical test shall—

''(i) report any modification to such test made pursuant to such change protocol approved under subsection (a)(3)(H) in a submission under section 587J(c)(2)(B); and

''(ii) include in such report—

''(I) a description of the modification;

''(II) the rationale for implementing such modification; and

''(III) as applicable, a summary of the evidence supporting that the test, as modified, meets the applicable standard, complies with performance standards required under section 587Q, and complies with any mitigating measures established under section 587E and any restrictions under section 587O.

''(E) REPORTING FOR CERTAIN SAFETY RELATED LABELING CHANGES.—The holder of the application for an in vitro clinical test approved under subsection (e) shall—

''(i) report to the Secretary any modification to the test described in subparagraph (C)(iii) 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 description of the change or changes;

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

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

''(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 requiring a supplement—

''(i) a description of the modification;

''(ii) data relevant to the modification to demonstrate that the applicable stand-

ard is met, not to exceed data requirements for the original submission;

''(iii) acceptance criteria; and

''(iv) any revised labeling; and

''(B) for manufacturing site changes—

''(i) the information 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 requirements under section 587K.

''(4) 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 if the data request is in accordance with the least burdensome requirements under section 587AA(c).

''(5) 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 compliance with restrictions under section 587O and conformance to performance standards under section 587R.

''(6) APPROVAL.—The Secretary shall approve a supplement under this subsection if—

''(A) the data demonstrate that the modified in vitro clinical test meets the applicable standard; and

''(B) the holder of the application approved under subsection (e) for the test has demonstrated compliance with applicable quality and inspection requirements, as applicable and appropriate.

''(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 provided that doing so does not disclose any information that—

''(A) is trade secret or confidential commercial or financial information; or

''(B) could compromise national security.

''(8) REVIEW OF DENIAL.—An applicant whose supplement under this subsection has been denied approval may, by petition filed on or before the 60th calendar day after the date upon which the applicant receives notice of such denial, obtain review of the denial in accordance with section 587P.

''(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 under subsection (e) are no longer met;

''(ii) there is a reasonable likelihood that the test would cause death or serious adverse health consequences, including by causing the absence, significant delay, or discontinuation of life-saving or life sustaining medical treatment;

''(iii) the holder of the approved application—

''(I) has failed to, or repeatedly or deliberately failed to, maintain records to make reports, as required under section 587M;

''(II) has refused to permit access to, or copying or verification of such records, as required under section 704;

''(III) has not complied with the requirements of section 587K; or

''(IV) has not complied with any mitigating measure required under section 587E or restriction under section 587O; or

''(iv) the labeling of such in vitro clinical test, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact.

''(B) CONTENT.—An order under subparagraph (A) withdrawing approval of an application shall state each ground for withdrawal and shall notify the holder of such application 60 calendar days prior to issuing such order.

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

ministration provided that doing so does not disclose—

''(i) any information that is trade secret or confidential commercial or financial information; or

''(ii) any other information that the Secretary determines, if published, could compromise national security.

''(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, based on scientific evidence, that there is a reasonable likelihood that the in vitro clinical test would cause death or serious adverse health consequences, such as by causing the absence, significant delay, or discontinuation of life-saving or life-sustaining 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.

''(3) APPEAL WITHDRAWING APPROVAL AND ORDERS OF TEMPORARY SUSPENSIONS.—An order of

withdrawal or an order of temporary suspension may be appealed under 587P.

"SEC. 587C. EXEMPTIONS.

"(a) IN GENERAL.—The following in vitro clinical tests are exempt from premarket review under section 587B, and may be lawfully offered subject to other applicable requirements of this Act:

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

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

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

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

"(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as specified in subparagraph (A) if such test—

''(i)(I)(aa) was offered for clinical use prior to the date of enactment of the VALID Act of 2023; and

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

''(II)(aa) was not offered for clinical use prior to such date of enactment;

''(bb) is not an instrument; and

''(cc) 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 devices and excluding class I devices described in section 510(l));

''(ii) meets the applicable standard as described in section 587(2);

''(iii) is not offered with labeling and advertising that is false or misleading; and

''(iv) is not likely to cause or contribute to serious adverse health consequences.

"(C) EFFECT ON SPECIAL CONTROLS.—For any in vitro clinical test, or category of in vitro clinical tests, that is exempt from premarket review based on the criteria in subparagraph (B), any special control that applied to a device within a predecessor category immediately prior to the date of enactment of the VALID Act of 2023 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.

"(D) NEAR-PATIENT TESTING.—Not later than 1 year after the date of enactment of the VALID Act of 2023, the Secretary shall issue draft 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).

''(2) LOW-RISK TESTS.—

''(A) EXEMPTION.—An in vitro clinical test is exempt from premarket review under section 587B and may be lawfully offered subject to the other applicable requirements of this Act, including section 587J(b), if such test meets the definition of low-risk under section 587 and if the developer of the test—

''(i) maintains documentation demonstrating that the in vitro clinical test meets and continues to meet the criteria set forth in subparagraph (B); and

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

''(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as specified in subparagraph (A) if—

''(i) the in vitro clinical test meets the applicable standard as described in 587(2);

''(ii) the labeling and advertising are not false or misleading;

''(iii) the in vitro clinical test is not likely to cause or contribute to serious adverse health consequences; and

''(iv) the in vitro clinical test falls within a category of tests listed as described in subparagraph (C).

''(C) LIST OF LOW-RISK TESTS.—

''(i) 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 paragraph.

''(ii) INCLUSION.—The list under clause (i) shall consist of—

''(I) all in vitro clinical tests and categories of in vitro clinical tests that are exempt from premarket review pursuant to paragraph (1) or this paragraph; and

''(II) all in vitro clinical tests and categories of in vitro clinical tests that are designated by the Secretary pursuant to subparagraph (D) as low-risk for purposes of this paragraph.

"(D) 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 (C)(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 paragraph. The Secretary may make such a designation on the Secretary's own initiative or in response to a request by a developer pursuant to subsection (a) or (b) of section 587F. 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;

"(ii) the existence of and ability to develop mitigating measures sufficient for such test category to meet the low-risk standard; and

"(iii) such other factors as the Secretary determines to be appropriate for the protection of the public health.

"(3) HUMANITARIAN TEST EXEMPTION.—

''(A) IN GENERAL.—An in vitro clinical test that meets the criteria under subparagraph (B) is exempt from premarket review under section 587B and may be lawfully offered subject to the other applicable requirements of this subchapter, if the developer of the test—

''(i) maintains documentation (which may include literature citations in specialized medical journals, textbooks, specialized medical society proceedings, and 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 this subsection; and

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

''(B) CRITERIA FOR EXEMPTION.—An in vitro clinical test is exempt as described in subparagraph (A) if—

''(i) the in vitro clinical test is intended by the developer for use for a diagnostic purpose for—

''(I) a noncontagious disease or condition that affects not more than 10,000 (or such other higher number determined by the Secretary) individuals in the United States per year; or

''(II) a contagious disease or condition that affects not more than 1,500 individuals in the United States per year;

''(ii) the in vitro clinical test meets the applicable standard described in section 587(2);

''(iii) the labeling and advertising for the in vitro clinical test are not false or misleading;

''(iv) the in vitro clinical test is not likely to cause or contribute to serious adverse health consequences; and

''(v) the in vitro clinical test is not intended for screening.

''(C) EXCEPTION FOR CERTAIN TESTS.—An in vitro clinical test intended to inform the use of a specific individual or specific type of biological product, drug, or device shall be eligible for an exemption from premarket review under

this subsection only if, the developer submits a request under section 587F(e) for informal feedback and the Secretary determines that such in vitro clinical test is eligible for an exemption from premarket review under this subsection.

''(4) CUSTOM TESTS AND LOW-VOLUME TESTS.—An in vitro clinical test is exempt from premarket review under section 587B, quality requirements under section 587K, and listing requirements under section 587J, and may be lawfully offered subject to the other applicable requirements of this Act, if—

''(A) such in vitro clinical test—

''(i) is a test protocol performed for not more than 5 patients per year (or such other higher number determined by the Secretary), in a laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

''(I) meets the requirements to perform tests of high-complexity in which the test protocol was developed; or

''(II) meets the requirements to perform tests of high-complexity within the same corporate organization and having common ownership by the same parent corporation as the laboratory in which such test protocol was developed; or

''(ii) is an in vitro clinical test developed to diagnose a unique pathology or physical condition of a specific patient or patients (including an in vitro clinical test modified for such purpose), upon the prescription or order of a health care practitioner licensed to prescribe or order such test, or a health care professional or other specially qualified person designated under regulations to prescribe or order such test, for which no other in vitro clinical test is commercially available in the United States, and is—

''(I) not intended for use with respect to more than 5 (or such other higher number determined by the Secretary) other patients; and

''(II) not included in any test menu or template test report or other promotional materials, and is not otherwise advertised; and

''(B) the developer of the in vitro clinical test—

''(i) maintains documentation demonstrating that such test meets the applicable criteria described in subparagraph (A);

''(ii) makes such documentation, such as a prescription order requesting the custom test for an individual patient, available to the Secretary upon request; and

''(iii) informs the Secretary, on an annual basis, in a manner prescribed by the Secretary by guidance, that such test was offered.

''(5) IN VITRO CLINICAL TESTS UNDER A TECHNOLOGY CERTIFICATION ORDER.—An in vitro clinical test that is within the scope of a technology certification order under section 587D is exempt from premarket review under section 587B.

''(6) MODIFIED TESTS.—

"(A) IN GENERAL.—An in vitro clinical test that is modified is exempt from premarket review under section 587B if—

"(i) the modification is made by—

"(I) the developer that obtained premarket approval for the unmodified version of the test under section 587B; or

"(II) a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements for performing high complexity testing, to a lawfully offered in vitro clinical test, including another developer's lawfully offered in vitro clinical test, excluding investigational in vitro clinical tests offered under section 587S, and the modified test is performed—

"(aa) in the same clinical laboratory in which it was developed for which a certification is still in effect under section 353 that meets the requirements to perform tests of high complexity;

''(bb) by another clinical laboratory for which a certificate is in effect under section 353 that meets the requirements to perform tests of high complexity, is within the same corporate organization, and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

''(cc) by a clinical laboratory for which a certificate is in effect under section 353 that meets the requirements to perform tests of high complexity and is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, if the test was developed by the Centers for Disease Control and Prevention or another laboratory within such public health laboratory network;

''(ii) the modification does not—

''(I) constitute a significant change to the indications for use, except for changes to a specimen type, as specified in the guidance issued under subparagraph (E);

''(II) cause the test to no longer comply with applicable mitigating measures under section 587E or restrictions under section 587O;

''(III) significantly change performance claims or significantly and adversely change performance, unless provided for under an approved change protocol under section 587B(a)(3)(H); or

''(IV) constitute an adverse change in the safety of the in vitro clinical test for individuals who come in contact with the in vitro clinical test;

''(iii) the test meets the applicable standard as described in section 587(2);

''(iv) the labeling and advertising are not false or misleading; and

"(v) the test is not likely to cause or contribute to serious adverse health consequences.

"(B) CERTAIN MODIFICATIONS.—A modification to extend specimen stability is exempt from premarket review under section 587B if the modified test meets the requirements in clauses (ii) through (v) of subparagraph (A).

"(C) MODIFICATIONS UNDER A CHANGE PROTOCOL.—Notwithstanding subparagraph (A), a modification made under a change protocol pursuant to subsection (a)(2)(H) of section 587B is exempt from review under such section.

"(D) DOCUMENTATION.—A person who modifies an in vitro clinical test in a manner that is a modification described in this paragraph shall—

"(i) document the modification that was made and the basis for determining that the modification, considering the changes individually and collectively, is a type of modification described in subparagraph (A), (B), or (C); and

''(ii) provide such documentation to the Secretary upon request or inspection.

''(E) GUIDANCE.—Not later than 30 months after the date of enactment of the VALID Act of 2023, the Secretary shall issue guidance regarding the in vitro clinical tests that are modified and exempt from premarket review under section 587B pursuant to this paragraph. Such guidance shall include considerations for changes to a specimen type that may be made by a developer without the requirement of premarket review under 587B.

''(b) MANUAL TESTS.—

''(1) EXEMPTION.—An in vitro clinical test is exempt from all requirements of this subchapter if the output of such in vitro clinical test is the result of direct, manual observation, without the use of automated instrumentation or software for intermediate or final interpretation, by a qualified laboratory professional, and such in vitro clinical test—

''(A) is developed and used within a single clinical 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;

''(B) is not a specimen receptacle, instrument, or an in vitro clinical test that includes an instrument or specimen receptacle that is not approved under or exempt from section 587B;

''(C) is not a high-risk test, or is a high-risk test that the Secretary has determined meets at least one condition in paragraph (2) and is otherwise appropriate for this exemption; and

''(D) is not intended for testing donors, donations, or recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products.

''(2) HIGH-RISK TEST LIMITATION OR CONDITION.—A high-risk test may be exempt under paragraph (1) from the requirements of this subchapter only if—

''(A) no components or parts of such test, including any reagent, is introduced into interstate commerce under the exemption under subsection (e), 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 subchapter; or

''(B) the test has been developed in accordance with the applicable test design and quality requirements under section 587K.

''(c) PUBLIC HEALTH SURVEILLANCE ACTIVITIES.—

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

''(2) EXCLUSION.—An in vitro clinical test used for public health surveillance activities is not excluded from the provisions of this subchapter pursuant to this subsection if such test is intended for use in making clinical decisions for individual patients.

''(d) GENERAL LABORATORY EQUIPMENT.—As set forth in section 201(ss)(3)(C), general purposes laboratory equipment is not an in vitro clinical tests and is not subject to the requirements of this subchapter.

''(e) COMPONENTS AND PARTS.—

''(1) IN GENERAL.—Subject to paragraph (2), a component or part described in section 201(ss)(2)(G) is—

''(A) exempt from the requirements of this subchapter if it is intended for further development as described in paragraph (3); or

''(B) subject to the requirements of this subchapter and regulated based on its risk when used as intended by the developer, notwithstanding its subsequent use by a developer as a component, part, or raw material of another in vitro clinical test.

''(2) INAPPLICABILITY TO OTHER TESTS.—Notwithstanding paragraph (1), an in vitro clinical test that is described in section 201(ss)(1)(B) and that uses a component or part described in such subparagraph shall be subject to the requirements of this subchapter, unless the test is otherwise exempt under this section.

''(3) FURTHER DEVELOPMENT.—A component, part, or raw material (as described in paragraph (1)) 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) in the case of such a test that is introduced or delivered for introduction into interstate commerce after the date of enactment

of the VALID Act of 2023, 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 if it is used with or in the development of an in vitro clinical test.'.

''(f) 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 for the protection of the public health and other relevant considerations.

''(g) OTHER EXEMPTIONS.—An in vitro clinical test that is intended solely for use in forensic analysis or law enforcement activity is exempt from the requirements of this subchapter. 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 forensic analysis or law enforcement purposes, is not intended solely for forensic

analysis or law enforcement for purposes of this subsection.

''(h) REVOCATION.—

''(1) IN GENERAL.—The Secretary may revoke any exemption under this section with respect to in vitro clinical tests with the same indications for use if new clinical information indicates that the exemption of an in vitro clinical test or tests from premarket review under section 587B has a reasonable probability of severe adverse health consequences, including the absence, delay, or discontinuation of appropriate medical treatment.

''(2) PROCESS.—Any action under paragraph (1) shall be made by publication of a notice of such proposed action on the website of the Food and Drug Administration, the consideration of comments to a public docket on such proposal, and publication of a final action on such website within 60 calendar days of the close of the comment period posted to such public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''(i) PRE-ANALYTICAL INSTRUMENT.—A pre-analytical instrument is exempt from premarket review under section 587B and may be lawfully offered subject to the

other applicable requirements of this Act, if either of the following applies:

''(1) Such instrument provides additional information regarding the sample or performs an action on the sample but is not preparing or processing the sample and does not perform any function of an analytical instrument. Such types of pre-analytical instruments include barcode readers, sample movers, and sample identifiers.

''(2) Such instrument processes or prepares the sample prior to use on an analytical instrument, does not perform any function of an analytical instrument, and does not select, isolate, or prepare a part of a sample based on specific properties. Such types of pre-analytical instruments may include sample mixers, DNA extractors and those used to dilute samples.

''SEC. 587D. TECHNOLOGY CERTIFICATION.

''(a) DEFINITIONS.—In this section:

''(1) ELIGIBLE IN VITRO CLINICAL TEST.—The term 'eligible in vitro clinical test' means an in vitro clinical test that is not—

''(A) a component or part of an in vitro clinical test as described in section 201(ss)(2)(G) unless it is a component or part

and is regulated based on its own risk under section 587C(e)(1)(B) or as part of an otherwise eligible in vitro clinical test;

''(B) an instrument under section 201(ss)(2)(D) or an in vitro clinical test that includes an instrument that is subject to section 587B, but is not approved under, or exempt from, section 587B;

''(C) a specimen receptacle under section 201(ss)(2)(E) or an in vitro clinical test that includes a specimen receptacle that is subject to section 587B, but is not approved under, or exempt from, section 587B;

''(D) an in vitro clinical test, including reagents used in such tests, intended for use for testing donors, donations, and recipients of blood, blood components, human cells, tissues, cellular-based products, or tissue-based products;

''(E) high-risk;

''(F) a combination product, unless such test has been determined to be eligible to be introduced into interstate commerce under a technology certification order pursuant to the regulatory pathway designation process described in

section 587F, or as described in subsection (k), and the drug or biological product constituent part complies with the requirements of section 503(g) applicable to the drug or biological product; or

''(G) a first-of-a-kind in vitro clinical test, unless such test has been determined to be eligible to be introduced into interstate commerce under a technology certification order pursuant to the regulatory pathway designation process described in section 587F, or as described in subsection (k).

''(2) ELIGIBLE PERSON.—The term 'eligible person' means an in vitro clinical test developer unless such developer—

''(A) is a laboratory subject to section 353 of the Public Health Service Act and does not have in effect a certificate applicable to the category of laboratory examination or other procedure;

''(B) was a laboratory, or an owner or operator or any employee of a laboratory, found to have committed a significant violation of section 353 of the Public Health Service Act that resulted in a suspended, revoked, or limited cer-

tificate within the 2-year period preceding the date of the submission of the application for a technology certificate under subsection (c) and such violation has not been resolved; or

''(C) has been found to have submitted information to the Secretary, or otherwise disseminated information, that—

''(i) made false or misleading statements relevant to the requirements of this subchapter; or

''(ii) violated any requirement of this Act, where such violation exposed individuals to serious risk of illness, injury, or death, unless—

''(I) such violation has been resolved; or

''(II) such violation is not pertinent to any in vitro clinical test within the scope of the technology certification that such developer seeks.

''(b) APPLICABILITY.—

''(1) IN GENERAL.—An in vitro clinical test is not subject to section 587B and may be introduced into interstate commerce if the in vitro clinical test—

''(A) is an eligible in vitro clinical test;

''(B) is developed by an eligible person;

''(C) falls within the scope of a technology certification order issued under this section and that is in effect;

''(D) complies with the conditions of the technology certification order, including with applicable mitigating measures under section 587E, restrictions under section 587O, and performance standards under section 587R; and

''(E) meets the applicable standard described in section 587(2).

