~~Title: To amend the Federal Food, Drug, and Cosmetic Act with respect to certain reauthorizations.~~

TITLE IX—DRUG APPROVAL AND PATIENT ACCESS

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

~~SECTION 1. SHORT TITLE.~~

~~[This Act may be cited as the "_____ Act of ____".]~~

~~SEC. 2~~ **SEC. 901**. ENHANCEMENT OF ACCELERATED PATIENT ACCESS TO NEW MEDICAL TREATMENTS.

(a) Findings; Sense of Congress.—

(1) FINDINGS.—Congress finds as follows:

(A) The Food and Drug Administration (referred to in this section as the "FDA") serves a critical role in helping to assure that new medicines are safe and effective. Regulatory innovation is 1 element of the Nation's strategy to address serious and life-threatening diseases or conditions by promoting investment in and development of innovative treatments for unmet medical needs.

(B) During the 2 decades following the establishment of the accelerated approval mechanism, advances in medical sciences, including genomics, molecular biology, and bioinformatics, have provided an unprecedented understanding of the underlying biological mechanism and pathogenesis of disease. A new generation of modern, targeted medicines is under development to treat serious and life-threatening diseases, some applying drug development strategies based on biomarkers or pharmacogenomics, predictive toxicology, clinical trial enrichment techniques, and novel clinical trial designs, such as adaptive clinical trials.

(C) As a result of these remarkable scientific and medical advances, the FDA should be encouraged to implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases or conditions, including those for rare diseases or conditions, using a broad range of surrogate or clinical endpoints and modern scientific tools earlier in the drug development cycle when appropriate. This may result in fewer, smaller, or shorter clinical trials for the intended patient population or targeted subpopulation without compromising or altering the high standards of the FDA for the approval of drugs.

(D) Patients benefit from expedited access to safe and effective innovative therapies to treat unmet medical needs for serious or life-threatening diseases or conditions.

(E) For these reasons, the statutory authority in effect on the day before the date of enactment of this Act governing expedited approval of drugs for serious or life-threatening diseases or conditions should be amended in order to enhance the authority

of the FDA to consider appropriate scientific data, methods, and tools, and to expedite development and access to novel treatments for patients with a broad range of serious or life-threatening diseases or conditions.

(2) SENSE OF CONGRESS.—It is the sense of Congress that the Food and Drug Administration should apply the accelerated approval and fast track provisions set forth in section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356), as amended by this section, to help expedite the development and availability to patients of treatments for serious or life-threatening diseases or conditions while maintaining safety and effectiveness standards for such treatments.

(b) Expedited Approval of Drugs for Serious or Life-Threatening Diseases or Conditions.—Section 506 ~~of the Federal Food, Drug, and Cosmetic Act~~(21 U.S.C. 356) is amended to read as follows:

"SEC. 506. EXPEDITED APPROVAL OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES OR CONDITIONS.

"(a) Designation of Drug as Fast Track Product.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. (In this section, such a drug is referred to as a 'fast track product'.)

"(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

"(b) Accelerated Approval of a Drug for a Serious or Life-Threatening Disease or Condition, Including a Fast Track Product.—

"(1) IN GENERAL.—

"(A) ACCELERATED APPROVAL.—The Secretary may approve an application for approval of a product for a serious or life-threatening disease or condition, including a fast track product, under section 505(c) or section 351(a) of the Public Health Service Act upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to

predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity ~~or~~**,** rarity**, or prevalence** of the condition and the availability **or lack** of alternative treatments. The approval described in the preceding sentence is referred to in this section as 'accelerated approval'.

"(B) EVIDENCE.—The evidence to support that an endpoint is reasonably likely to predict clinical benefit under subparagraph (A) may include epidemiological, pathophysiological, therapeutic**, pharmacologic,** or other evidence developed using biomarkers, for example, or other scientific methods or tools.

"(2) LIMITATION.—Approval of a product under this subsection may be subject to 1 or both of the following requirements:

"(A) That the sponsor conduct appropriate post-approval studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit.

"(B) That the sponsor submit copies of all promotional materials related to the product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

"(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a product approved under accelerated approval using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

"(A) the sponsor fails to conduct any required post-approval study of the drug with due diligence;

"(B) a study required to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical benefit of the product fails to verify and describe such effect or benefit;

"(C) other evidence demonstrates that the product is not safe or effective under the conditions of use; or

"(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

"(c) Review of Incomplete Applications for Approval of a Fast Track Product.—

"(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

"(A) provides a schedule for submission of information necessary to make the application complete; and

"(B) pays any fee that may be required under section 736.