''(2) SCOPE.—

''(A) IN GENERAL.—Subject to subparagraph (B), the scope of a technology certification order issued under this section shall apply to one or more technologies with multiple in vitro clinical tests utilizing a technology that does not significantly differ in control mechanisms, energy sources, or operating principles and for which development, including design, and analytical and clinical validation, of the in vitro clinical tests would be addressed through similar procedures, and be no broader than—

''(i) a single technology type; or

"(ii) a fixed combination of technologies.

"(B) TECHNOLOGY TYPE.—A technology type described in this paragraph may include clot detection, colorimetric (non-immunoassay), electrochemical (non-immunoassay), enzymatic (non-immunoassay), flow cytometry, fluorometry (non-immunoassay), immunoassay, mass spectrometry or chromatography, microbial culture, next generation sequencing, nephlometric or turbidimetric (non-immunoassay), singleplex or multiplex non-NGS nucleic acid analysis, slide-based technology, spectroscopy, and any other technology, as the Secretary determines appropriate.

"(c) APPLICATION FOR TECHNOLOGY CERTIFICATION.—

"(1) IN GENERAL.—A developer seeking a technology certification order shall submit an application under this subsection, which shall contain the information specified under paragraph (2).

"(2) CONTENT OF APPLICATION.—A developer that submits an application for a technology certification shall include all necessary information to make a showing that all eligible in vitro clinical tests

developed within the scope of the technology certification order will meet the applicable standard, including—

''(A) the name and address of the developer;

''(B) a table of contents for the application and the identification of the information the developer claims as trade secret or confidential commercial or financial information;

''(C) the signature of the individual filing the application or an authorized representative;

''(D) a statement identifying the scope of the proposed technology certification intended to be introduced into interstate commerce under the application;

''(E) information establishing that the developer submitting the application is an eligible person;

''(F) quality procedures showing that eligible in vitro clinical tests covered under the technology certification will conform to the applicable quality requirements of section 587K with respect to—

''(i) design controls, including related purchasing controls and acceptance activities;

''(ii) complaint investigation, adverse event reporting, and corrections and removals; and

''(iii) process validation, as applicable;

''(G) procedures for analytical and clinical validation, including all procedures for validation, verification, and acceptance criteria, and an explanation as to how such procedures, when used, provide a showing that eligible in vitro clinical tests within the proposed scope of the technology certification order are analytically and clinically valid;

''(H) procedures that provide a showing that in vitro clinical tests covered by the proposed scope of the technology certification order will be safe for individuals who come into contact with in vitro clinical tests covered by such order;

''(I) a proposed listing submission under section 587J(b) for in vitro clinical tests that the developer intends to introduce into interstate commerce upon receiving a technology cer-

tification order, which shall not be construed to limit the developer from introducing additional tests not included in such submission under the same technology certification order;

''(J) information concerning one or more representative in vitro clinical tests, including—

''(i) a test within the scope of the technology certification application with the appropriate analytical complexity at the time of the submission of the application under this section to serve as the representative test;

''(ii) the information specified in subsection (a) or (b) of section 587B, as applicable, for the representative in vitro clinical test or tests, unless the Secretary determines that such information is not necessary;

''(iii) a summary of a risk assessment of the in vitro clinical test;

''(iv) an explanation of the choice of the representative in vitro clinical test or tests for the technology certification application and how such test adequately demonstrates the range of procedures that the

developer includes in the application under subparagraphs (F), (G), (H), and (I); and

''(v) a brief explanation of the ways in which the procedures included in the application under subparagraphs (F), (G), (H), and (I) have been applied to the representative in vitro clinical test or tests; and

''(K) such other information necessary to make a determination on a technology certification application as the Secretary may determine necessary.

''(3) REFERENCE TO EXISTING APPLICATIONS.—With respect to the content requirements in the technology certification application described in paragraph (2), a developer may incorporate by reference any content of an application previously submitted by the developer.

''(d) ACTION ON AN APPLICATION FOR TECHNOLOGY CERTIFICATION.—

''(1) SECRETARY RESPONSE.—

''(A) IN GENERAL.—As promptly as practicable, and not later than 90 days after receipt of an application under subsection (c), the Secretary shall—

''(i) if the Secretary finds that all of the grounds in paragraph (3) are met, issue a technology certification order granting the application, which—

''(I) may include reasonable conditions of certification; and

''(II) shall specify the scope of the technology certification; or

''(ii) 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.

''(B) EXTENSION.—The timeline described in subparagraph (A) may be extended by mutual agreement between the Secretary and the applicant.

''(2) DEFICIENT APPLICATIONS.—

''(A) IN GENERAL.—If, after receipt of an application under this section, the Secretary determines that any portion of such application is deficient, the Secretary, not later than 60 days after receipt of such application, shall provide to the applicant a description of such defi-

ciencies and identify the information required to resolve such deficiencies.

''(B) CONVERTING TO PREMARKET APPLICATIONS.—When responding to the deficiency letter, the developer may convert the application for technology certification under subsection (c) into a premarket application under section 587B.

''(3) TECHNOLOGY CERTIFICATION ORDER.—The Secretary shall issue an order granting a technology certification under this section if, on the basis of the information submitted to the Secretary as part of the application and any other information with respect to such applicant, the Secretary finds that—

''(A) there is a showing that in vitro clinical tests within the scope of the technology certification order will meet the applicable standard;

''(B) the methods used in, and the facilities or controls used for, the development of eligible in vitro clinical tests covered by the proposed scope of the technology certification conform to the applicable requirements of section 587K with respect to—

''(i) design controls, including related purchasing controls and acceptance activities;

''(ii) complaint investigation, adverse event reporting, and corrections and removals; and

''(iii) process validation, as applicable;

''(C) based on a fair evaluation of all material facts, the applicant's proposed labeling and advertising are not false or misleading in any particular;

''(D) the application does not contain a false statement of material fact;

''(E) there is a showing that the representative in vitro clinical test or tests—

''(i) meet the applicable standard; and

''(ii) reasonably represent the range of procedures required to be submitted in the application;

''(F) the applicant has agreed to permit, upon request, authorized employees of the Food and Drug Administration or persons accredited, or recognized 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; and

''(G) based on other data and information the Secretary may require under subsection (c)(2)(K), the Secretary finds that such data and information support granting a technology certification order.

''(4) REVIEW OF DENIALS.—An applicant whose application has been denied under this subsection may obtain review of such denial under section 587P.

''(e) SUPPLEMENTS.—

''(1) SUPPLEMENTAL APPLICATIONS.—

''(A) IN GENERAL.—With respect to any of the following changes related to a technology certification order, a supplemental application to a technology certification order shall be sub-

mitted by the holder of the technology certification order describing such proposed changes, and the in vitro clinical test with such changes may not be introduced into interstate commerce until a technology certification order for such supplemental application is granted:

''(i) Any significant change to the procedures provided in support of the application for technology certification submitted under subparagraph (G) or (H) of subsection (c)(2).

''(ii) Any significant change to the procedures provided in support of the application for technology certification submitted under subparagraph (F) of subsection (c)(2).

''(B) SECRETARY ACTION ON SUPPLEMENTAL APPLICATIONS.—Any action by the Secretary on a supplemental application shall be in accordance with subsection (d), and any order resulting from such supplement shall be treated as an amendment to a technology certification order.

''(2) CONTENT OF APPLICATION.—

"(A) IN GENERAL.—A supplemental application for a change to an in vitro clinical test under a technology certification order shall—

"(i) contain all necessary information to make a showing that any in vitro clinical test affected by such change that is within the scope of the technology certification order will meet the applicable standard; and

"(ii) be limited to such information that is needed to support the change.

"(B) CONTENT.—Unless otherwise specified by the Secretary, a supplemental application under this subsection shall include—

"(i) a description of the change, including a rationale for implementing such change;

"(ii) a description of how the change was evaluated;

"(iii) data from a representative in vitro clinical test or tests that supports a showing that, in using the modified procedure or procedures, all eligible in vitro clinical tests within the scope of the tech-

nology certification will meet the applicable standard;

''(iv) as applicable, information to demonstrate that the modified procedure or procedures submitted under subsection (c)(2)(F) continue to conform to applicable requirements under section 587K; and

''(v) any other information requested by the Secretary.

''(3) CHANGES IN RESPONSE TO A PUBLIC HEALTH RISK.—

''(A) IN GENERAL.—If the holder of a technology certification makes a change to an in vitro clinical test or tests to address a potential risk to public health by adding a new specification or test method, such holder may immediately implement such change and shall submit a notification for such change to the Secretary within 30 days.

''(B) CONTENT.—Any notification to the Secretary under this paragraph shall include—

''(i) a summary of the relevant change;

''(ii) the rationale for implementing such change;

''(iii)(I) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, the modified procedures; or

''(II) if the procedures were not changed, an explanation as to why they were not changed; and

''(iv) if such a change necessitates a change to the procedures reviewed as part of the granted technology certification order, data from a representative in vitro clinical test or tests that support a showing that, in using the modified procedures, all eligible in vitro clinical tests within the scope of the technology certification will meet the applicable standard.

''(f) TEMPORARY HOLD.—

''(1) IN GENERAL.—Subject to the process specified in paragraph (2), and based on one or more findings under paragraph (4), the Secretary may issue a temporary hold prohibiting any holder of a technology certification order issued under this section from introducing into interstate commerce an in vitro clinical test that was not previously the subject of a listing under section 587J. The tem-

porary hold shall identify the grounds for the temporary hold under paragraph (4) and the rationale for such finding.

''(2) PROCESS FOR ISSUING A TEMPORARY HOLD.—If the Secretary makes a finding that a temporary hold may be warranted based on one or more grounds specified in paragraph (4), the Secretary shall promptly notify the holder of the technology certification order of such finding and provide 30 calendar days for the developer to come into compliance with or otherwise resolve the finding.

''(3) WRITTEN REQUESTS.—Any written request to the Secretary from the holder of a technology certification order that a temporary hold under paragraph (1) be removed shall receive a decision, in writing and specifying the reasons therefore, within 90 days after receipt of such request. Any such request shall include information to support the removal of the temporary hold.

''(4) GROUNDS FOR TEMPORARY HOLD.—The Secretary may initiate a temporary hold under this subsection upon a finding that the holder of a technology certification order—

''(A) is not in compliance with the conditions of the technology certification order pursuant to subsection (b)(1)(D);

''(B) offers one or more in vitro clinical tests with advertising or labeling that is false or misleading;

''(C) has reported a correction or removal of an in vitro clinical test that is offered under a technology certification order under this section and has failed to demonstrate that the issue or issues causing the correction or removal does not adversely impact the ability of other in vitro clinical tests offered under the same technology certification order to meet the applicable standard; or

''(D) has introduced into interstate commerce an in vitro clinical test under a technology certification order and such test is adulterated or misbranded, based on a determination by the Secretary, and has failed to demonstrate that the issue or issues causing the adulteration or misbranding does not adversely impact the ability of other in vitro clinical tests offered under the same technology certification

granted under this section to meet the applicable standard.

''(g) WITHDRAWAL.—The Secretary may, after due notice and opportunity for an informal hearing, issue an order withdrawing a technology certification order including all tests introduced into interstate commerce under the technology certification order if the Secretary finds that—

''(1) the application, supplement, or report under subsection (h) contains false or misleading information or fails to reveal a material fact;

''(2) such holder fails to correct false or misleading labeling or advertising upon the request of the Secretary;

''(3) in connection with a technology certification, the holder provides false or misleading information to the Secretary; or

''(4) the holder of such technology certification order fails to correct the grounds for a temporary hold within a timeframe specified in the temporary hold order.

''(h) REPORTS TO CONGRESS.—

''(1) IN GENERAL.—Not later than 1 year after the effective date of the VALID Act of 2023, and annually thereafter for the next 4 years, the Secretary shall submit to the Committee on Health,

Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, and make publicly available, including through posting on the website of the Food and Drug Administration, a report containing the information described in paragraph (2).

''(2) CONTENT.—

''(A) IN GENERAL.—Each report under paragraph (1) shall address, at a minimum—

''(i) the total number of applications for technology certifications filed, issued, withdrawn, and denied;

''(ii) the total number of technology certification orders the Secretary put on temporary hold under subsection (h) and the number of technology certification orders withdrawn under subsection (i);

''(iii) the types of technologies for which the Secretary issued technology certification orders;

''(iv) the total number of holders of technology certification orders that are in effect; and

''(v) the total number of in vitro clinical test categories that required premarket

review under section 587B that were redesignated as eligible in vitro clinical tests under this section.

''(B) FINAL REPORT.—The fifth report submitted under paragraph (1) shall include a summary of, and responses to, comments raised in the docket.

''(C) PERFORMANCE REPORTS.—The reports required under this section may be issued with performance reports as required under section 9 of the VALID Act of 2023.

''(i) PUBLIC MEETING AND INPUT.—

''(1) PUBLIC DOCKET.—Not later than 30 days after the date of enactment of the VALID Act of 2023, the Secretary shall establish a public docket to receive comments concerning recommendations for implementation of this section, including criteria and procedures for subsections (c) through (h). The public docket shall remain open for at least 1 year after the establishment of the public docket.

''(2) PUBLIC MEETING.—Not later than 180 days after the date of enactment of the VALID Act of 2023, the Secretary shall convene a public meeting to which stakeholders from organizations representing patients and consumers, academia, and the

in vitro clinical test industry are invited to discuss the technology certification process including application requirements, inspections, alignment with third-party accreditors, and the definition of the term 'technology' under section 587.

''(j) REGULATIONS.—The Secretary shall issue regulations regarding the technology certification process, including describing criteria or procedures relating to technology certification under this section, which shall be subject to public comment for a minimum of 60 days from issuance prior to finalizing such regulations after considering the comments received. The regulation shall include an outline of the application process, opportunities to meet with officials of the Food and Drug Administration, and plans to streamline inspections.

''(k) NOTIFICATION.—

''(1) IN GENERAL.—Notwithstanding subsection (a)(1), a first-of-a-kind in vitro clinical test or a combination product that meets the definition of a moderate-risk test under section 587 may be introduced into interstate commerce under a technology certification order that has been issued by the Secretary, subject to other applicable requirements if—

''(A) the developer provides notification to the Secretary 60 days prior to introducing such

tests into interstate commerce that includes information demonstrating that the test is moderate-risk and within the scope of the applicable technology certification order; and

''(B) the Secretary has not issued a notification to the developer under paragraph (2) before such time has elapsed.

''(2) NOTIFICATION FROM SECRETARY.—The Secretary shall issue a notification to the developer that such test may not be introduced into interstate commerce under such order if the Secretary determines that—

''(A) such test—

''(i) does not meet the definition of a moderate-risk test under section 587;

''(ii) is not eligible to be introduced into interstate commerce under any of subparagraphs (A) through (E) of subsection (a)(1); or

''(iii) is not eligible to be introduced into interstate commerce under the referenced technology certification order issued by the Secretary because it is not within the scope of the technology certification order under subsection (b)(2); or

''(B) based on the information included in the notification submitted by the developer pursuant to this subsection, there is insufficient information for the Secretary to make the determinations described in clauses (i), (ii), and (iii) of subparagraph (A).

''SEC. 587E. MITIGATING MEASURES.

''(a) ESTABLISHMENT OF MITIGATING MEASURES.—

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

''(A) ESTABLISHMENT.—The Secretary may establish and require, on the basis of evidence, mitigating measures for any in vitro clinical test or category of in vitro clinical tests with the same indications for use that is introduced or delivered for introduction into interstate commerce after the Secretary establishes any such mitigating measures.

''(B) METHODS OF ESTABLISHMENT.—The Secretary may establish mitigating measures—

''(i) under the process set forth in subparagraph (D);

''(ii) as provided under section 587F; or

''(iii) through a premarket approval or technology certification order, which may establish mitigating measures for an individual in vitro clinical test or a category of in vitro clinical tests.

''(C) METHODS OF CHANGE OR WITHDRAWAL.—The Secretary may change or withdraw mitigating measures—

''(i) under the process set forth in subparagraph (D); or

''(ii) as provided under section 587F.

''(D) PROCESS FOR ESTABLISHMENT, CHANGE, OR WITHDRAWAL.—Notwithstanding subchapter II of chapter 5 of title 5, United States Code, the Secretary may, upon the initiative of the Secretary or upon petition of an interested person, establish, change, or withdraw mitigating measures for an in vitro clinical test or category of in vitro clinical tests by—

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

''(ii) providing an opportunity for public comment for a period of not less than 30 60 calendar days; and

''(iii) after consideration of any comments submitted, publishing a final order in the Federal Register that responds to the comments submitted, and which shall include a reasonable transition period.

''(E) EFFECT OF MITIGATING MEASURES ON GRANDFATHERED TESTS.—A mitigating measure shall not be required by the Secretary for an in vitro clinical test subject to section 587G(a).

''(2) IN VITRO CLINICAL TESTS PREVIOUSLY CLEARED OR EXEMPT AS DEVICES WITH SPECIAL CONTROLS.—

''(A) IN GENERAL.—Any special controls applicable to an in vitro clinical test previously cleared or exempt under section 510(k), or classified under section 513(f)(2) prior to date of enactment of the VALID Act of 2023, including any such special controls established during the period beginning on the date of enactment of the VALID Act of 2023 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 in vitro clinical test after such effective date; and

''(ii) are deemed to be mitigating measures as of the effective date specified in section 5(a)(1)(A) of the VALID Act of 2023.

''(B) CHANGES.—Notwithstanding subparagraph (A), the Secretary may establish, change, or withdraw mitigating measures for such tests or category of tests using the procedures under paragraph (1).

''(b) DOCUMENTATION.—

''(1) IN VITRO CLINICAL 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 maintain documentation in accordance with the applicable quality requirements under section 587K and make such documentation available to the Secretary upon request or inspection.

''(2) OTHER TESTS.—The developer of an in vitro clinical test that is offered under a technology certification order or other exemption from pre-

market review under section 587B and to which mitigating measures apply shall—

''(A) maintain documentation in accordance with the applicable quality requirements under section 587K demonstrating that such mitigating measures continue to be met following a test modification by the developer;

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

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

''SEC. 587F. REGULATORY PATHWAY DESIGNATION.

''(a) PATHWAY DETERMINATIONS.—

''(1) IN GENERAL.—After considering available evidence with respect to an in vitro clinical test or category of in vitro clinical tests with the same intended use, including the identification, establishment under paragraph (4), and implementation of mitigating measures under section 587E, as appropriate, the Secretary may, upon the initiative of the Secretary or upon request of a developer, determine that—

''(A) such in vitro clinical test is high-risk and subject to premarket review under section 587B;

''(B) such in vitro clinical tests, including a first-of-a-kind test, is moderate-risk and subject to abbreviated premarket review under section 587B(b) or technology certification under section 587D(a)(1); or

''(C) such in vitro clinical test, including a first-of-a-kind test is low-risk or otherwise exempt from premarket review under section 587B.

''(2) REQUESTS.—

''(A) SUBMISSIONS BY DEVELOPERS.—

''(i) ABBREVIATED PREMARKET REVIEW; TECHNOLOGY CERTIFICATION.—A developer submitting a request that the Secretary make a determination as described in paragraph (1)(B) shall submit information to support that the in vitro clinical test is moderate-risk or propose mitigating measures, if applicable, that would support such a determination.