"(2) EXCEPTION.—Any time period for review of human drug applications that has been

agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

"(d) Awareness Efforts.—The Secretary shall—

"(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to accelerated approval and fast track products; and

"(2) establish a program to encourage the development of surrogate and clinical endpoints, including biomarkers, and other scientific methods and tools that can assist the Secretary in determining whether the evidence submitted in an application is reasonably likely to predict clinical benefit for serious or life-threatening conditions for which significant unmet medical needs exist.

"(e) Construction.—

"(1) PURPOSE.—The amendments made by the ~~[insert short title]~~ **Food and Drug Administration Safety and Innovation Act** to this section are intended to encourage the Secretary to utilize innovative and flexible approaches to the assessment of products under accelerated approval for treatments for patients with serious or life-threatening diseases or conditions and unmet medical needs.

"(2) CONSTRUCTION.—Nothing in this section shall be construed to alter the standards of evidence under subsection (c) or (d) of section 505 (including the substantial evidence standard in section 505(d)) of this Act or under section 351(a) of the Public Health Service Act. Such sections and standards of evidence apply to the review and approval of products under this section, including whether a product is safe and effective. Nothing in this section alters the ability of the Secretary to rely on evidence that does not come from adequate and well-controlled investigations for the purpose of determining whether an endpoint is reasonably likely to predict clinical benefit as described in subsection (b)(1)(B).".

(c) Guidance; Amended Regulations.—

(1) DRAFT GUIDANCE.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance to implement the amendments made by this section. In developing such guidance, the Secretary shall specifically consider issues arising under the accelerated approval and fast track processes under section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), for drugs designated for a rare disease or condition under section 526 of such Act (21 U.S.C. 360bb) **and shall also consider any unique issues associated with very rare diseases**.

(2) FINAL GUIDANCE.—Not later than 1 year after the issuance of draft guidance under paragraph (1), and after an opportunity for public comment, the Secretary shall issue final guidance.

(3) CONFORMING CHANGES.—The Secretary shall issue, as necessary, conforming amendments to the applicable regulations under title 21, Code of Federal Regulations,

governing accelerated approval.

(4) NO EFFECT OF INACTION ON REQUESTS.—If the Secretary fails to issue final guidance or amended regulations as required by this subsection, such failure shall not preclude the review of, or action on, a request for designation or an application for approval submitted pursuant to section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b).

(d) Independent Review.—The Secretary may, in conjunction with other planned reviews, contract with an independent entity with expertise in assessing the quality and efficiency of biopharmaceutical development and regulatory review programs to evaluate the Food and Drug Administration's application of the processes described in section 506 of the Federal Food, Drug, and Cosmetic Act, as amended by subsection (b), and the impact of such processes on the development and timely availability of innovative treatments for patients suffering from serious or life-threatening conditions. Any such evaluation shall include consultation with regulated industries, patient advocacy and disease research foundations, and relevant academic medical centers.

SEC. ~~3~~ **902**. BREAKTHROUGH THERAPIES.

(a) In General.—Section 506 ~~of the Federal Food, Drug, and Cosmetic Act~~(21 U.S.C. 356), as amended by section 2, is further amended—

(1) by redesignating subsections (a) through (c) as subsections (b) through (d), respectively;

(2) by redesignating subsection (d) as subsection (f);

(3) by inserting before subsection (b), as so redesignated, the following:

"(a) Designation of a Drug as a Breakthrough Therapy.—

"(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a drug, expedite the development and review of such drug if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. (In this section, such a drug is referred to as a 'breakthrough therapy'.)

"(2) REQUEST FOR DESIGNATION.—The sponsor of a drug may request the Secretary to designate the drug as a breakthrough therapy. A request for the designation may be made concurrently with, or at any time after, the submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

"(3) DESIGNATION.—

"(A) IN GENERAL.—Not later than 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a breakthrough therapy and shall take such actions as are appropriate to expedite the development and review of the application for approval of such drug.