''(ii) LOW-RISK; EXEMPT FROM PREMARKET REVIEW.—A developer submitting

a request that the Secretary make a determination as described in paragraph (1)(C) shall submit information that the in vitro clinical test is low-risk, or otherwise appropriate for exemption from premarket review under section 587B and propose mitigating measures, if applicable, that would support such a determination.

''(B) RESPONSE BY THE SECRETARY.—Not later than 30 days after receiving a request under clause (i) or (ii) of subparagraph (A), the Secretary shall provide a timely response describing whether or not the Secretary will initiate the process for making a determination under paragraph (1)(B) or (1)(C) as described in paragraph (4).

''(3) SUFFICIENCY OF MITIGATING MEASURES.—When determining whether mitigating measures for an in vitro clinical test, or category of in vitro clinical tests, are sufficient to make such test moderate-risk or low-risk, the Secretary shall take into account the following:

''(A) The degree to which the technology for the intended use of the in vitro clinical test is well-characterized, taking into consideration

factors that include one or more of the following:

''(i) Peer-reviewed literature.

''(ii) Practice guidelines.

''(iii) Consensus standards.

''(iv) Recognized standards of care.

''(v) Use of such technology, including historical use.

''(vi) Multiple scientific publications by different authors.

''(vii) Adoption by the scientific or clinical community.

''(viii) Real world evidence.

''(B) Whether the criteria for performance of the test are well-established to be sufficient for the intended use.

''(C) The clinical circumstances under which the in vitro clinical test is used, including whether the in vitro clinical test is the sole determinate for the diagnosis or treatment of the targeted disease, and the availability of other tests (such as confirmatory or adjunctive tests) or relevant material standards.

''(D) Whether such mitigating measures sufficiently mitigate the risk of harm such that

the test or category of tests is moderate-risk or low-risk.

''(4) PROCESS.—

''(A) IN GENERAL.—For a test that is not first-of-a-kind, any action under paragraph (1) shall be made by publication of a notice of such proposed action on the website of the Food and Drug Administration, the consideration of comments to a public docket on such proposal, and publication of a final action on such website within 60 calendar days of the close of the comment period posted to such public docket, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''(B) PROCESS FOR FIRST-OF-A-KIND TEST.—In the case of an in vitro clinical test that is first-of-a-kind, the process is as follows:

''(i) Any determination that the test is subject to premarket approval or abbreviated premarket review under subparagraph (A) or (B) of paragraph (1) shall be published on the website of the Food and Drug Administration, notwithstanding subclause II of chapter 5 of title 5, United States Code, only after the in vitro clinical

test is approved under section 587B. Until that time, the determination shall not be binding on other in vitro clinical tests.

''(ii) Any determination other than those made under clause (i) shall be made by publication of a notice of final action on the website of the Food and Drug Administration, notwithstanding subchapter II of chapter 5 of title 5, United States Code.

''(5) NO EFFECT ON GRANDFATHERING DETERMINATIONS.—A determination under paragraph (1) shall have no effect on the applicability of section 587G to an in vitro clinical tests.

''(b) TRANSITION PERIOD.—Upon a decision by the Secretary to change a regulatory pathway designation, or reclassifies an in vitro clinical test, or category of in vitro clinical tests, the Secretary shall provide an appropriate transition period with respect to any new requirements.

''(c) APPEALS.—A decision by the Secretary under this section shall be deemed a significant decision subject to appeal under section 587P.

''(d) ADVISORY COMMITTEE.—The Secretary may request recommendations from an advisory committee under section 587H pursuant to carrying out this section.

''(e) REQUEST FOR INFORMAL FEEDBACK.—Before submitting a premarket application or technology certification application for an in vitro clinical test—

''(1) the developer of the test may submit to the Secretary a written request for a meeting, conference, or written feedback to discuss and provide information relating to the regulation of such in vitro clinical test which may include—

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

''(B) which regulatory pathway is appropriate for an in vitro clinical test; and

''(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) if a meeting is requested—

''(i) within 60 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

''(ii) within 15 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; and

''(B) if written feedback is requested, provide feedback to the requestor within 75 days after such receipt.

''SEC. 587G. GRANDFATHERED IN VITRO CLINICAL TESTS.

''(a) IN GENERAL.—Subject to subsection (d), an in vitro clinical test is exempt from the requirements of this subchapter specified in subsection (b) if—

''(1) the test was first offered for clinical use, and was not intended solely for investigational use, not later than 45 days after the date of enactment of the VALID Act of 2023;

''(2) the test was developed by a clinical laboratory for which a certificate was in effect under section 353 of the Public Health Service Act that meets the requirements for performing tests of high complexity;

''(3) the test is performed—

''(A) in the same clinical laboratory in which the test was developed for which a certification is still in effect under section 353 of the

Public Health Service Act that meets the requirements to perform tests of high complexity;

''(B) by another clinical laboratory for which a certificate is in effect under section 353 of such Act that meets the requirements to perform tests of high complexity, and that is within the same corporate organization and having common ownership by the same parent corporation as the laboratory in which the test was developed; or

''(C) in the case of a test that was developed by the Centers for Disease Control and Prevention or another laboratory in a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, by a clinical laboratory for which a certificate is in effect under section 353 of such Act that meets the requirements to perform tests of high complexity, and that is within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention;

''(4) the test 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 exemption under section 520(m), or licensure under section 351 of the Public Health Service Act;

''(5) any modification to the test on or after the date that is 45 days after the date of enactment of the VALID Act of 2023 is made by the initial developer, conforms with section 587C(a)(6)(A)(ii), and does not meet the criteria in subsection (d)(1);

''(6) when used as an investigational in vitro clinical test, such test complies with section 587S, as applicable;

''(7) the test is offered with an order from an authorized person as required under section 353 of the Public Health Service Act, and was offered with a prescription required under section 809.30(f) of title 21, Code of Federal Regulations prior to the effective date of this subchapter;

''(8) the test is not for use with home specimen collection, unless the specimen is collected with a collection container, receptacle, or kit that—

''(A) has been approved, cleared, or authorized by the Secretary for home specimen collection and the collection is performed pursuant to the approved, cleared, or authorized labeling, including any indication for use as prescription use or over-the-counter use, or

''(B) is exempt from premarket review and its use is consistent with applicable limitations on the exemption;

''(9) the test is not a specimen receptacle or instrument;

''(10) each test report for the test bears a statement that reads as follows: 'This in vitro clinical test was introduced into commerce prior to the application of the VALID Act and is exempt from FDA premarket review.'; and

''(11) the developer of the test—

''(A) maintains documentation demonstrating that the test meets and continues to meet the criteria set forth in this subsection; and

''(B) makes such documentation available to the Secretary upon request.

''(b) EXEMPTIONS APPLICABLE TO GRANDFATHERED TESTS.—An in vitro clinical test that meets the criteria specified in subsection (a) is exempt from premarket review under 587B, labeling requirements under 587L, and test design requirements and quality requirements under 587K, and may be lawfully offered subject to the other applicable requirements of this Act.

''(c) MODIFICATIONS.—In the case of an in vitro clinical test that meets the criteria specified in subsection (a), such test continues to qualify for the exemptions described in subsection (b) if the test is modified and the modification is of a type described in subsection (a)(5), and the person modifying such in vitro clinical test—

''(1) documents each such modification and maintains documentation of the basis for such determination;

''(2) provides such documentation relating to the change to the Secretary upon request or inspection; and

''(3) does not modify the in vitro clinical test such that it no longer meets the criteria under subsection (a).

''(d) REQUEST FOR INFORMATION.—

''(1) CRITERIA.—The criteria described in this paragraph are any of the following:

''(A) There is a lack of valid scientific evidence to support that the in vitro clinical test is analytically valid or clinically valid.

''(B) Such in vitro clinical test is being offered by its developer with any false or misleading analytical or clinical claims.

''(C) It is probable that such in vitro clinical test will cause serious adverse health consequences.

''(2) PROCESS.—

''(A) WRITTEN REQUEST FOR INFORMATION.—The Secretary may issue a written request to a developer identifying specific scientific concerns, based on credible information, with an in vitro clinical test, which indicate that one or more of the criteria described in paragraph (1) apply to such in vitro clinical test. Such written request shall include specific information requests pertaining to such criteria.

''(B) DEADLINE FOR SUBMITTING INFORMATION.—Not later than 45 days after receiving a request for information under subparagraph (A)—

''(i) the developer of an in vitro clinical test—

''(I) may seek a teleconference prior to the submission of information under subclause (II) to discuss the Secretary's request; and

''(II) shall submit the information requested pursuant to subpara-

graph (A), and may include in such submission a request for a teleconference; and

''(ii) the Secretary shall—

''(I) schedule a teleconference requested under clause (i)(I); and

''(II) hold a teleconference if requested within 10 days of the Secretary's receipt of the information submitted under clause (i)(II).

''(C) REVIEW DEADLINE.—Upon receiving a submission under subparagraph (B), the Secretary shall—

''(i) review the submitted information within 45 calendar days of such receipt, which may include communication with the developer; and

''(ii) determine whether the criteria listed in paragraph (1) apply to the in vitro clinical test and communicate such determination to the developer as described in subparagraph (D).

''(D) COMMUNICATION AND RESULTS OF DETERMINATION.—The Secretary shall notify

the developer, in writing, of the Secretary's determination under subparagraph (C), as follows:

''(i) If the Secretary determines that none of the criteria listed in paragraph (1) apply to the in vitro clinical test, such test shall be exempt from relevant requirements of this subchapter, as set forth in subsection (b), subject to the criteria under subsection (a).

''(ii) If the Secretary determines that one or more of the criteria listed in paragraph (1) apply to the test but such a determination may be resolved within a reasonable time, and the test has not been previously subject to this subsection on the basis of the same or substantially similar scientific concerns identified in the written request issued under paragraph (d)(2)(A)—

''(I) the Secretary shall notify the developer of such a determination and allow the developer to seek a teleconference to discuss the finding;

''(II) the developer shall submit information demonstrating resolution

of the determination within 15 days of receiving such notification; and

''(III) the Secretary shall make a determination within 30 days of the receipt of such submission of information as to whether the criteria under paragraph (1) continue to apply to the test and, if through such determination the Secretary determines that—

''(aa) none of the criteria listed in paragraph (1) apply to the test, such test shall be exempt from relevant requirements of the subchapter as set forth in subsection (b), subject to applicable limitations; or

''(bb) one or more of the criteria listed in paragraph (1) apply to the in vitro clinical test, such test is not exempt as set forth in this section and shall not be offered unless approved under section 587B, or, upon a determination by the Secretary pursuant to section 587F, offered

under a technology certification order under section 587D or offered as a low-risk test.

''(iii) If the Secretary determines that one or more of the criteria listed in paragraph (1) apply to the in vitro clinical test and clause (ii) does not apply, the in vitro clinical test is not exempt as set forth in this section and shall not be offered unless approved under section 587B, or upon a determination by the Secretary pursuant to section 587F, offered under a technology certification order under section 587D or offered as a low-risk test.

''SEC. 587H. ADVISORY COMMITTEES.

''(a) IN GENERAL.—The Secretary may establish advisory committees or use advisory committee panels of experts established before the date of enactment of the VALID Act of 2023 (including a device classification panel under section 513) for the purposes of providing expert scientific advice and making recommendations related to—

''(1) the approval of an application for an in vitro clinical test submitted under this subchapter, including for evaluating, as applicable, the analytical

validity, clinical validity, and safety of in vitro clinical tests;

''(2) the potential effectiveness of mitigating measures for a determination of the applicable regulatory pathway under section 587F(b) or risk evaluation for an in vitro clinical test or tests;

''(3) quality requirements under section 587K or applying such requirements to in vitro clinical tests developed or imported by developers;

''(4) appeals under section 587P; or

''(5) 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 referred to the committee for the purposes specified in subsection (a), including individuals with, to the extent feasible, scientific expertise in the development of such 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.

''(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 in vitro clinical test developers not directly affected by the matter to be brought before the committee.

''(3) LIMITATION.—No individual who is a regular full-time employee 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) EDUCATION AND TRAINING.—The Secretary shall, as appropriate, provide education and training to each new committee member before such member participates in a committee's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to committee meetings.

''(5) MEETINGS.—The Secretary shall ensure that scientific advisory committees meet regularly

and at appropriate intervals so that any matter to be reviewed by such a committee can be presented to the committee not more than 60 calendar days after the matter is ready for such review. Meetings of the committee may be held using electronic or telephonic communication to convene the meetings.

''(6) 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 be entitled to receive compensation at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above level GS–15 of the General Schedule; 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. 587I. BREAKTHROUGH IN VITRO CLINICAL TESTS.

''(a) IN GENERAL.—The purpose of this section is to encourage the Secretary, and provide the Secretary with

sufficient authority, to apply efficient and flexible approaches to expedite the development of, and prioritize the review of, in vitro clinical tests that represent breakthrough technologies.

''(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program to expedite the development of, and provide for the priority review of, in vitro clinical tests.

''(c) ELIGIBILITY.—The program developed under subsection (b) shall be available for any in vitro clinical test that—

''(1) provides or enables more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; and

''(2) is a test—

''(A) that represents a breakthrough technology;

''(B) for which no approved alternative in vitro clinical test exists, including no in vitro clinical test offered under a technology certification order;

''(C) that offers a clinically meaningful advantage over existing alternative in vitro clinical tests that are approved (including in vitro clinical tests offered under a technology certifi-

cation order), including the potential 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.

''(d) DESIGNATION.—

''(1) REQUEST.—To receive breakthrough designation under this section, an applicant may request that the Secretary designate the in vitro clinical test for expedited development and priority review. Any such request for designation may be made at any time prior to, or at the time of, the submission of an application under section 587B or 587D, and shall include information demonstrating that the test meets the criteria described in subsection (c).

''(2) DETERMINATION.—Not later than 60 calendar days after the receipt of a request under paragraph (1), the Secretary shall determine whether the in vitro clinical test that is the subject of the request meets the criteria described in subsection (c). If the Secretary determines that the test meets the criteria,

the Secretary shall designate the test for expedited development and 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) IN GENERAL.—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 designation under this section, if an application for approval for such test under section 587B or 587D is denied. Such test shall be eligible for breakthrough designation upon a new request for such designation.

''(B) EXCEPTION.—The Secretary may not withdraw a designation granted under this subsection based on the subsequent approval or technology certification of another in vitro clinical test that—

''(i) is designated under this section; or

''(ii) was given priority review under section 515B.

''(e) ACTIONS.—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 paragraphs (1) and (2), respectively, of section 515B(e) when reviewing such tests. 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.

''(f) GUIDANCE.—Not later than 30 months after the date of enactment of the VALID Act of 2023, the Secretary shall issue final guidance on the implementation of this section. Such guidance shall—

''(1) set forth the process by which a person may seek a designation under subsection (d);

''(2) provide a template for request under subsection (d);

''(3) identify the criteria the Secretary will use in evaluating a request for designation; and

''(4) identify the criteria and processes the Secretary will use to assign a team of staff, including team leaders, to review in vitro clinical tests designated for expedited development and priority review, including any training required for such personnel to ensure effective and efficient review.

''(g) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to affect—

''(1) the criteria and standards for evaluating an application pursuant to section 587B or 587D, including the recognition of valid scientific evidence as described in section 587(20) and consideration and application of the least burdensome means described under section 587AA(c);

''(2) the authority of the Secretary with respect to clinical holds under section 587S;

''(3) the authority of the Secretary to act on an application pursuant to section 587B before completion of an establishment inspection, as the Secretary determines appropriate; or

''(4) the authority of the Secretary with respect to postmarket surveillance under section 587X.

''SEC. 587J. REGISTRATION AND LISTING.

''(a) REGISTRATION REQUIREMENT.—

''(1) IN GENERAL.—Each person described in subsection (b)(1) 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 establishment registration number 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)—

''(i) in accordance with the timelines for submission under subsection (c), if the establishment is engaged in any activity described in subsection (b)(1) on the effective date of this section, unless the Secretary establishes by guidance a date later than such date for all or a category of such establishments; or

''(ii) not later than 30 days prior to engaging in any activity described in subsection (b)(1), if the establishment is not engaged in any activity described in this paragraph on the effective date of this section.

''(2) REGISTRATION NUMBERS.—The Secretary may assign a registration number to any person or an establishment registration number to any estab-

lishment 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, in accordance with subsection (d).

''(3) INSPECTION.—Each 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) LISTING INFORMATION FOR IN VITRO CLINICAL TESTS.—

''(1) IN GENERAL.—Each person who—

''(A) is a developer; and

''(B) introduces or proposes to begin the introduction or delivery for introduction into interstate commerce through an exemption under subsection (a)(1), (a)(2), (a)(3), or (g) of section 587C or section 587G or through the filing of an application under section 587B or section 587D,

shall submit a listing to the Secretary containing the information described in paragraph (2), or (4), as applicable, in accordance with the applicable schedule described under subsection (c). Such listing shall be prepared in such form and manner as the Sec-

retary may specify in guidance. Listing information shall be submitted through the comprehensive test information system in accordance with section 587T, as appropriate.

''(2) SUBMISSIONS.—Each developer submitting a listing under paragraph (1) shall electronically submit to the comprehensive test information system described in section 587T the following information, as applicable, for each in vitro clinical test for which such person is a developer in the form and manner prescribed by the Secretary, taking into account the least burdensome requirements under section 587AA(c):

''(A) Name of the establishment and its establishment registration number.

''(B) Contact information for the official correspondent for the listing.

''(C) Name (common name and trade name, if applicable) of the in vitro clinical test and its test listing number (when available).

''(D) The certificate number for any laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements to perform high-complexity testing and that is the developer of the

in vitro clinical test, and the certificate number under such section for any laboratory that is performing the test, is within the same corporate organization, and has common ownership by the same parent corporation.

''(E) Whether the in vitro clinical test is, as applicable, offered as a test approved under section 587B, offered under a granted technology certification order, or offered as an exempt in vitro clinical test under section 587C or 587G.

''(F) Indications for use information under section 587(10).

''(G) A brief summary of the analytical and clinical performance of the in vitro clinical test, and as applicable, the lot release criteria.

''(H) A brief description of conformance with any applicable mitigating measures, restrictions, and standards.

''(I) Representative labeling for the in vitro clinical test, as appropriate.

''(3) TEST LISTING NUMBER.—The Secretary may assign a test listing number to each in vitro clinical test that is the subject of a listing under this section. The process for assigning test listing num-

bers may be established through guidance, and may include the recognition of standards, formats, or conventions developed by a third-party organization.

''(4) GRANDFATHERED TESTS.—A developer offering a test that is a grandfathered in vitro clinical test under section 587G(a) shall submit listing information required under subparagraphs (A) through (F) of paragraph (2), and may submit a statement of the performance specifications for such in vitro clinical tests.

''(5) EXEMPT TESTS.—A developer of an in vitro clinical test who introduces or proposes to begin the introduction or delivery for introduction into interstate commerce that is otherwise exempt from the requirement to submit listing information pursuant to an exemption under section 587C may submit listing information under this subsection.

''(c) TIMELINES FOR SUBMISSION OF LISTING INFORMATION.—

''(1) IN GENERAL.—The timelines for submission of registration and listing under subsections (a) and (b) are as follows:

''(A) For an in vitro clinical test that was listed as a device under section 510(j) prior to the effective date of this section, a person shall

maintain a device listing under section 510 until such time as the system for submitting the listing information required under subsection (b) becomes available and thereafter shall submit the listing information not later than the later of 1 year after the system for submitting the listing under this section becomes available or the effective date of this section.

''(B) For an in vitro clinical test that is subject to grandfathering under section 587G(a) a person shall submit the listing information required under subsection (b)(4) within 10 calendar days of offering the test after the effective date of this section.

''(C) For an in vitro clinical test that is not described in subparagraph (A) or (B), a person shall submit the required listing information as follows:

''(i) For an in vitro clinical test that is not exempt from premarket approval under section 587B, a person shall submit the required listing information, prior to offering the in vitro clinical test and not later than 30 business days after the date

of approval of the premarket approval application.

''(ii) For an in vitro clinical test that is exempt from premarket review under section 587C, the required listing information shall be submitted prior to offering the in vitro clinical test.

''(2) UPDATES.—

''(A) UPDATES AFTER CHANGES.—Each developer required to submit listing information under this section shall update such information within 10 business days of any change that causes any previously listed information to be inaccurate or incomplete.

''(B) ANNUAL UPDATES.—Each developer required to submit listing information under this section shall update its information annually during the period beginning on October 1 and ending on December 31 of each year.

''(d) PUBLIC AVAILABILITY OF LISTING INFORMATION.—

''(1) IN GENERAL.—Listing information submitted pursuant to this section shall be made publicly available on the website of the Food and Drug Administration in accordance with paragraph (3).

''(2) CONFIDENTIALITY.—Listing information for an in vitro clinical test that is subject to premarket approval or technology certification shall remain confidential until such date as the in vitro clinical test receives the applicable premarket approval or the developer receives a technology certification order and for subsequent tests introduced under a technology certification order until their introduction.

''(3) EXCEPTIONS FROM PUBLIC AVAILABILITY REQUIREMENTS.—The public listing requirements of this subsection shall not apply to any registration and listing information submitted under subsection (a) or (b), if the Secretary determines that such information—

''(A) is a trade secret or confidential commercial or financial information; or

''(B) if posted, could compromise national security.

''(e) SUBMISSION OF INFORMATION BY ACCREDITED PERSONS.—If agreed upon by the developer, the information required under this section may be submitted by a person accredited under section 587Q.

''SEC. 587K. TEST DESIGN AND QUALITY REQUIREMENTS.

''(a) APPLICABILITY.—

''(1) IN GENERAL.—Each developer shall establish and maintain quality requirements in accordance with the applicable requirements set forth in subsection (b).

''(2) CERTIFIED LABORATORY REQUIREMENTS.—A developer shall establish and maintain quality requirement under subsection (b)(2) or (b)(3), as applicable, if such developer is a clinical laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

''(A) is certified to perform high-complexity testing;

''(B) develops an in vitro clinical test that is for use only—

''(i) within the laboratory certified by the Secretary under such section 353 in which such test was developed; or

''(ii) within another laboratory certified by the Secretary under such section 353 if such laboratory is—

''(I) within the same corporate organization and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

''(II) within a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, if the test is developed by a public health laboratory or the Centers for Disease Control and Prevention; and

''(C) does not manufacture, produce, or distribute in vitro clinical tests other than laboratory test protocols.

''(3) REGULATIONS.—The Secretary shall promulgate quality system regulations implementing this section. In promulgating such regulations under this section, the Secretary shall consider whether, and to what extent, international harmonization is appropriate.

''(4) QUALITY SYSTEMS FOR HYBRID DEVELOPERS OF BOTH LABORATORY TEST PROTOCOLS AND OTHER IN VITRO CLINICAL TESTS.—An entity that develops both laboratory test protocols and other in vitro clinical tests shall comply with subsection (b)(1) for activities related to the development of any in vitro clinical test that is not a laboratory test protocol and with subsection (b)(2) or (b)(3), as ap-

plicable, for activities related to the development of any laboratory test protocol.

''(b) QUALITY REQUIREMENTS.—

''(1) IN GENERAL.—The quality requirements applicable under this section shall—

''(A) avoid duplication of regulations and guidance under section 353 of the Public Health Service Act, such that laboratories would not be subject to conflicting regulatory obligations with respect to the same activity;

''(B) not apply to laboratory operations; and

''(C) include, as applicable, subject to subparagraphs (A) and (B) and paragraphs (2) and (3)—

''(i) management responsibilities;

''(ii) quality audits;

''(iii) personnel;

''(iv) design controls;

''(v) document controls;

''(vi) purchasing controls;

''(vii) identification and traceability;

''(viii) production and process controls;

''(ix) acceptance activities;

''(x) nonconforming in vitro clinical tests;

''(xi) corrective and preventive action;

''(xii) labeling and packaging controls;

''(xiii) handling, storage, distribution, and installation;

''(xiv) complaints and records;

''(xv) servicing; and

''(xvi) statistical techniques.

''(2) EXCEPTION FOR LABORATORY TEST PROTOCOLS.—Developers that are developing test protocols for use as described in subsection (a)(2)(B)(i) are exempt from the requirements under paragraph (1)(C) except for the requirements described in clauses (iv), (ix), (xi), and (xiv) of such paragraph.

''(3) QUALITY REQUIREMENTS FOR CERTAIN LABORATORIES DISTRIBUTING LABORATORY TEST PROTOCOLS WITHIN ORGANIZATIONS OR PUBLIC HEALTH NETWORKS.—Quality requirements applicable to the developer who is distributing a laboratory test protocol as described in subsection (a)(2)(B)(ii) shall consist of the following:

''(A) Clauses (iv), (ix), (xi), (xiv), (xii) of paragraph (1)(B).

''(B) The requirement to maintain records of the laboratories to which the laboratory test protocol is distributed.

''(c) REGULATIONS.—In implementing quality requirements for test developers that participate in international audit programs under this section, the Secretary shall—

''(1) for purposes of facilitating international harmonization, consider whether the developer participates in an international audit program in which the United States participates and recognizes compliance with, or conformance to, such standards recognized by the Secretary; and

''(2) ensure a least burdensome approach described in section 587AA(c) by leveraging, to the extent applicable, the quality assurance requirements applicable to developers certified by the Secretary under section 353 of the Public Health Service Act.

''SEC. 587L. LABELING REQUIREMENTS.

''(a) IN GENERAL.—An in vitro clinical test shall bear or be accompanied by labeling, as applicable, that meets the requirements set forth in subsections (b) and (c), unless such test is exempt under subsection (d) or (e).

''(b) LABELS.—

''(1) IN GENERAL.—The label of an in vitro clinical test, shall meet the requirements set forth in paragraph (2) if there is an immediate container to which the label is applied.

''(2) REGULATIONS.—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 regulations promulgated in accordance with this section.

''(c) LABELING.—

''(1) IN GENERAL.—Labeling of an in vitro clinical test, including labeling in the form of a package insert, website, standalone laboratory reference document, or other similar document shall include—

''(A) adequate directions for use and shall meet the requirements set forth in regulations promulgated under this section, except as provided in subsection (d) or (e); and

''(B) the information described in paragraph (2), as applicable.

''(2) CONTENT.—Labeling of an in vitro clinical test shall include—

''(A) the test listing number that was provided to the developer at the time of listing;

''(B) information to facilitate reporting an adverse event;

''(C) information regarding accessing the performance summary data displayed in the listing database for the test;

''(D) the indications for use of the in vitro clinical test; and

''(E) any warnings, contraindications, or limitations.

''(3) PUBLIC AVAILABILITY OF INFORMATION.—The Secretary shall make all of the information described in paragraph (2) with respect to each in vitro clinical test available to the public, as applicable, in accordance with section 587T, except to the extent that the Secretary determines that such information—

''(A) is trade secret or confidential commercial or financial information; or

''(B) if posted, could compromise national security.

''(4) ADDITIONAL REQUIREMENTS.—Labeling for an in vitro clinical test used for immunohematology testing shall meet the applicable requirements set forth in part 660 of title 21, Code of Federal Regulations (or any successor regula-

tions), related to the labeling of blood grouping reagents, reagent red blood cells, and anti-human globulin.

''(d) EXEMPTIONS AND ALTERNATIVE REQUIREMENTS.—

''(1) IN GENERAL.—

''(A) IN GENERAL.—With respect to an in vitro clinical test that meets the criteria of subparagraph (B), the 'state in one place' regulations under section 809.10(b) of title 21, Code of Federal Regulations (or any successor regulations) may be satisfied by the laboratory posting such information on its website or in multiple documents, if such documents are maintained and accessible in one place.

''(B) APPLICABLE TESTS.—An in vitro clinical test meets the criteria of this subparagraph if such test is—

''(i) developed by a laboratory certified by the Secretary under section 353 of the Public Health Service Act that meets the requirements to perform tests of high-complexity; and

''(ii) performed in—

''(I) the same laboratory in which such test was developed; or

''(II) by another laboratory certified by the Secretary under section 353 of the Public Health Service Act that—

''(aa) meets the requirements to perform tests of high complexity; and

''(bb) is under common ownership and control as the laboratory that developed the test.

''(2) TEST INSTRUMENT LABELING.—Unless the instrument is the entire test system, the labeling for an instrument 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, Code of Federal Regulations (or any successor regulations).

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

''(4) INVESTIGATIONAL USE.—A shipment or other delivery of an in vitro clinical test for investigational use pursuant to section 587S shall be exempt from the labeling requirements of subsections (b) and (c)(1) and from any standard promulgated through regulations, except as required under section 353 of the Public Health Service Act or section 587R of this Act.

''(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 (c)(1)(A).

''(6) OVER-THE-COUNTER TEST SPECIMEN RECEPTACLE LABELING.—The labeling for over-the-counter test specimen receptacles for drugs of abuse testing shall bear the name and place of business of the developer included in the registration under section 587J and any information specified in applicable regulations promulgated under this section, in language appropriate for the intended users.

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

''(1) IN GENERAL.—The Secretary may grant an exception or alternative to any provision listed in this section, unless explicitly required by a statutory provision outside this subchapter, 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 availability of such products that are, or will be, included in the Strategic National Stockpile under section 319F–2 of the Public Health Service Act.

''(2) REGULATIONS.—The Secretary may issue regulations amending section 809.11 of title 21, 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) REGULATIONS.—The Secretary shall issue regulations related to standardized, general content and format for in vitro clinical test labeling pursuant to this subsection.

''SEC. 587M. ADVERSE EVENT REPORTING.

''(a) IN GENERAL.—Each in vitro clinical test developer shall establish and maintain a system for establishing and maintaining records of adverse events and reporting adverse events in accordance with this section.

''(b) SUBMISSION OF INDIVIDUAL REPORTS.—A developer shall submit an individual adverse event report not later than 5 calendar days after the developer receives or becomes aware of an adverse event that reasonably suggests that an in vitro clinical test may—

''(1) have caused or contributed to a patient or user death; or

''(2) present an imminent threat to public health.

''(c) SUBMISSION OF QUARTERLY REPORTS.—As applicable, a developer shall submit quarterly reports that include any in vitro clinical test errors and serious injuries that occurred during the applicable quarter. Such quarterly reports shall be submitted not later than the end of the quarter following the quarter in which the developer receives or becomes aware of such adverse events.

''(d) DEFINITIONS.—For the purposes of this section—

''(1) the term 'in vitro clinical test error' means a failure of an in vitro clinical test to meet its performance specifications, or to otherwise perform as intended by the developer, including an inaccurate result resulting from such failure; and

''(2) the term 'serious injury' means—

''(A) a significant delay in a diagnosis that results in the absence, delay, or discontinuation of critical medical treatment or that irreversibly or seriously and negatively alters the course of a disease or condition; 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.

''(e) REGULATIONS.—The Secretary shall promulgate regulations to implement this section.

''SEC. 587N. CORRECTIONS AND REMOVALS.

''(a) REGULATIONS.—The Secretary shall promulgate regulations, or amend existing regulations, as appropriate, to implement this section.

''(b) REPORTS OF CORRECTIONS AND REMOVALS.—

''(1) IN GENERAL.—Each in vitro clinical test developer shall report to the Secretary any correction or removal of an in vitro clinical test under-

taken by such developer if the correction or removal was undertaken—

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

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

"(2) EXCEPTION FOR IN VITRO CLINICAL TESTS OFFERED UNDER A TECHNOLOGY CERTIFICATION ORDER.—For any eligible test offered under a technology certification order under section 587D, a correction and removal report for any correction or removal of an in vitro clinical test should demonstrate that the issue or issues causing the correction or removal do not adversely impact the ability of other in vitro clinical tests offered under the same technology certification order to meet the applicable standard.

"(c) TIMING.—A developer shall submit any report required under this subsection to the Secretary within 15 business days of initiating such correction or removal.

"(d) RECORDKEEPING.—A developer of an in vitro clinical test that 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.

''(e) RECALL COMMUNICATIONS.—Upon the reporting of a correction or removal by the developer—

''(1) the Secretary shall classify such correction or removal under this section within 45 calendar days; and

''(2) not later than 70 calendar days after the developer or other responsible party notifies the Secretary that it has completed a recall action, the Secretary shall provide the developer or other responsible party with a written statement closing the recall action or stating the reasons the Secretary cannot close the recall at that time.

''SEC. 587O. RESTRICTED IN VITRO CLINICAL TESTS.

''(a) APPLICABILITY.—

''(1) IN GENERAL.—For the types of in vitro clinical tests described in paragraph (3), the Secretary may require, in issuing an approval of an in vitro clinical test under section 587B, granting a technology certification order under section 587D, or in issuing a determination under section 587F(a), or by issuing a regulation, that such test, or category of tests, be restricted to sale, distribution, or use upon such conditions as the Secretary may prescribe under paragraph (2).

''(2) CONDITIONS.— The Secretary may prescribe conditions under this section, based on available evidence, with respect to an in vitro clinical test described in paragraph (3), that are determined to be needed due to the potential for harmful effect of such test (including any resulting absence, significant delay, or discontinuation of appropriate medical treatment), and are necessary to ensure that the test meets the applicable standard.

''(3) IN VITRO CLINICAL TESTS SUBJECT TO RESTRICTIONS.—The restrictions or conditions authorized under this section may be applied by the Secretary to any high-risk or moderate-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.

''(b) LABELING AND ADVERTISING OF A RESTRICTED IN VITRO CLINICAL TEST.—The labeling and advertising of an in vitro clinical test to which restrictions apply under subsection (a) shall bear such appropriate statements of the restrictions as the Secretary may prescribe in an approval under section 587B, an order under section 587D, a determination under section 587F(a), or in regulation, as applicable.

''(c) DEVICE RESTRICTIONS.—An in vitro clinical test that was offered as a restricted device prior to the date of enactment of this subchapter—

''(1) shall continue to comply with the applicable restrictions under section 515 or section 520(e) until this subchapter takes effect; and

''(2) except for in vitro clinical tests required to meet the requirements of section 809.30 of title 21, Code of Federal Regulations prior to the effective date of this subchapter specified in section 5(a)(1)(A) of the VALID Act of 2023, such restrictions described in paragraph (1) shall be deemed to be restrictions under this subchapter as of such effective date.

''SEC. 587P. APPEALS.

''(a) SIGNIFICANT DECISION.—

''(1) IN GENERAL.—The Secretary shall—

''(A) maintain a substantive summary of the scientific and regulatory rationale for any significant decision of the Food and Drug Administration pursuant to section 587F, regarding—

''(i) the submission of an application for, or a review of, an in vitro clinical test under section 587B or section 587D;

"(ii) an exemption under section 587C; or

"(iii) any requirements for mitigation measures to an in vitro clinical test or category of in vitro clinical tests; and

"(B) include in such summaries documentation of significant controversies or differences of opinion and the resolution of such controversies or differences of opinion.

"(2) PROVISION OF DOCUMENTATION.—Upon request, the Secretary shall furnish a substantive summary described in paragraph (1) to the person who has made, or is seeking to make, a submission described in such paragraph.

"(3) APPLICATION OF LEAST BURDENSOME REQUIREMENTS.—The substantive summary required under this subsection shall include a brief statement regarding how the least burdensome requirements were considered and applied consistent with section 587AA(c), as applicable.

"(b) REVIEW OF SIGNIFICANT DECISIONS.—

"(1) REQUEST FOR SUPERVISORY REVIEW OF SIGNIFICANT DECISION.—A developer may request a supervisory review of the significant decision described in subsection (a)(1). Such review may be

conducted at the next supervisory level or higher above the agency official who made the significant decision.

''(2) SUBMISSION OF REQUEST.—A developer requesting a supervisory review under paragraph (1) shall submit such request to the Secretary not later than 30 days after the decision for which the review is requested and shall indicate in the request whether such developer seeks an in-person meeting or a teleconference review.

''(3) TIMEFRAME.—The Secretary shall schedule an in-person or teleconference review, if so requested, not later than 30 days after such request is made. The Secretary shall issue a decision to the developer requesting a review under this subsection not later than 45 days after the request is made under paragraph (1), or, in the case of a developer who requests an in-person meeting or teleconference, 30 days after such meeting or teleconference.

''(c) ADVISORY PANELS.—The process established under subsection (a) shall permit the appellant to request review by an advisory committee established under section 587G when there is a dispute involving substantial scientific fact. If an advisory panel meeting is held, the Secretary shall make a determination under this subsection

not later than 45 days after the requested advisory committee meeting has concluded.

''(d) LEAST BURDENSOME REVIEW.—Any developer who has submitted an application under section 587B or 587D may request a supervisory review of a request for additional information during an evaluation of such submission within 60 calendar days of receipt of the additional information request from the Secretary.

''(e) AVAILABILITY OF ALL REMEDIES.—The procedures set forth in this section shall be in addition to, and not in lieu of, other remedies available to the developer.

''SEC. 587Q. ACCREDITED PERSONS.

''(a) IN GENERAL.—

''(1) AUTHORIZATION.—Beginning on the date of enactment of the VALID Act of 2023, the Secretary shall accredit persons for any of the following purposes:

''(A) Reviewing applications for premarket approval under section 587B and making findings with respect to such applications.

''(B) Reviewing applications for technology certification under section 587D and making recommendations to the Secretary with respect to such applications.

''(C) Conducting inspections as specified in subsection (c) of in vitro clinical test developers and other persons required to register pursuant to section 587J.

''(2) PERSONS SUBMITTING APPLICATIONS.—A person submitting an application for premarket approval under section 587B or an application for technology certification under section 587D may submit such application to the Secretary or to a person accredited pursuant to subparagraph (A) or (B) of paragraph (1).

''(b) ACCREDITED PERSONS APPLICATION REVIEWS, FINDINGS AND RECOMMENDATIONS.—

''(1) REQUIREMENTS FOR PREMARKET APPLICATION.—

''(A) REVIEW, FINDING, AND RECOMMENDATION REQUIREMENTS.—An accredited person receiving an application for premarket approval under section 587B shall either—

''(i) provide to the Secretary, together with the application for premarket approval submitted by the applicant, a recommendation based on a finding that the criteria for approval of the application under section 587B(e)(2)(A) are met and

issue a copy of such finding to the applicant, which finding shall plainly state—

''(I) the basis for the accredited person's finding that the criteria under section 587B(e)(2)(A) are met; and

''(II) any proposed restrictions, mitigating measures, or conditions of approval under section 587B(e)(2)(B), as applicable; or

''(ii) provide a notification to the applicant that the accredited person cannot find that the criteria for approval of the application under section 587B(e)(2)(A) are met and the reasons for such decision.