"(B) ACTIONS.—The actions to expedite the development and review of an application under subparagraph (A) may include, as appropriate—

"(i) holding meetings with the sponsor and the review team throughout the development of the drug;

"(ii) providing timely advice to, and interactive communication with, the sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable;

"(iii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;

"(iv) assigning a cross-disciplinary project lead for the Food and Drug Administration review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and

"(v) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients ~~enrolled in the trials and the duration of the trials.";~~ **exposed to a potentially less efficacious treatment.";**

(4) in subsection (f)(1), as so redesignated, by striking "applicable to accelerated approval" and inserting "applicable to breakthrough therapies, accelerated approval, and"; and

(5) by adding at the end the following:

"(g) Report.—Beginning in fiscal year 2013, the Secretary shall annually 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, and make publicly available, with respect to this section for the previous fiscal year—

"(1) the number of drugs for which a sponsor requested designation as a breakthrough therapy;

"(2) the number of products designated as a breakthrough therapy; and

"(3) for each **product designated** ~~breakthrough therapy approved in the fiscal year—~~

~~"(A) the point in the drug development and review process at which such breakthrough designation occurred;~~

~~"(B) the total time from designation~~ as a breakthrough therapy**, a summary of the actions taken under subsection (a)(3).".** ~~to a final decision on the approvability of the drug; and~~

~~"(C) the number of breakthrough therapies approved, including the number approved on the first review out of the total number of such therapies so approved.".~~

(b) Guidance; Amended Regulations.—

(1) IN GENERAL.—

(A) GUIDANCE.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall issue draft guidance on implementing the requirements with respect to breakthrough therapies, as set forth in section 506(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356(a)), as amended by this section. The Secretary shall issue final guidance not later than 1 year after the close of the comment period for the draft guidance.

(B) AMENDED REGULATIONS.—If the Secretary determines that it is necessary to amend the regulations under title 21, Code of Federal Regulations in order to implement the amendments made by this section to section 506(a) of the Federal Food, Drug, and Cosmetic Act, the Secretary shall amend such regulations not later than 2 years after the date of enactment of this Act.

(2) REQUIREMENTS.—Guidance ~~promulgated~~ **issued** under this section shall—

(A) specify the process and criteria by which the Secretary makes a designation under section 506(a)(3) of the Federal Food, Drug, and Cosmetic Act; and

(B) specify the actions the Secretary shall take to expedite the development and review of a breakthrough therapy pursuant to such designation under such section 506(a)(3), including updating good review management practices to reflect breakthrough therapies.

(c) Independent Review.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States, in consultation with appropriate experts, shall assess the manner by which the Food and Drug Administration has applied the processes described in section 506(a) of the Federal Food, Drug, and Cosmetic Act, as amended by this section, and the impact of such processes on the development and timely availability of innovative treatments for patients affected by serious or life-threatening conditions. Such assessment shall be made publicly available upon completion.

(d) Conforming Amendments.—Section 506B(e) ~~of the Federal Food, Drug, and Cosmetic Act~~(21 U.S.C. 356b) is amended by striking "section 506(b)(2)(A)" each place such term appears and inserting "section 506(c)(2)(A)".

[Note: the following three provisions were moved to Title XI]

~~SEC. 4. GUIDANCE DOCUMENT REGARDING PRODUCT PROMOTION USING THE INTERNET.~~

~~Not later than 2 years after the date of enactment this Act, the Secretary of Health and Human Services shall issue a guidance document that describes the policy of the Food and Drug Administration regarding the promotion, using the Internet (including social media), of medical products that are regulated by such Administration.~~

~~SEC. 5. REAUTHORIZATION OF PROVISION RELATING TO EXCLUSIVITY OF CERTAIN DRUGS CONTAINING SINGLE ENANTIOMERS.~~

~~Section 505(u)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(u)(4)) is amended by striking "2012" and inserting "2017".~~

~~SEC. 6. REAUTHORIZATION OF THE CRITICAL PATH PUBLIC-PRIVATE PARTNERSHIPS.~~

~~Section 566(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb5(f)) is amended by striking "2012" and inserting "2017".~~

~~SEC. 7~~ **SEC. 903**. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

Subchapter E of chapter V ~~of the Federal Food, Drug, and Cosmetic Act~~(21 U.S.C. 360bbb et seq.) is amended by adding at the end the following:

"SEC. 568. CONSULTATION WITH EXTERNAL EXPERTS ON RARE DISEASES, TARGETED THERAPIES, AND GENETIC TARGETING OF TREATMENTS.