''(B) REQUESTING MISSING OR CLARIFYING INFORMATION.—After receipt of an application from an accredited person under this section, the Secretary may request missing or clarifying information from the applicant concerning the application, which the accredited person shall promptly provide.

''(C) SECRETARY ACTION ON RECOMMENDATION THAT APPROVAL CRITERIA ARE MET.—If the accredited person transmits a rec-

ommendation to the Secretary under subparagraph (A)(i), then prior to the date that is 45 calendar days after the transmittal date, the Secretary shall consider such recommendation and make a determination to—

''(i) approve the application for premarket approval under section 587B(e)(2) with appropriate restrictions, mitigating measures, or conditions of approval, as applicable; or

''(ii) deny approval of the application by issuing a written notice that reflects appropriate management input and concurrence to the accredited person and the applicant detailing the scientific basis for the Secretary's determination that the criteria for issuance of an approval under section 587B(e)(2)(A) have not been met.

''(D) EFFECT OF INACTION ON RECOMMENDATION.—If the Secretary fails to take an action under subparagraph (C) the Secretary shall—

''(i) within 45 calendar days after the transmittal date, provide written feedback to the applicant that—

''(I) includes all outstanding issues with the application preventing the Secretary from taking an action under subparagraph (B);

''(II) reflects appropriate management input and concurrence; and

''(III) includes action items for the Secretary, the applicant, or both, as appropriate, with an estimated date of completion for the Secretary and the applicant to complete their respective tasks, as applicable; and

''(ii) promptly schedule a meeting or teleconference to discuss the feedback provided under clause (i), unless the Secretary and applicant agree that the outstanding issues are adequately presented through written correspondence and a meeting or teleconference is not necessary.

''(2) REQUIREMENTS FOR TECHNOLOGY CERTIFICATION.—

''(A) REVIEW AND RECOMMENDATION REQUIREMENTS.—An accredited person receiving an application for technology certification under section 587D shall either—

''(i) provide to the Secretary, together with the application for technology certification submitted by the applicant, a recommendation that the criteria for issuance of a technology certification order under section 587D(d)(3) are met and issue a copy of such recommendation to the applicant, which recommendation shall plainly state the basis for the accredited person's recommendation that the criteria under section 587D(d)(3) are met; or

''(ii) provide a notification to the applicant that the accredited person cannot recommend that the criteria for issuance of a technology certification order under section 587D(d)(3) are met and the reasons for such decision.

''(B) REQUESTING MISSING OR CLARIFYING INFORMATION.—After receipt of an application under this section, the accredited person may request missing or clarifying information from the applicant concerning the application, which the applicant shall promptly provide.

''(C) SECRETARY ACTION ON RECOMMENDATION FOR ISSUANCE OF A TECHNOLOGY CERTIFICATION ORDER.—If the accredited person transmits a recommendation to the Secretary under clause (i) of subparagraph (A), then prior to the date that is 60 calendar days after the transmittal date the Secretary shall—

''(i) issue the technology certification order under section 587D(d)(3), consistent with such recommendation from the accredited person; or

''(ii) deny approval of the application by issuing a written notice to the accredited person and the applicant detailing the scientific basis for a determination by the Secretary that the criteria for issuance of a technology certification order under section 587D(d)(3) have not been met.

''(c) REQUIREMENTS FOR INSPECTIONS.—

''(1) IN GENERAL.—When conducting inspection, persons accredited under subsection (a)(1)(C) shall record in writing their specific observations and shall present their observations to the designated representative of the inspected establishment.

''(2) INSPECTION REPORT REQUIREMENTS.—Each person accredited under subsection (a)(1)(C) shall prepare and submit to the Secretary an inspection report in a form and manner designated by the Secretary for conducting inspections. Any statement or representation made by an employee or agent of an establishment to a person accredited to conduct inspections under subsection (a)(1)(C) shall be subject to section 1001 of title 18, United States Code.

''(3) SAVINGS CLAUSE.—Nothing in this section affects the authority of the Secretary to inspect any in vitro clinical test developer or other person registered under section 587J or recognize inspections conducted by auditing organizations as described under section 704(g)(15).

''(4) INSPECTION LIMITATIONS.—The Secretary shall ensure that inspections carried out under this section are not duplicative of inspections carried out under section 353 of the Public Health Service Act. Inspections under this section shall be limited to the data and information necessary—

''(A) for routine surveillance activities of facilities associated with an approved application under section 587B or issuance of a tech-

nology certification order under section 587D; or

''(B) to meet the requirements for premarket approval under section 587B or issuance of a technology certification order under section 587D, as applicable.

''(d) ACCREDITATION.—

''(1) ACCREDITATION PROGRAM.—The Secretary may provide for accreditation under this section through programs administered by the Food and Drug Administration, by other non-Federal government agencies, or by qualified nongovernmental organizations. A person may be accredited for the review of applications submitted under sections 587B as described in subsection (a)(1)(A), for the review of applications submitted under section 587D as described in subsection (a)(1)(B), and to conduct inspection activities under subsection (a)(1)(C), or for a subset of such reviews or activities.

''(2) ELIGIBLE PERSONS.—

''(A) MINIMUM QUALIFICATIONS.—An accredited person, at a minimum, shall—

''(i) not be an employee of the Federal Government;

''(ii) not engage in the activities of a developer, as defined in section 587(7);

''(iii) not be a person required to register under section 587J, unless such person has established sufficient processes and protocols to separate activities to develop in vitro clinical tests and the activities for which such person would be accredited under subsection (a) and discloses applicable information under this section;

''(iv) 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 587J;

''(v) be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

''(vi) ensure that the operations of such person are in accordance with generally accepted professional and ethical business practices; and

''(vii) include in its request for accreditation a commitment to, at the time of accreditation and at any time it is per-

forming activities pursuant to this section—

''(I) certify that the information reported to the Secretary accurately reflects the data or protocol reviewed, and the documented inspection findings, as applicable;

''(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.

''(B) WAIVER.—The Secretary may waive any requirements in clauses (i), (ii), (iii), or (iv) of subparagraph (A) upon making a determination that such person has implemented other

appropriate controls sufficient to ensure a competent and impartial review.

''(3) ACCREDITATION PROCESS.—

''(A) ACCREDITATION PROCESS GUIDANCE AND REGULATIONS.—Not later than 180 days after the date of enactment of the VALID Act of 2023, the Secretary shall issue draft 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, including the criteria that the Secretary will consider to accredit or deny accreditation and, not later than 1 year after the close of the comment period for the draft guidance, issue final guidance.

''(B) RESPONSE TO REQUEST.—The Secretary shall respond to a request for accreditation or reaccreditation within 60 calendar 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. If the Secretary requests additional information, the Secretary shall respond within 60 cal-

endar days of receipt of such additional information to accredit or deny the accreditation.

''(C) TYPE OF ACCREDITATION.—The accreditation or reaccreditation of a person shall specify the particular activity or activities under subsection (a) for which such person is accredited, and shall include any limitation to certain eligible in vitro clinical tests.

''(D) PUBLIC LIST.—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.

''(E) AUDIT.—The Secretary may audit the performance of persons accredited under this section for purposes of ensuring that such persons 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.

''(F) SUSPENSION OR WITHDRAWAL.—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.

''(G) REACCREDITATION.—Accredited persons may be initially accredited for up to 3 years. After expiration of such initial period, persons may be reaccredited for unlimited additional 5-year periods, as determined by the Secretary.

''(e) COMPENSATION OF ACCREDITED PERSONS.—Compensation of an accredited person 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.

''(f) INTERNATIONAL HARMONIZATION.—Notwithstanding any other provision of this section, to facilitate international harmonization the Secretary may recognize persons accredited or recognized by governments, who

have also entered into information sharing agreements, including confidentiality commitments, with the Commissioner of Food and Drugs.

''(g) INFORMATION SHARING AGREEMENTS.—An accredited person may enter into an agreement with a test developer to provide information to the comprehensive test information system under section 587T, including any requirements under section 587J.

''(h) REPORTS.—Not later than 2 years after the effective date of the VALID Act of 2023, and annually thereafter for the next 4 years, the Secretary shall post on the website of the Food and Drug Administration, a report describing the Secretary's performance in implementing this section, including the Secretary's progress in minimizing duplicative reviews of applications for which an accredited person finds the criteria for approval are met. Such reports shall include, for each period—

''(1) with regard to premarket approval applications—

''(A) the total number of findings transmitted to the Secretary under subsection (b)(1)(A)(i);

''(B) the total number of determinations made by the Secretary under subsection

(b)(1)(B)(i) within 30 calendar days of the transmittal date to approve an application;

''(C) the total number of determinations made by the Secretary under subsection (b)(1)(B)(ii) within 30 calendar days of the transmittal date to deny approval of an application; and

''(D) the total number of applications that were approved and the total number of applications that were denied approval, after the Secretary failed to make a determination within 30 calendar days of the transmittal date under subsection (b)(1)(B); and

''(2) with regard to applications for technology certification—

''(A) the total number of recommendations transmitted to the Secretary under subsection (b)(2)(A)(i);

''(B) the total number of determinations made by the Secretary under subsection (b)(2)(B)(i) to issue a technology certification order, including determinations made within 30 days of the transmittal date;

''(C) the total number of determinations made by the Secretary under subsection

(b)(2)(B)(ii) to deny the application for technology certification, including determinations made within 30 calendar days of the transmittal date; and

''(D) the total number of technology certification orders issued, and the total number of applications for technology certification that were denied, including applications denied after the Secretary failed to make a determination within 30 calendar days of the transmittal date under subsection (b)(2)(B).

''SEC. 587R. RECOGNIZED STANDARDS.

''(a) IN GENERAL.—The Secretary may recognize all or part of appropriate standards established by nationally or internationally recognized standards development organizations for which a person may submit a declaration of conformity in order to meet a requirement under this subchapter to which that standard is applicable. Standards for in vitro diagnostic devices previously recognized under section 514(c) shall be considered recognized standards under this section. Recognized and proposed standards shall be accessible to the public at no charge. The application of any such consensus standard shall only apply prospectively. The Secretary shall issue regulations estab-

lishing the criteria and process, for such recognition and adoption.

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

"SEC. 587S. INVESTIGATIONAL USE.

''(a) IN GENERAL.—Subject to the conditions prescribed in subsections (c), (d), (e), (f), and (g), an in vitro clinical test for investigational use shall be exempt from the requirements of this subchapter, other than sections 587A, 587P, 587T, and 587V. The Secretary may amend parts 50, 54, and 56 of title 21 of the Code of Federal Regulations to apply to in vitro clinical tests to permit the investigational use of such tests by experts qualified by scientific training and experience.

''(b) REGULATIONS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of the VALID Act of 2023, the Secretary shall promulgate regulations to implement this section.

''(2) VARIATION.—The requirements in the regulations promulgated under this section shall take into account variations 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 to the in vitro clinical test involved during testing conducted in accordance with a plan required under subsection (c)(6); 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.

''(c) APPLICATION FOR INVESTIGATIONAL USE.—The following shall apply with respect to in vitro clinical tests for investigational use:

''(1) SIGNIFICANT RISK AND OTHER STUDIES.—In the case of an in vitro clinical test the investigational use of which poses a significant risk to the human subject or involves an exception from informed consent for emergency research, 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 in vitro clinical test in accordance with paragraphs (3) and (4).

''(2) NON-SIGNIFICANT RISK STUDIES.—In the case of an in vitro clinical test, the investigational use of which is not described in paragraph (1)—

''(A) the sponsor of such investigation shall—

''(i) ensure such investigation is conducted in compliance with an investigational plan approved by an institutional review committee and the labeling of the in vitro clinical test involved clearly and conspicuously states, 'For investigational use only', as specified in paragraph (4)(A)(ii);

''(ii) ensure each investigator obtains informed consent as required under part 50, 54, and 56 of title 21, Code of Federal Regulations (or any successor regulations), subject to the exceptions set forth in paragraph (6)(C);

''(iii) establish and maintain records with respect to all requirements in this subparagraph;

''(iv) maintain records and make reports as required by the Secretary pursuant to regulations issued under subsection (b); and

''(v) ensure that investigators monitor investigations, maintain records and make reports as required by the Secretary pursuant to regulations issued under subsection (b); and

''(B) the sponsor may rely on any exception or exemption described in paragraph (4) or as established by the Secretary in regulations issued under subsection (b).

''(3) APPLICATION.—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 an investigational plan for proposed clinical testing and assurances that the sponsor submitting the application will—

''(A) establish and maintain records relevant to the investigation of such in vitro clinical test; and

''(B) submit to the Secretary annual 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 the exemption specified in paragraph (4);

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

''(iii) to evaluate the ability to meet the applicable standard.

''(4) CONDITIONS FOR EXEMPTION.—An application for an investigational use exemption with respect to a significant risk study shall be granted if each of the following conditions is met:

''(A) The risks to the subjects of the in vitro clinical test are outweighed by the anticipated benefits of the test to the subjects and the importance of the knowledge to be gained, and adequate assurance of informed consent is provided in accordance with paragraphs (6)(B) and (6)(C).

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

''(C) Such other requirements the Secretary determines—

''(i) are necessary for the protection of the public health and safety; and

''(ii) do not unduly delay investigation.

''(5) COORDINATION WITH INVESTIGATIONAL NEW DRUG APPLICATIONS.—Any requirement for the submission of a report to the Secretary pursuant to an application for an investigational new drug exemption involving an in vitro clinical test shall supersede the reporting requirement under paragraph (3)(B), but only to the extent the requirement with respect to the application for exemption with respect to the drug is duplicative of the reporting requirement under such paragraph.

''(6) INVESTIGATIONAL PLAN, PROCEDURES, AND CONDITIONS.—With respect to an investigational plan submitted under paragraph (3), the sponsor submitting such plan shall—

''(A) promptly notify the Secretary of the approval or the suspension or termination of the approval of such plan by an institutional review committee;

''(B) in the case of an in vitro clinical test made available to investigators for clinical testing, obtain agreements from each investigator that any testing of the in vitro clinical test involving human subjects will be under such in-

vestigator's supervision and in accordance with paragraph (C) and submit such agreements to the Secretary that ensure—

''(i) all investigators will comply with this section, regulations promulgated or revised under this section, and applicable human subjects regulations; and

''(ii) the investigator will ensure that—

''(I) informed consent is obtained as required under part 50 of title 21, Code of Federal Regulations (or any successor regulations), amended to apply to in vitro clinical tests; and

''(II) the requirements for institutional review board under part 56 of title 21 of the Code of Federal Regulations (or successor regulations), amended to apply to in vitro clinical tests, are met; and

''(C) ensure 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, ex-

cept where, 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 clinical testing determines in writing that there exists a life-threatening situation involving the human subject of such testing which necessitates the use of such in vitro clinical test and it is not feasible to obtain informed consent from the subject and there is not sufficient time to obtain such consent from a representative of such subject.

''(7) CONCURRED BY LICENSED PHYSICIAN.—The determination required by paragraph (6)(C)(ii) shall be concurred in writing by a licensed physician who is not involved in the testing of the human subject with respect to which such determination is made unless immediate use of the in vitro clinical test is required to save the life of the human subject

of such testing and there is not sufficient time to obtain such concurrence.

''(8) SIGNIFICANT RISK.—For purposes of this subsection, the term 'significant risk' means, with respect to an in vitro clinical test, that the use of such in vitro clinical test—

''(A) is of substantial importance in performing an activity or activities described in section 201(ss)(1) for, a serious or life-threatening disease or condition without confirmation of the diagnosis by a medically established diagnostic product or procedure;

''(B) requires an invasive sampling procedure that presents a significant risk to the human subject, provided that routine venipuncture shall not be considered an invasive sampling procedure; or

''(C) otherwise presents a potential for serious risk to the health of a human subject.

''(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 30 calendar days after the date of the submission of an application for an investigational use exemption that meets the requirements of subsection (c), issues an order under paragraph (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) DENIAL.—The Secretary may deny 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). A notification of such denial submitted to the sponsor with respect to such a request shall contain the order of disapproval and a complete statement of the reasons for the Secretary's denial of the application.

''(e) WITHDRAWAL OF EXEMPTION.—

''(1) IN GENERAL.—The Secretary may, by administrative order, withdraw an exemption approved under this section with respect to an in vitro clinical test, including an exemption treated as approved based on the Secretary's failure to act pursuant to subsection (d)(2), if the Secretary determines that

an investigation conducted under such an exemption does not meet the applicable conditions under subsection (c)(3) for such exemption.

''(2) OPPORTUNITY TO BE HEARD.—

''(A) IN GENERAL.—Subject to subparagraph (B), an order withdrawing an investigational use exemption granted under this section may be issued only after the Secretary provides the sponsor of the in vitro clinical test with an opportunity for an informal hearing.

''(B) EXCEPTION.—An order referred to in subparagraph (A) with respect to an investigational use exemption granted under this section 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 regulations promulgated under subsection (b) shall provide, with re-

spect to an in vitro clinical test for which an exemption under this subsection is in effect, procedures and conditions under which changes are allowed without the additional approval of an application for an exemption or submission of a supplement to such an application. Such regulations shall provide that such a change may be made if—

''(A) the sponsor determines, on the basis of credible information (as defined in regulations) that the change meets the conditions specified in paragraph (2); and

''(B) the sponsor 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 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, or the relationship of likely patient risk to benefit relied upon to approve a product;

''(ii) the scientific soundness of a plan submitted under subsection (c)(3); or

''(iii) the rights, safety, or welfare of the human subjects 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 written 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 may immediately appeal any such determination pursuant to section 587P.

''(2) DETERMINATION.—

''(A) IN GENERAL.—For purposes of paragraph (1), a determination described in this subparagraph with respect to a clinical hold is a determination that, based on credible evidence, 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) REMOVAL OF CLINICAL HOLD.—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. 587T. COMPREHENSIVE TEST INFORMATION SYSTEM.

"(a) ESTABLISHMENT.—Not later than 2 years after the date of enactment of the VALID Act of 2023, the Secretary shall make available a comprehensive test information system for in vitro clinical tests that is designed to—

"(1) provide a transparent interface on the website of the Food and Drug Administration for stakeholders, to the extent permitted by applicable law, which may include access to the—

"(A) regulatory pathway designation information for each in vitro clinical test or tests with the same indications for use;

"(B) registration and listing information provided by developers under section 587J, including the use of a link for labels;

"(C) adverse event reports submitted under section 587M, as appropriate;

"(D) reports of corrections and removals submitted under section 587N; and

"(E) other information pertaining to an in vitro clinical test or tests with the same indications for use, as the Secretary determines appropriate; and

"(2) provide a secure portal for electronic submission, including applications and other in vitro clinical test submissions, registration and listing in-

formation, and adverse event reports, which provides protections from unauthorized disclosure of information, including of—

''(A) trade secret or confidential commercial or financial information; and

''(B) information that could compromise national security.

''(b) SUBMISSION FUNCTION.—The comprehensive test information system shall serve as the electronic submission service for test developers submitting information for applications under sections 587B and 587D.

''SEC. 587U. PREEMPTION.

''(a) IN GENERAL.—Except as provided in subsection (b), no State, Tribal, or local government (or political subdivision thereof) may establish or continue in effect any requirement—

''(1) that is different from, or in addition to, any requirement applicable to an in vitro clinical test under this Act; or

''(2) with respect to the analytical validity, clinical validity, or safety for individuals who come into contact with such an in vitro clinical test.

''(b) EXCEPTIONS.—Subsection (a) shall not be construed to affect the authority of a State, Tribal, or local government to do any of the following:

''(1) To license laboratory personnel, health care practitioners, or health care facilities or to regulate any aspect of a health care practitioner-patient relationship.

''(2) To enforce laws of general applicability, such as zoning laws, environmental laws, labor laws, and general business laws.

''(3) To authorize laboratories to develop and perform an in vitro clinical test, pursuant to a law enacted by a State prior to January 1, 2022, as long as such law does not impose requirements that are different from any requirement applicable to an in vitro clinical test under this Act. If a State has enacted such a law, the Secretary shall exempt such test for laboratories in that State from compliance with this subchapter.

''(c) CLARIFICATION.—Nothing in this section shall be construed to—

''(1) modify any action for damages or the liability of any person under the law of any State; or

''(2) shift liability to health care practitioners or other users.

''SEC. 587V. 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 developed, 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 container or 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, as applicable, or with respect to a specimen receptacle, its safety, 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 performance standard established or recognized under section 587R and is not in conformity with such standard.

''(7) If it is required to be in compliance with mitigating measures established under section 587E

and is not in conformity with such mitigating measures.

''(8) If it fails to have in effect an approved premarket application under section 587B, unless such in vitro clinical test is in compliance with the requirements for—

''(A) offering without an approved premarket application under section 587D(b)(1);

''(B) an exemption from premarket approval under section 587C or 587G; or

''(C) investigational use pursuant to section 587S.

''(9) If it is not in conformity with any condition established under section 587B or 587D.

''(10) If it purports to be an in vitro clinical test subject to an exemption under section 587C and it fails to meet or maintain any criteria, condition, or requirement of such exemption.

''(11) If it has been granted an exemption under section 587S 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 requirements prescribed in or established under section 587K (as applicable), or the methods used in, or facilities or controls used for, its development, packaging, storage, or installation are not in conformity with applicable requirements established under such section.

''(13) If it has been developed, processed, packaged, 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 required under section 587O.

''SEC. 587W. 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, packager, or distributor; and

''(B) an accurate statement of the quantity of contents in terms of weight, measure, or numerical count, unless an exemption is granted by the Secretary by the issuance of guidance, such as 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) 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, blood establishments, 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, 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.

''(5) If there is a reasonable probability that it could cause serious or adverse health consequences or death, including through absence, delay, or discontinuation in diagnosis or treatment, when used in the manner prescribed, recommended, or suggested in the labeling thereof.

''(6) If it was developed, sterilized, packaged, repackaged, relabeled, installed, or imported in an establishment not duly registered under section 587J or it was not included in a listing under section 587J, in accordance with timely reporting requirements under this subchapter.

''(7) In the case of any in vitro clinical test subject to restrictions under section 587O, (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 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 indications for use of the in vitro clinical test and relevant warnings, precautions, side effects, and contraindications. This paragraph shall not be applicable to any printed matter that the Secretary determines to be labeling as defined in section 201(m).

''(8) If it is subject to a mitigating measure established under section 587E and does not bear such labeling as may be prescribed in such mitigating measure.

''(9) If it is subject to a standard established under section 587R and it does not bear such labeling as may be prescribed in such standard.

''(10) Unless it bears such labeling as may be required by or established under an applicable labeling requirement under this Act.

''(11) If there was a failure to comply with any requirement prescribed in or under section 587D, 587J, 587K, 587L, 587M, 587N, 587X, 587Y, 587Z, or to provide any report, material, or other information required with respect to in vitro clinical tests under this subchapter.

''SEC. 587X. POSTMARKET SURVEILLANCE.

''(a) IN GENERAL.—

''(1) IN GENERAL.—In addition to other applicable requirements under this Act, the Secretary may issue an order requiring a developer of a high-risk or moderate-risk in vitro clinical test to conduct postmarket surveillance of such in vitro clinical test, if the failure of the in vitro clinical test is reasonably likely to result in serious adverse health consequences or death from use of such in vitro clinical test.

''(2) CONSIDERATION.—In determining whether to require a developer to conduct postmarket surveillance of an in vitro clinical test, the Secretary shall take into consideration the benefits and risks for the patient and the least burdensome requirements under section 587AA(c).

''(b) SURVEILLANCE APPROVAL.—

''(1) IN GENERAL.—Each developer required to conduct 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) TIMELINE.—The developer shall commence surveillance under this section not later than 15 months after the day on which the Secretary orders such postmarket surveillance, unless the Secretary determines more time is needed to commence surveillance.

''(3) PROSPECTIVE SURVEILLANCE.—The Secretary may order a prospective surveillance period of up to 3 years. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the developer or, if no agreement can be reached, upon the completion of a dispute resolution process pursuant to section 562.

''SEC. 587Y. ELECTRONIC FORMAT FOR SUBMISSIONS.

''(a) IN GENERAL.—All submissions to the Food and Drug Administration with respect to an in vitro clinical test, unless otherwise agreed to by the Secretary, shall—

''(1) be made electronically; and

''(2) with respect to the information required under sections 587B and 587D, utilize the system described in section 587T.

''(b) ELECTRONIC FORMAT.—Beginning on such date as the Secretary specifies in final guidance issued under subsection (c), submissions for in vitro clinical tests, including recommendations submitted by accredited and recognized persons under section 587Q, and any appeals of action taken by the Secretary with respect to such submissions, shall be submitted in such electronic format as specified by the Secretary in such guidance.

''(c) GUIDANCE.—The Secretary shall issue guidance implementing this section. Such guidance may—

''(1) provide standards for the electronic submission 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 subsection (a) or (b); and

''(3) provide any other information for the efficient implementation and enforcement of this section.

''SEC. 587Z. POSTMARKET REMEDIES.

''(a) SAFETY NOTICE.—

''(1) IN GENERAL.—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 ensure that adequate safety notice is provided in an appropriate form, by the persons and means best suited under the circumstances, to all health care professionals who prescribe, order, or use the in vitro clinical test and to any other person (including developers, importers, distributors, retailers, and users) who should properly receive such notice.

''(2) NOTICE TO INDIVIDUALS.—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 the health care professionals who prescribed, ordered, or used the in vitro clinical test provide notification 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. Before issuing an order under this subsection, the Secretary shall consult with the persons required to give notice under the order.

''(b) REPAIR, REPLACEMENT, OR REFUND.—

''(1) DETERMINATION AFTER AN INFORMAL HEARING.—

''(A) IN GENERAL.—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 developed or manufactured considering the state of the art as it existed at the time of its development;

''(iii) there are reasonable grounds to believe that the unreasonable risk was not caused by failure of a person other than a developer, 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, 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 the Secretary determines bears such responsibility.

''(B) SECRETARY APPROVAL OF PLAN.—The Secretary shall approve a plan submitted pursuant to an order issued under subparagraph (A) unless the Secretary 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, the Secretary shall order a revised plan to be submitted 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 developer, 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) ACTIONS ON A PLAN.—The actions that may be taken under a plan submitted under an order issued under paragraph (1)(A) 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)(A) 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)(A), whichever occurs first).

''(3) NO CHARGE.—No charge shall be made to any person (other than a developer, importer, distributor, or retailer) for using a 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 using such remedy.

''(c) REIMBURSEMENT.—An order issued under subsection (b)(1)(A) with respect to an in vitro clinical test may require any person who is a developer, importer, distributor, or retailer of the in vitro clinical test to reimburse any other person who is a developer, 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) IN GENERAL.—If the Secretary finds that there is a reasonable probability that an in vitro clinical test approved under section 587B or offered under a technology certification order under section 587D would cause serious, adverse health consequences or death, including by the absence, significant delay, or discontinuation of appropriate medical treatment, the Secretary shall issue an order requiring the appropriate person (including the developers, 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 applicable in vitro clinical test user facilities of the order and to instruct such professionals and facilities to cease use of such in vitro clinical test.

''(2) INFORMAL HEARING.—The order issued under paragraph (1)(A), shall provide the person subject to the order with an opportunity for an in-

formal hearing, to be held not later than 10 calendar 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) AMENDED ORDER.—

''(A) IN GENERAL.—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 subparagraph (B), amend the order to require a recall. The Secretary shall specify a timetable in which the recall will occur and shall require periodic reports describing the progress of the recall.

''(B) REQUIREMENTS.—An amended order under subparagraph (A)—

''(i) shall not include recall of the in vitro clinical test from individuals;

''(ii) shall not include recall of an in vitro clinical test from test 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

''(iii) 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) CLARIFICATION.—The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c).

''SEC. 587AA. APPLICABILITY.

''(a) IN GENERAL.—An in vitro clinical test shall be subject to the requirements of this subchapter, except as otherwise provided in this subchapter. Laboratory operations shall not be subject to the requirements of this subchapter.

''(b) INTERSTATE COMMERCE.—Any in vitro clinical test that is offered, including by making available for clinical use in the United States is deemed to be an act that constitutes introduction into interstate commerce for purposes of enforcing the requirements of this Act.

''(c) LEAST BURDENSOME REQUIREMENTS.—

''(1) IN GENERAL.—In carrying out this subchapter, the Secretary shall consider the least burdensome means necessary to meet the applicable standard, and other regulatory requirements, as determined by the Secretary.

''(2) NECESSARY DEFINED.—For purposes of paragraph (1), the term 'necessary' means the minimum required information that would support a determination by the Secretary that the application meet the applicable standard or regulatory requirement, as determined by the Secretary.

''(d) SERVICE OF ORDERS.—Orders of the Secretary under this section with respect to applications under subsection (a) or (b) of section 587B or supplements under subsection (f) of such 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 the last known address in the records of the Secretary.

''(e) LABORATORIES AND BLOOD AND TISSUE ESTABLISHMENTS.—

''(1) RELATION TO LABORATORY CERTIFICATION PURSUANT TO SECTION 353 OF THE PUBLIC HEALTH SERVICE ACT.—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.

''(2) AVOIDING DUPLICATION.—In implementing this subchapter, the Secretary shall avoid issuing or enforcing regulations or guidance that are duplicative of regulations or guidance under section 353 of the Public Health Service Act such that laboratories would be subject to conflicting regulatory obligations with respect to the same activity.

''(3) 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 prepara-

tion, including filling, labeling, packaging, and storage, of blood, blood components, human cells, tissues, or tissue products pursuant to any requirements under this Act or section 351 or 361 of the Public Health Service Act.

''(f) NOT COMBINATION PRODUCT.—

''(1) IN GENERAL.—A product constituted of a device and an in vitro clinical test is not a combination product and may be regulated as a device or as a device and in vitro clinical test, notwithstanding section 201(ss)(3).

''(2) GUIDANCE.—Not later than October 1, 2026, the Secretary shall issue final guidance, after an opportunity for public comment, addressing the considerations for regulating a product described in paragraph (1). Such guidance shall take into account the least burdensome requirements under subsection (c).

''(g) PRACTICE OF MEDICINE.—Nothing in this subchapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any lawfully offered in vitro clinical test for any condition or disease within a legitimate health care practitioner-patient relationship pursuant to applicable Federal or State law.

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

''(i) PROMOTION OF UNAPPROVED USES.—Nothing in this section shall be construed to alter any prohibition on the promotion of unapproved uses of legally offered in vitro clinical tests.

''(j) VOLUNTARY SUBMISSIONS.—Nothing in section 587C shall be construed to prevent a developer developing a test described in such section, including an academic medical center laboratory described in subsection (a)(7) of such section, from filing an application under section 587B or section 587D, or from adhering to the requirements of section 587K with regard to a test protocol described in section 587K or for any other test or use of a test.

''SEC. 587BB. JUDICIAL REVIEW.

''(a) IN GENERAL.—Not later than 30 days after an order issued pursuant to sections 587B or 587D, any person adversely affected by such order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has a principal place of business for judicial review of

such order, in accordance with the procedure set forth in section 517(a).

''(b) APPLICATION OF PROVISIONS.—Subsections (a) through (e) of section 517 shall apply with respect to a petition under subsection (a) of this section in the same manner such subsections apply to a petition under section 517. Subsection (f) of section 517 shall apply to an order issued under section 587B or 587D.''.

SEC. 4. 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), (h), (k), (q), (r), and (y), by inserting ''in vitro clinical test,'' after ''device,'' each place it appears;

(2) in paragraph (g), by inserting after ''misbranded'' the following: '', and the development within any Territory of any in vitro clinical test that is adulterated or misbranded'';

(3) in paragraph (y), by inserting ''or 587Q'' after ''section 523'' each place it appears;

(4) in paragraph (ff), by striking ''or device'' and inserting '', device, or in vitro clinical test''; and

(5) by adding at the end, the following:

''(fff)(1) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification upon any in vitro clinical test or container, packaging, or labeling thereof so as to render such in vitro clinical test a counterfeit in vitro clinical test.

''(2) Making, selling, disposing of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark or imprint of another or any likeness of any of the foregoing upon any in vitro clinical test or container, packaging, or labeling thereof so as to render such in vitro clinical test a counterfeit in vitro clinical test.

''(3) The doing of any act which causes an in vitro clinical test to be a counterfeit in vitro clinical test, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit in vitro clinical test.

''(ggg)(1) The introduction or delivery for introduction into interstate commerce of an in vitro clinical test in violation of section 587A(a).

''(2) The making of a false, fraudulent, or deceptive statement about an in vitro clinical test that is exempt from premarket review under section 587C.

''(3) The failure to maintain complete and accurate documentation for an exemption as required under section 587C or the failure to provide labeling required under section 587L.

''(4) With respect to an in vitro clinical test, the submission of any application, report, or listing under this Act that is false or misleading in any material respect.

''(5) The failure to comply with a condition of approval, or restriction required under an approved application under section 587B; the failure to perform a risk analysis required by section 587B; the failure to submit an annual update required under section 587J(c)(2)(B); or the failure to complete postmarket surveillance as required under section 587X.

''(6) The failure to comply with applicable requirements to submit an application or report under section 587D(e).

''(7) The failure to comply with applicable mitigating measures established under section 587E or to submit, maintain, or make available the documentation required under section 587E(b); or the failure to comply with applicable performance standards established under section 587R.

''(8) The failure to register in accordance with section 587J, the failure to provide information required under

section 587J(b), or the failure to maintain or submit information required under section 587J(c).

''(9) The failure to comply with requirements under section 587M or 587N, the failure to comply with a restriction required under section 587O, or the failure to comply with labeling and advertising requirements under section 587O(b).

''(10) The failure to comply with the requirements of section 587Q.

''(11) The failure to comply with any requirement of section 587S; the failure to furnish any notification, information, material, or report required under section 587S; or the failure to comply with an order issued under section 587S.

''(12) The failure to furnish information requested by the Secretary under 587G(d)(2).''.

(b) PENALTIES.—Section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) is amended—

(1) in subsection (b)(8), by inserting ''or counterfeit in vitro clinical test'' after ''counterfeit drug'';

(2) in subsection (c)—

(A) by striking ''; or (5)'' and inserting ''; (5)''; and

(B) by inserting before the period at the end the following: ''; or (6) for having violated

section 301(fff)(2) if such person acted in good faith and had no reason to believe that use of the punch, die, plate, stone, or other thing involved would result in an in vitro clinical test being a counterfeit in vitro clinical test, or for having violated section 301(fff)(3) if the person doing the act or causing it to be done acted in good faith and had no reason to believe that the in vitro clinical test was a counterfeit in vitro clinical test''; and

(3) in subsection (f)(1)—

(A) in subparagraph (A)—

(i) by inserting ''or in vitro clinical tests'' after ''which relates to devices'';

(ii) by inserting ''or section 587Q(a)(1)'' after ''section 704(g)''; and

(iii) by inserting ''or in vitro clinical tests, as applicable'' before the period at the end of the second sentence; and

(B) in subparagraph (B)(i), by striking ''or 520(f)'' and inserting '', 520(f), 587K, or 587M,''.

(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 (E)’’ and inserting ‘‘, (E)’’; and

(B) by inserting before the period at the end the following: ‘‘, and (F) Any in vitro clinical test that is a counterfeit in vitro clinical test, (G) Any container, packaging, or labeling of a counterfeit in vitro clinical test, and (H) Any punch, die, plate, stone, labeling, container, or other thing used or designed for use in making a counterfeit in vitro clinical test’’;

(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 for a violation of section 301(gg) or 301(fff)(1), the Secretary shall debar such person from being accredited under section 587Q 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) 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)) of subsection (c)) and inserting '', investigational device, or investigational in vitro clinical test'';

(2) in subsection (b)(4) by striking ''or 520(g)'' each place it appears and inserting '', 520(g), or 587S'';

(3) 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 under section 587S'';

(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'';

(D) in paragraph (5), by striking ''or 520(g)'' and inserting '', 520(g), or 587S''; and

(E) in the matter following paragraph (7) by striking ''or 520(g)'' each place it appears and inserting '', 520(g), or 587S''; and

(4) 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.''.

(f) OPTIMIZING GLOBAL CLINICAL TRIALS.—Section 569A(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8a(b)) is amended—

(1) by striking ''subsection'' each place it appears and inserting ''paragraph''; and

(2) by inserting ''an in vitro clinical test, as defined in paragraph (ss) of such section,'' before ''or a biological product''.

(g) 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''.

(h) REGULATIONS AND HEARINGS.—Clause (ii) of section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(h)(1)(C)) is amended—

(1) by inserting ''and in vitro clinical tests'' after ''devices''; and

(2) by moving the margin of such clause 2 ems to the left.

(i) RECORDS.—Section 703 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 373) is amended—

(1) by inserting ''in vitro clinical tests,'' after ''devices,'' each place such term appears; and

(2) by inserting ''in vitro clinical test,'' after ''device,'' each place such term appears.

(j) 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)(1), in the fourth sentence, by striking ''or chapter IX'' and inserting ''section 587S, section 587M, section 587N, or chapter IX'';

(3) after making the amendments in paragraphs (1) and (2), by inserting ''in vitro clinical tests,'' after ''devices,'' each place it appears;

(4) 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'';

(5) by inserting ''in vitro clinical test,'' after ''device,'' each place it appears;

(6) in subsection (e), by inserting '', or section 587M, 587N, or 587S,'' after ''section 519 or 520(g)'';

(7) 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 587Q.''; and

(8) by adding at the end the following:

''(i) For purposes of this section, the term 'establishment' includes a laboratory performing an in vitro clinical test.''.

(k) 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,''.

(l) 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,''.

(m) LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS.—Section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)) is amended—

(1) in the matter preceding paragraph (1), by inserting ''or in vitro clinical tests'' after ''or devices''; and

(2) in the flush text following paragraph (2)—

(A) by inserting ''or an in vitro clinical test'' after ''a device''; and

(B) by inserting ''or in vitro clinical tests'' after ''devices''.

(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; and

(B) by inserting ''in the case of an in vitro clinical test, the test does not conform to the applicable requirements of section 587K, 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,'';

(3) in subsection (e)(1), by inserting ''in vitro clinical test,'' after ''device,''; and

(4) in subsection (o)—

(A) by inserting ''or in vitro clinical test'' after ''device''; and

(B) by inserting ", or under section 587J of each foreign establishment," after "section 510(i) of each establishment".

(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 striking ", and" and inserting "and quality requirements established under section 587K; and"; 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 of foreign establishments registered under section 587J," 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,'' after ''device manufacturers,''.

(s) COUNTERMEASURE PROVISIONS OF THE PUBLIC HEALTH SERVICE ACT.—Title III of the Public Health Service Act is amended—

(1) in section 319F–1(a)(2)(A) (42 U.S.C. 247d–6a(a)(2)(A))—

(A) in the matter preceding clause (i)—

(i) by striking ''or device'' and inserting ''device''; and

(ii) by inserting ''or an in vitro clinical tests (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))),'' after ''Act (21 U.S.C. 321(h))),''; and

(B) in each of clauses (ii) and (iii), by striking ''or device'' and inserting ''device, or in vitro clinical test'';

(2) in section 319F–2(c)(1)(B) (42 U.S.C. 247d–6b(c)(1)(B))—

(A) by striking ''or device'' and inserting ''device''; and

(B) by inserting '', or an in vitro clinical test (as that term is defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss)))'' after ''Act (21 U.S.C. 321(h))),''; and

(3) in section 319F–3(i)(7) (42 U.S.C. 247d–6d(i)(7))—

(A) in the matter preceding subparagraph (A)—

(i) by striking ''or device'' and inserting ''device''; and

(ii) by inserting ''or an in vitro clinical tests (as that term is defined in sec-

tion 201(ss) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ss))),'' after ''Act (21 U.S.C. 321(h))'';

(B) in subparagraph (A)—

(i) by moving the margin of clause (iii) 2 ems to the left; and

(ii) in clause (iii), by striking ''or device'' and inserting ''device, or in vitro clinical test''; and

(C) in subparagraph (B)—

(i) in clause (i), by striking ''approved or cleared'' and inserting ''approved, cleared, or offered under a technology certification order''; and

(ii) in clause (ii), by striking ''or 520(g)'' and inserting '', 520(g), or 587S''.

SEC. 5. TRANSITION.

(a) IMPLEMENTATION.—

(1) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as otherwise provided in this section, the amendments made by this Act shall take effect on October 1, 2028 (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 section as the ''effective date of this Act'').

(B) EXCEPTIONS.—

(i) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') may take the actions described in paragraph (2), and may expend such funds as the Secretary determines necessary to ensure an orderly transition prior to the effective date of this Act.

(ii) IMPLEMENTATION OF CERTAIN PROVISIONS.—The Secretary may implement sections 587J and 587U of the Federal Food, Drug, and Cosmetic Act (as added by section 3) beginning on October 1, 2024, and such sections may take effect not earlier than October 1, 2028, to the extent and for the purposes indicated in such sections. In the case of a developer who, between October 1, 2024, and the effective date of this Act, registers under such section 587J with respect to an article that is an in vitro clinical test, such developer shall not be required to register

with respect to such article under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360).

(2) ACTIONS.—The Secretary—

(A) shall—

(i) within 1 year of the date of enactment of this Act, hold the public meetings described in section 587D(i) of the Federal Food, Drug, and Cosmetic Act (as added by section 3); and

(ii) within 3 years of the date of enactment of this Act, promulgate final regulations required under the amendments made by this Act; and

(B) may take additional actions after the date of enactment that the Secretary determines necessary to ensure an orderly transition, including—

(i) establishment of mitigating measures for an in vitro clinical test or category of in vitro clinical tests, which may not take effect until after the effective date described in paragraph (1)(A); and

(ii) establishment of the comprehensive test information system under section

587T of the Federal Food, Drug, and Cosmetic Act, as added by section 3.

(3) APPLICABILITY OF GUIDANCE AND REGULATIONS.—Notwithstanding the date on which guidance or regulations are issued under paragraph (2) and section 587K of the Federal Food, Drug, and Cosmetic Act, as added by section 3, no guidance or regulations issued pursuant to the amendments made by this Act shall be implemented or take effect until the effective date of this Act, except as otherwise specified in this Act (including the amendments made by this Act).

(4) IMPLEMENTATION REQUIREMENTS.—In the event that the Secretary fails to promulgate the regulations required under section 587B(a)(4), 587D(j), or 587S(b)(1) of the Federal Food, Drug, and Cosmetic Act, as added by section 3, by the deadline described in subsection (a)(2)(A)(ii), the Secretary shall, within 15 days of such missed deadline—

(A) submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives pro-

viding information related to the status of such regulations, including—

(i) a rationale for missing the applicable deadline described in such subsection;

(ii) a description of actions taken to the date of submission of the report to promulgate each such regulations;

(iii) the expected timeline for promulgating each such regulations;

(iv) an assessment of the impact of the delay in promulgating such regulations on developers of in vitro clinical tests, including an economic assessment; and

(v) an assessment of the impact of the delay in promulgating such regulations on patients; and

(B) open a public docket for purposes of soliciting public comments on the impact of the delay in promulgating such regulations.

(b) APPLICATION OF AUTHORITIES TO IN VITRO CLINICAL TESTS UNDER REVIEW ON THE EFFECTIVE DATE OF THIS ACT.—For any in vitro clinical test for which a submission for approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e), clearance under section 510(k) of such Act (21 U.S.C.

360(k)), authorization under section 513(f)(2) of such Act (21 U.S.C. 360c(f)(2)), or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) is pending on the effective date of this Act, including transitional in vitro clinical tests as described in subsection (c), 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.

(c) APPLICATION OF AUTHORITIES TO TRANSITIONAL IN VITRO CLINICAL TESTS.—

(1) DEFINITION.—For purposes of this section, the term ''transitional in vitro clinical test'' means an in vitro clinical test that—

(A)(i) is first offered for clinical use during the period beginning on the date that is 45 days after the date of enactment of this Act and ending on the effective date of this Act; or

(ii) is offered solely for investigational use during the period beginning on the date of enactment of this Act and ending on the effective date of this Act;

(B) is developed by a clinical 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 and performed—

(i) in the same clinical laboratory in which the test was developed and for which a certification is still in effect under such section 353 that meets the requirements to perform tests of high complexity;

(ii) by another laboratory for which a certificate is in effect under such section 353 that meets the requirements to perform tests of high complexity, is within the same corporate organization, and has common ownership by the same parent corporation as the laboratory in which the test was developed; or

(iii) in the case of a test that was developed by the Centers for Disease Control and Prevention or another laboratory in a public health laboratory network coordinated or managed by the Centers for Disease Control and Prevention, by a clinical laboratory for which a certificate is in effect under such section 353 that meets the requirements to perform tests of high complexity, and that is within a public health

laboratory network coordinated or managed by the Centers for Disease Control and Prevention; and

(C) when first offered, is not approved under section 515 of the Federal Food, Drug, and Cosmetic Act, cleared under section 510(k) of such Act, authorized under section 513(f)(2) of such Act, subject to a humanitarian device exemption under section 520(m) of such Act (21 U.S.C. 360j(m)), subject to an exemption for investigation use under section 520(g) of such Act (21 U.S.C. 360j(g)), authorized under section 564 of such Act (21 U.S.C. 360bbb–3), or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(2) PREMARKET REVIEW OR TECHNOLOGY CERTIFICATION.—A transitional in vitro clinical test that is not exempt from premarket review under section 587C of the Federal Food, Drug, and Cosmetic Act, as added by section 3, may continue to be offered, sold, or distributed, as applicable, without marketing authorization until completion of the Secretary's review of the premarket application or technology certification application under section 587B or 587D, as applicable, if—

(A) such in vitro clinical test is a high-risk test (as defined in section 587 of the Federal Food, Drug, and Cosmetic Act, as added by section 3) and the application for such test is submitted not later than 90 days after the effective date of this Act; or

(B) such in vitro clinical test is a moderate-risk test (as defined in such section 587), the developer lists the test in accordance with section 587J within 10 calendar days of the effective date of this subchapter, and the application for such test is submitted not later than 1 year after the effective date of this Act.

(3) INVESTIGATIONAL USE REQUEST.—A transitional in vitro clinical test described in paragraph (1)(A)(ii) that is used in a significant risk investigation may continue to be offered for investigational use until completion of the Secretary's review of an application under 587S, if such application is submitted not later than 90 days after the effective date of this Act.

(4) TESTS APPROVED BY NEW YORK STATE.—Notwithstanding paragraph (2), a transitional in vitro clinical test that has been approved by the New York State Department of Health may continue to

be offered, sold, or distributed, as applicable, after the effective date if—

(A) starting on the effective date of this Act, the in vitro clinical test complies with the requirements of subchapter J of the Federal Food, Drug, and Cosmetic Act, as added by this Act, except for section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 3, and design control provisions of section 587K of such Act;

(B) each test report 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 the effective date of the VALID Act of 2023. This test was approved by the New York State Department of Health, but the test has not been reviewed by the Food and Drug Administration.'';

(C) a premarket application under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 3, or technology certification application under section 587D of such Act, as added by section 3, is submitted no later than—

(i) 5 years after the effective date of this Act, if the in vitro clinical test is approved by the New York State Department of Health as a genetic testing molecular test, a microbiology molecular test, an oncology molecular test, or any other type of molecular test; or

(ii) 2 years after the effective date of this Act, if the in vitro clinical test is approved by the New York State Department of Health as a type of test not described in clause (i); and

(D) a test in compliance with this paragraph may continue to be offered, sold, or distributed, as applicable, until the completion of the Secretary's review of the premarket application or technology certification application described in subparagraph (C).

(d) CONVERSION.—

(1) DEEMED PREMARKET APPROVAL.—Beginning on the effective date of this Act—

(A) any in vitro clinical test with a premarket approval under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) or a licensure under section 351 of the

Public Health Service Act (42 U.S.C. 262) is deemed to be approved pursuant to an application under section 587B(a) of the Federal Food, Drug, and Cosmetic Act, as added by this Act; and

(B) any in vitro clinical test (as so defined) that was cleared under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) or authorized under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(2)) is deemed to be approved pursuant to an application under section 587B(b) of the Federal Food, Drug, and Cosmetic Act, as added by this Act.

(2) DEEMED INVESTIGATIONAL USE EXEMPTION.—Any in vitro clinical test that has an investigational device exemption in effect under section 520(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)) is deemed to have an investigational use exemption in effect under section 587S of such Act, as added by this Act, beginning on the effective date of this Act.

(3) DEEMED HUMANITARIAN DEVICE EXEMPTION.—Any in vitro clinical test that has an approved humanitarian device exemption under section

520(m) of such Act is deemed to have a humanitarian test exemption under section 587A(g) of such Act, as added by this Act, beginning on the effective date of this Act.

(4) DEEMED DESIGNATED BREAKTHROUGH.—Any in vitro clinical test that has received a breakthrough device designation under section 515B(e)(1)(D) of such Act (21 U.S.C. 360e–3(e)(1)(D)) is deemed to have a breakthrough in vitro clinical test designation under section 587C of such Act, as added by this Act, beginning on the effective date of this Act.

(5) DEEMED REQUEST FOR INFORMAL FEEDBACK.—With regard to any in vitro clinical test that is the subject of a pre-submission request described in the guidance, ''Requests for Feedback and Meetings for Medical Device Submissions: The Q–Submission Program'', issued by the Food and Drug Administration on January 6, 2021, such request is deemed to constitute a request for informal feedback under section 587F of the Federal Food, Drug, and Cosmetic Act, as added by section 3, beginning on the effective date of this Act.

(e) PREVIOUSLY CLASSIFIED DEVICES.—Notwithstanding section 587 of the Federal Food, Drug, and Cos-

metic Act, as added by section 3, for purposes of subchapter J of chapter V of such Act, as added by section 3, the following apply:

(1) In the case of an in vitro clinical test type that has been classified by the Secretary as a class I device pursuant to section 513 of such Act (21 U.S.C. 360c), such in vitro clinical test shall be low-risk, unless the in vitro clinical test is a test described in the second sentence of section 510(l)(1) of such Act or the test is redesignated by the Secretary pursuant to section 587F of such Act.

(2) In the case of an in vitro clinical test type that has been classified by the Secretary as a class II device pursuant to section 513 of such Act (21 U.S.C. 360c), such in vitro clinical test shall be moderate-risk, unless inaccurate results from the test would be immediately life threatening or the test is redesignated by the Secretary pursuant to section 587F of such Act.

(3) In the case of an in vitro clinical test type that has been classified by the Secretary as a class III device pursuant to section 513 of such Act (21 U.S.C. 360c) or an in vitro clinical test licensed pursuant to section 351 of the Public Health Service Act (42 U.S.C. 262), such in vitro clinical test shall

be high-risk, unless redesignated by the Secretary pursuant to section 587F of the Federal Food, Drug, and Cosmetic Act.

SEC. 6. EMERGENCY USE AUTHORIZATION.

(a) IN GENERAL.—Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended—

(1) by inserting ''or developer'' after ''manufacturer'', each place such term appears;

(2) in subsection (a)—

(A) in paragraphs (1) and (4)(C), by inserting ''in vitro clinical test,'' before ''or biological product'' each place such term appears;

(B) in paragraph (2)(A), by striking ''or 515'' and inserting ''515, or 587B''; and

(C) by adding at the end the following:

''(F) The terms 'develop' and 'developer', with respect to an in vitro clinical test, have the meanings given such terms in section 587.'';

(3) in subsection (b), by inserting ''or developer'' after ''manufacturer'' each place such term appears;

(4) in subsection (e)—

(A) by inserting ''or developers'' after ''manufacturers'' each place such term appears;

(B) in paragraph (2)(B)(ii), by inserting ''or develop'' after ''not manufacture'';

(C) in paragraph (3)—

(i) in subparagraph (A), by striking ''or 520(f)(1)'' and inserting '', 520(f)(1), or 587V'';

(ii) in subparagraph (B), by striking ''and'' at the end;

(iii) in subparagraph (C), by striking the period and inserting '' or 587O; and''; and

(iv) by adding at the end the following:

''(D) quality requirements (with respect to in vitro clinical tests) under section 587K.''; and

(D) in paragraph (4)—

(i) in subparagraph (A), by striking ''; or'' and inserting a semicolon;

(ii) in subparagraph (B), by striking the period and inserting ''; or''; and

(iii) by adding at the end the following:

''(C) with respect to in vitro clinical tests, requirements applicable to restricted in vitro clinical tests pursuant to section 587O.'';

(5) in subsection (k), by striking ''or 520(g)'' and inserting ''520(g), or 587S''; and

(6) in subsection (m)—

(A) in the subsection heading, by striking ''LABORATORY TESTS ASSOCIATED WITH DEVICES'' inserting ''IN VITRO CLINICAL TESTS'' after ''DEVICES''; and

(B) in paragraph (1)—

(i) by striking ''to a device'' and inserting ''to an in vitro clinical test''; and

(ii) by striking ''such device'' and inserting ''such in vitro clinical test''.

(b) EMERGENCY USE OF MEDICAL PRODUCTS.—Section 564A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3a) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by inserting ''in vitro clinical test,'' after ''device,''; and

(B) by adding at the end the following:

''(3) DEVELOPER.—The term 'developer', with respect to an in vitro clinical test, has the meaning given such term in section 587.'';

(2) by inserting ''or developer'' after ''manufacturer'' each place it appears; and

(3) in subsection (c)(1)—

(A) by inserting ''or quality requirements'' after ''good manufacturing practice requirements''; and

(B) by striking ''or 520(f)(1)'' and inserting '', 520(f)(1), or 587K''.

(c) PRODUCTS HELD FOR EMERGENCY USE.—Section 564B(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3b(2)) is amended—

(1) in subparagraph (A), by striking ''or 515'' and inserting ''515, or 587B''; and

(2) in subparagraph (B), by striking ''or 520'' and inserting 520, or 587S.

SEC. 7. 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 striking ''clear under section 510(k), classify under section 513(f)(2), or approve under section 515'' and inserting ''approve under section 587B, exempt from premarket review under section 587C, or grant a

technology certification order under section 587D''; and

(B) by striking ''testing devices'' and inserting ''in vitro clinical tests'';

(2) in subsection (c)(5)—

(A) by striking ''drug or device'' and inserting ''drug, device, or in vitro clinical test''; and

(B) by striking ''the drug or the device'' and inserting ''the drug, device, or in vitro clinical test'';

(3) in subsection (e)—

(A) in the heading, by striking ''TESTING DEVICES'' and inserting ''IN VITRO CLINICAL TESTS'';

(B) in paragraph (1)—

(i) by striking ''510, 513, and 515,'' and inserting ''587B, and 587D'';

(ii) by striking ''antimicrobial susceptibility testing device'' and inserting ''antimicrobial susceptibility in vitro clinical test''; and

(iii) by striking ''such device'' and inserting ''such in vitro clinical test''; and

(C) in paragraph (2)—

(i) in the heading, by striking ''TESTING DEVICES'' and inserting ''IN VITRO CLINICAL TESTS'';

(ii) in subparagraphs (A) and (B) (other than clause (iii) of such subparagraph (B)), by striking ''device'' each place it appears and inserting ''in vitro clinical test'';

(iii) in subparagraph (B)(iii), by striking ''a device'' and inserting ''an in vitro clinical test''; and

(iv) 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, to be exempted from premarket review under section 587C, or to be offered under a technology certification order 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 de-

termine and report the in vitro susceptibility of certain microorganisms to a drug (or drugs).''; and

(5) in subsection (g)(2)—

(A) by amending the matter preceding subparagraph (A) to read as follows:

''(2) with respect to approving an application under section 587B or granting a technology certification order under section 587D—''; and

(B) in subparagraph (A)—

(i) by striking ''device'' and inserting ''in vitro clinical test''; and

(ii) by striking ''antimicrobial susceptibility testing device'' and inserting ''antimicrobial susceptibility in vitro clinical test''.

SEC. 8. 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) in subparagraph (A), by striking ''or biological product'' and inserting ''in vitro clinical test (except for a product constituted of a device and an in vitro clinical test), or biological product'';

(B) in subparagraph (B), by adding at the end the following: ''For purposes of this Act, a product that constitutes a combination of a device and an in vitro clinical test is not a combination product within the meaning of this subsection and an in vitro clinical test that is offered as a separate product intended to inform the use of a drug, biological product, or device is not a combination product within the meaning of this subsection.''; and

(C) in subparagraph (D)(ii)—

(i) by inserting ''or in vitro clinical test'' after ''device''; and

(ii) by inserting ''and in vitro clinical tests'' before ''shall'';

(2) 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'';

(3) in paragraph (4)—

(A) in subparagraph (A), by striking ''or 513(f)(2) (submitted in accordance with paragraph (5))'' and inserting ''513(f)(2) (sub-

mitted in accordance with paragraph (5)), 587B, or 587D''; and

(B) in subparagraph (C), by striking ''or 515'' and inserting ''515, or 587B, or that is under an order under section 587D'';

(4) in paragraph (5)(A), by striking ''or 510(k)'' and inserting '', 510(k), 587B, or 587D'';

(5) in paragraph (7), by striking ''or substantial equivalence'' and inserting '', substantial equivalence, or analytical validity and clinical validity'';

(6) in paragraph (8), by adding at the end the following:

''(I) This paragraph shall not apply to a product constituted of a device and an in vitro clinical test.''; and

(7) in paragraph (9)—

(A) in subparagraph (C)(i), by striking ''or 520(g)'' and inserting ''520(g), 587B, or 587D''; and

(B) in subparagraph (D), by striking ''or 520'' and inserting ''520, 587B, or 587D''.

(b) CLASSIFICATION OF PRODUCTS.—Section 563 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–2) is amended by adding at the end the following:

''(d) EXEMPTION.—This section shall not apply to a product constituted of only a device and an in vitro clinical test.''.

SEC. 9. RESOURCES.

(a) FINDINGS.—Congress finds that 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 Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, 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, 2025, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall initiate the development of recommendations in accordance with this section 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 submissions and applications under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act,

for the first 4 fiscal years after fiscal year 2028 and for the authorization of the In Vitro Clinical Test User Fee Program for such fiscal years. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PRIOR PUBLIC INPUT.—Prior to beginning negotiations with the regulated industry on the authorization of the In Vitro Clinical Test User Fee Program, as described in this section, the Secretary shall—

(i) publish a notice in the Federal Register requesting public input on the authorization of user fees;

(ii) hold a public meeting at which the public may present its views on the author-

ization, including specific suggestions for the recommendations submitted under subparagraph (E);

(iii) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes to the In Vitro Clinical Test User Fee Program; and

(iv) publish any comments received under clause (iii) on the website of the Food and Drug Administration.

(C) PERIODIC CONSULTATION.—Not less frequently than once every month during negotiations with the regulated industry, the Secretary shall hold discussions with representatives of patient and consumer advocacy groups to continue discussions of the authorization of the In Vitro Clinical Test User Fee Program and to solicit suggestions to be included in the recommendations transmitted to Congress under subparagraph (F).

(D) UPDATES TO CONGRESS.—The Secretary, in consultation with regulated industry, shall provide regular updates on negotiations on the reauthorization of the In Vitro Clinical Test

User Fee Program to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives.

(E) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives;

(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.

(F) TRANSMITTAL OF RECOMMENDATIONS.—

(i) IN GENERAL.—Not later than January 15, 2027, the Secretary shall transmit to Congress the revised recommendations under subparagraph (A), 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.

(ii) RECOMMENDATION REQUIREMENTS.—The recommendations transmitted under this subparagraph shall—

(I) include the number of full-time equivalent employees per fiscal year that are agreed to be hired to carry out the goals included in such recommendations for each year of the 5-year period;

(II) provide that the amount of operating reserve balance in the user fee program established under this section is not more than the equivalent of 10 weeks of operating reserve;

(III) require the development of a strategic plan for any surplus within the operating reserve account above the 10-week operating reserve within 2 years of the establishment of the program;

(IV) include an operating reserve adjustment such that, if the Secretary has an operating reserve balance in excess of 10 weeks of such operating reserves, the Secretary shall decrease such fee revenue and fees to provide for not more than 10 weeks of such operating reserves;

(V) if an adjustment is made as described in subclause (IV), provide the rationale for the amount of the decrease in fee revenue and fees shall be contained in the Federal Register; and

(VI) provide that the fees assessed and collected for the full-time equivalent employees at the Center for Devices and Radiological Health, with respect to which the majority of time

reporting data indicates are dedicated to the process for the review of in vitro clinical test submissions and applications under paragraph (5), are not supported by the funds authorized to be collected and assessed under section 738 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j).

(G) PUBLICATION OF RECOMMENDATIONS.—The Secretary shall publish on the website of the Food and Drug Administration the revised recommendations under subparagraph (F), a summary of the recommendations, views, and comments received under subparagraphs (B), (C), and (E), and any changes made to the recommendations originally proposed by the Secretary in response to such recommendations, views, and comments.

(H) MINUTES OF NEGOTIATION MEETINGS.—

(i) PUBLIC AVAILABILITY.—The Secretary shall make publicly available, on the website of the Food and Drug Administration, minutes of all negotiation meetings conducted under this subsection between

the Food and Drug Administration and the regulated industry not later than 30 days after such meeting.

(ii) CONTENT.—The minutes described under clause (i) shall summarize any substantive proposal made by any party to the negotiations, any significant controversies or differences of opinion during the negotiations, and the resolution of any such controversy or difference of opinion.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—Effective on October 1, 2028, provided that the Secretary transmits the recommendations under paragraph (1)(F), the Secretary is authorized to collect user fees relating to the review of in vitro clinical test submissions and applications submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this Act, and any other activities or goals included in recommendations transmitted to Congress pursuant to this subsection. Fees under such program shall be assessed and collected only if the requirements under paragraph (4) are met.

(3) AUDIT.—

(A) IN GENERAL.—Beginning 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, the Secretary shall, on a biennial basis, perform an audit of the costs of reviewing such applications and any other activities under such subchapter J included in recommendations transmitted to Congress pursuant to this subsection. Such an audit shall compare the costs of reviewing such applications and other activities under such subchapter J to the amount of the user fee applicable to such applications and make any necessary adjustments as described in subparagraph (B).

(B) ALTERATION OF USER FEE.—The following adjustments shall apply with respect to audits performed under subparagraph (A):

(i) If the audit performed 2 years after first receiving a user fee applicable to submission of an in vitro clinical test application described under subparagraph (A) indicates that the user fees collected for purposes of such subchapter J exceed 33

percent of the costs of reviewing such applications and carrying out activities included in recommendations transmitted to Congress pursuant to this subsection, 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.

(ii) If the audit performed 6 years after first receiving a user fee applicable to submission of an in vitro clinical test application described under subparagraph (A) indicates that the user fees collected for purposes of such subchapter J exceed 40 percent of the costs of reviewing such applications, and carrying out activities included in recommendations transmitted to Congress pursuant to this subsection, 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.

(iii) If the audit performed 12 years after first receiving a user fee applicable to submission of an in vitro clinical test appli-

cation described under subparagraph (A), and any audit performed after such date, indicates that the user fees collected for purposes of such subchapter J exceed 49 percent of the costs of reviewing such applications, and carrying out activities included in recommendations transmitted to Congress pursuant to this subsection, 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 subparagraph (A) 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 States Code, to ensure the validity of any potential variability.

(D) IMPLEMENTATION REQUIREMENTS.—In the event that the Secretary fails to promulgate the regulations described in sections 587B(a)(4), 587D(j), or 587S(b)(1) of the Federal Food, Drug, and Cosmetic Act, as added

by section 3, by the applicable deadline for each such regulations as described in section 5(a)(2)(A)(ii), the Secretary shall provide that the user fees applicable to applications submitted under subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by section 3, do not exceed 30 percent of the costs of reviewing such applications.

(4) CONDITIONS.—The user fee program described in this subsection shall take effect only if the Food and Drug Administration issues a regulation related to the review requirements for in vitro diagnostic tests that would be subject to premarket review under section 587B of the Federal Food, Drug, and Cosmetic Act, as added by section 3, the review requirements for test categories eligible for technology certification under section 587D of such Act, as added by section 3, and the parameters for the test categories that would be exempt from any review under subchapter J of chapter V of such Act.

(5) USER FEE PROGRAM DEFINITIONS AND RESOURCE REQUIREMENTS.—

(A) IN GENERAL.—The term ''process for the review of in vitro clinical test submissions and applications'' means the following activities

of the Secretary with respect to the review of in vitro clinical test premarket and technology certification applications including supplements for such applications:

(i) The activities necessary for the review of premarket applications, premarket reports, technology certification applications, and supplements to such applications.

(ii) Actions related to submissions in connection with in vitro clinical test development, the issuance of action letters that allow the marketing of in vitro clinical tests or which set forth in detail the specific deficiencies in such applications, reports, supplements, or submissions and, where appropriate, the actions necessary to support the development of in vitro clinical tests.

(iii) The inspection of manufacturing establishments and other facilities undertaken as part of the Secretary's review of pending premarket applications, technology certifications, and supplements.

(iv) Monitoring of research conducted in connection with the review of such applications, supplements, and submissions.

(v) Review of in vitro clinical test applications subject to section 351 of the Public Health Service Act (42 U.S.C. 262) and activities conducted in anticipation of the submission of such applications for investigational use under section 587S of the Federal Food, Drug, and Cosmetic Act (as added by section 3).

(vi) The development of guidance, policy documents, or regulations to improve the process for the review of premarket applications, technology certification applications, and supplements.

(vii) The development of voluntary test methods, consensus standards, or mandatory performance standards in connection with the review of such applications, supplements, or submissions and related activities.

(viii) The provision of technical assistance to in vitro clinical test developers in connection with the submission of such ap-

plications, reports, supplements, or submissions.

(ix) Any activity undertaken in connection with the initial classification or reclassification of an in vitro clinical test in connection with any requirement for approval or eligibility for an exemption from premarket review of an in vitro clinical test.

(x) Any activity undertaken in connection with making a pathway determination of an in vitro clinical test, including the identification, establishment, and implementation of mitigation measures.

(xi) Evaluation of postmarket studies required as a condition of an approval of a premarket application of an in vitro clinical test and ensuring such studies are conducted as required.

(xii) Any activity undertaken in connection with ensuring in vitro clinical tests offered under an exemption from premarket review pursuant to section 587C or 587G meet the criteria for such exemption and the applicable standard.

(xiii) Compiling, developing, and reviewing information on in vitro clinical tests necessary to identify issues with the ability of in vitro clinical tests to meet the applicable standard, as applicable.

(B) RESOURCE REQUIREMENTS.—Fees collected and assessed under this section shall be used for the process for the review of in vitro clinical test applications, as described in subparagraph (A), and shall—

(i) be subject to the limitation under section 738(g)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379j(g)(3)), in the same manner that fees collected and assessed under section 737(9)(C) of such Act (21 U.S.C. 379i(9)(C)) are subject to such limitation;

(ii) include travel expenses for officers and employees of the Food and Drug Administration only if the Secretary determines that such travel is directly related to an activity described in subparagraph (A); and

(iii) not be allocated to purposes described under section 722(a) of the Con-

solidated Appropriations Act, 2018 (Public Law 115–141).

(c) REPORTS.—

(1) PERFORMANCE REPORT.—

(A) IN GENERAL.—

(i) GENERAL REQUIREMENTS.—Beginning with fiscal year 2028, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives annual reports concerning the progress of the Food and Drug Administration in achieving the goals identified in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(ii) ADDITIONAL INFORMATION.—Beginning with fiscal year 2028, the annual report under this subparagraph shall include the progress of the Food and Drug

Administration in achieving the goals, and future plans for meeting the goals, including—

(I) the number of premarket applications filed under section 587B of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year;

(II) the number of technology certification applications submitted under section 587D of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year for each review division;

(III) the number of breakthrough designations under section 587I of the Federal Food, Drug, and Cosmetic Act during the applicable fiscal year; and

(IV) the number of information requests requested by the Secretary pursuant to section 587G(d) of such Act.

(iii) REAL-TIME REPORTING.—

(I) IN GENERAL.—Not later than 30 calendar days after the end of the second quarter of fiscal year 2028, and not later than 30 calendar days after the end of each quarter of each fiscal year thereafter, the Secretary shall post the data described in subclause (II) on the website of the Food and Drug Administration for such quarter and on a cumulative basis for such fiscal year, and may remove duplicative data from the annual report under this subparagraph.

(II) DATA.—The Secretary shall post the following data in accordance with subclause (I):

(aa) The number and titles of draft and final regulations on topics related to the process for the review of in vitro clinical test submissions and applications, and whether such regulations were required by statute or pursuant to the recommendations transmitted to Congress by the

Secretary pursuant to subsection (b)(1)(F).

(bb) The number and titles of draft and final guidance on topics related to the process for the review of in vitro clinical test submissions and applications, and whether such guidances were issued as required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F).

(cc) The number and titles of public meetings held on topics related to the process for the review of in vitro clinical tests, and if such meetings were required by statute or pursuant to the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F).

(iv) RATIONALE FOR IVCT USER FEE PROGRAM CHANGES.—Beginning with fiscal year 2028, the Secretary shall include

in the annual performance report under paragraph (1)—

(I) data, analysis, and discussion of the changes in the number of individuals hired as agreed upon in the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F) and the number of remaining vacancies, the number of full-time equivalents funded by fees collected pursuant to this section, and the number of full-time equivalents funded by budget authority at the Food and Drug Administration by each division within the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner;

(II) data, analysis, and discussion of the changes in the fee revenue amounts and costs for the process for the review of in vitro clinical test sub-

missions and applications, including identifying—

(aa) drivers of such changes; and

(bb) changes in the average total cost per full-time equivalent in the in vitro clinical test review program;

(III) for each of the Center for Devices and Radiological Health, the Center for Biologics Evaluation and Research, the Office of Regulatory Affairs, and the Office of the Commissioner, the number of employees for whom time reporting is required and the number of employees for whom time reporting is not required; and

(IV) data, analysis, and discussion of the changes in the average full-time equivalent hours required to complete review of each type of in vitro clinical test application.

(v) ANALYSIS.—For each fiscal year, the Secretary shall include in the report

under clause (i) an analysis of the following:

(I) The difference between the aggregate number of premarket applications filed under section 587B or section 587D of the Federal Food, Drug, and Cosmetic Act and the aggregate number of major deficiency letters, not approvable letters, and denials for such applications issued by the agency, accounting for—

(aa) the number of applications filed under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act during one fiscal year for which a decision is not scheduled to be made until the following fiscal year; and

(bb) the aggregate number of applications under each of sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act for each fiscal year that did not meet the goals as

identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F).

(II) Relevant data to determine whether the Center for Devices and Radiological Health has met performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F).

(III) The most common causes and trends for external or other circumstances affecting the ability of the Food and Drug Administration to meet review time and performance enhancement goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F).

(B) PUBLICATION.—With regard to information to be reported by the Food and Drug Administration to industry on a quarterly and annual basis pursuant to recommendations transmitted to Congress by the Secretary pur-

suant to subsection (b)(1)(F), the Secretary shall make such information publicly available on the website of the Food and Drug Administration not later than 60 days after the end of each quarter or 120 days after the end of each fiscal year, respectively, to which such information applies.

(C) UPDATES.—The Secretary shall include in each report under subparagraph (A) information on all previous cohorts for which the Secretary has not given a complete response on all in vitro clinical test premarket applications and technology certification orders and supplements, premarket, and technology certification notifications in the cohort.

(2) CORRECTIVE ACTION REPORT.—Beginning with fiscal year 2029, for each fiscal year for which fees are collected under this section, the Secretary shall prepare and submit a corrective action report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives. The report shall include the following information, as applicable:

(A) GOALS MET.—For each fiscal year, if the Secretary determines, based on the analysis under paragraph (1)(A)(v), that each of the goals identified by the recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F) for the applicable fiscal year have been met, the corrective action report shall include recommendations on ways in which the Secretary can improve and streamline the in vitro clinical test premarket application and technology certification review process.

(B) GOALS MISSED.—For each of the goals identified by the letters described in recommendations transmitted to Congress by the Secretary pursuant to subsection (b)(1)(F) for the applicable fiscal year that the Secretary determines to not have been met, the corrective action report shall include—

(i) a justification for such determination;

(ii) a description of the types of circumstances, in the aggregate, under which applications or reports submitted under sections 587B and 587D of the Federal Food, Drug, and Cosmetic Act missed the

review goal times but were approved during the first cycle review, as applicable;

(iii) a summary and any trends with regard to the circumstances for which a review goal was missed; and

(iv) the performance enhancement goals that were not achieved during the previous fiscal year and a description of efforts the Food and Drug Administration has put in place for the fiscal year in which the report is submitted to improve the ability of such agency to meet each such goal for the such fiscal year.

(3) FISCAL REPORT.—

(A) IN GENERAL.—For fiscal years 2029 and annually thereafter, not later than 120 days after the end of each fiscal year during which fees are collected under this section, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administra-

tion, of the fees collected during such fiscal year for which the report is made.

(B) CONTENTS.—Such report shall include expenditures delineated by budget authority and user fee dollars related to administrative expenses and information technology infrastructure contracts and expenditures.

(C) OPERATING RESERVE.—Such report shall provide the amount of operating reserves of carryover user fees available each year, and any planned allocations or obligations of such balance of operating reserves for the program.

(4) PUBLIC AVAILABILITY.—The Secretary shall make the reports required under paragraphs (1) through (3) available to the public on the website of the Food and Drug Administration.

(5) ENHANCED COMMUNICATION.—

(A) COMMUNICATIONS WITH CONGRESS.—Each fiscal year, as applicable and requested, representatives from the Centers with expertise in the review of in vitro clinical tests shall meet with representatives from the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives to report

on the contents described in the reports under this section.

(B) PARTICIPATION IN CONGRESSIONAL HEARING.—Each fiscal year, as applicable and requested, representatives from the Food and Drug Administration shall participate in a public hearing before the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to report on the contents described in the reports under this section. Such hearing shall occur not later than 120 days after the end of each fiscal year for which fees are collected under this section.

SEC. 10. AUTHORIZATION OF APPROPRIATIONS.

For purposes of funding implementation of this Act (including the amendments made by this Act), including undertaking activities for the development of regulations and guidances, hiring of necessary staff, and the development of technology systems to implement this Act (including the amendments made by this Act) in a timely, effective, and efficient manner, there is authorized to be appropriated $480,000,000, to remain available through the end of fiscal year 2028.

SEC. 11. GUIDANCE ON DIAGNOSTIC INNOVATION.

Not later than January 1, 2025, the Secretary shall issue guidance to assist developers of in vitro clinical tests intended to identify or diagnose rare diseases and in vitro clinical tests intended to address an unmet medical need. Such guidance shall include considerations for addressing barriers to developing sufficient data to demonstrate clinical validity for such tests, such as challenges associated with data collection and obstacles to the timely generation of evidence.

SEC. 12. GAO REPORT ON UNIQUE CONSIDERATIONS.

Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report—

(1) evaluating the unique considerations for hospital-based laboratories, laboratories serving academic medical centers, and other health care practitioners, as appropriate, in implementing this Act, including the amendments made by this Act; and

(2) including recommendations based on the findings of the report.

SEC. 13. ASSESSMENTS.

Section 1834A(g) of the Social Security Act (42 U.S.C. 1395m–1(g)) is amended by adding at the end the following new paragraph:

''(3) DETERMINATIONS WITH RESPECT TO IN VITRO CLINICAL TESTS.—On or after the date that is 45 days after the date of enactment of the VALID Act of 2023, for purposes of determining whether an in vitro clinical test (as defined in section 201(ss) of the Federal Food, Drug, and Cosmetic Act) is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)), any assessment of the analytical validity or clinical validity of such test shall apply the definitions given such terms in subchapter J of chapter V of the Federal Food, Drug, and Cosmetic Act.''.

SEC. 14. SEVERABILITY.

If any provision of this Act is declared unconstitutional, or the applicability of this Act to any person or circumstance is held invalid, the constitutionality of the remainder of this Act and the applicability thereof to other persons and circumstances shall not be affected.