"(a) In ~~General.—~~ **General.—For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biologic products that are genetically targeted, the following shall apply:**

~~"(1) Opportunities for consultation.—The~~**"(1) CONSULTATION WITH STAKEHOLDERS.—Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the** Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for ~~consultation with external experts~~ **consultations with stakeholders** on the topics described in subsection (c)~~, for the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of drugs and biologic products for rare diseases and drugs and biologic products that are genetically targeted.~~**.**

~~"(2) Consultation.—The Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research shall, when appropriate, seek the opinion~~**"(2)**

CONSULTATION WITH EXTERNAL EXPERTS.—The Secretary shall develop and maintain a list of external experts **who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (c). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts, or other experts as appropriate,** on any topic, including the topics described in subsection (c), ~~by initiating contact with such experts. External experts may also request the opportunity to meet with a review division regarding any topic described in subsection (c).~~ **when such consultation is necessary because the Secretary lacks specific scientific, medical, or technical expertise necessary for the performance of its regulatory responsibilities and the necessary expertise can be provided by the external experts.**

~~"(b) External Experts.—The external experts under subsection (a) may include—~~

~~"(1) representatives of patient, consumer, research, and health professional organizations with expertise relevant to the review of rare disease products;~~

~~"(2) experts on rare diseases, rare subtypes of rare and other diseases, and genetic targeting of treatments, including experts from academia; and~~

~~"(3) experts in innovative clinical trial designs for small target populations.~~**"(b) External Experts.—For purposes of subsection (a)(2), external experts are those who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.**

"(c) Topics for Consultation.—Topics for consultation **pursuant to this section** may include—

"(1) rare diseases;

"(2) the severity of rare diseases;

"(3) the unmet medical need associated with rare diseases;

"(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;

"(5) an assessment of the ~~benefits and risks, including side effects, of current and investigational therapies;~~ **risk-benefit tolerance of patients with rare diseases;**

~~"(6) the~~ **"(6) the general** design of clinical trials for rare disease populations and subpopulations~~, including regulatory and scientific policies affecting the design of such trials~~; and

"(7) demographics and the clinical description of patient populations.

"(d) Classification as Special Government Employees.—The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18, United States Code.

"(e) **Protection of** Proprietary Information.—Nothing in this section shall be construed to ~~create a right for any external expert, as described in subsection (b), to obtain access to proprietary information of a sponsor without the permission of such sponsor.~~ **alter the protections offered by laws, regulations, and policies governing disclosure of confidential**

commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5, United States Code, as such provisions would be applied to consultation with individuals and organizations prior to the date of enactment of this section.

~~"(f) No Right or Obligation.—Nothing~~**"(f) Other Consultation.—Nothing** in this section shall be construed to **limit the Secretary's ability to consult with individuals and organizations as authorized prior to the date of enactment of this section.**

"(g) No Right or Obligation.—Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular ~~expert.".~~ **expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before the date of enactment of this section.".**

~~[SEC. 8~~ **SEC. 904**. ACCESSIBILITY OF INFORMATION ~~IN~~ **ON** PRESCRIPTION DRUG ~~LABELING~~ **CONTAINER LABELS** BY VISUALLY-IMPAIRED AND BLIND CONSUMERS.

~~To be supplied.]~~**(a) Establishment of Working Group.—**

(1) IN GENERAL.—The Architectural and Transportation Barriers Compliance Board (referred to in this section as the "Access Board") shall convene a stakeholder working group (referred to in this section as the "working group") to develop best practices on access to information on prescription drug container labels for individuals who are blind or visually impaired.

(2) MEMBERS.—The working group shall be comprised of representatives of national organizations representing blind and visually-impaired individuals, national organizations representing the elderly, and industry groups representing stakeholders, including retail, mail order, and independent community pharmacies, who would be impacted by such best practices. Representation within the working group shall be divided equally between consumer and industry advocates.

(3) BEST PRACTICES.—

(A) IN GENERAL.—The working group shall develop, not later than 1 year after the date of the enactment of this Act, best practices for pharmacies to ensure that blind and visually-impaired individuals have safe, consistent, reliable, and independent access to the information on prescription drug container labels.

(B) PUBLIC AVAILABILITY.—The best practices developed under subparagraph (A) may be made publicly available, including through the Internet Web sites of the working group participant organizations, and through other means, in a manner that provides access to interested individuals, including individuals with disabilities.

(C) LIMITATIONS.—The best practices developed under subparagraph (A) shall not be construed as accessibility guidelines or standards of the Access Board, and shall not confer any rights or impose any obligations on working group participants or other persons. Nothing in this section shall be construed to limit or condition any right, obligation, or remedy available under the Americans with Disabilities Act of 1990 (42 U.S.C. 12101 et seq.) or any other Federal or State law requiring effective communication, barrier removal, or nondiscrimination on the basis of disability.

(4) CONSIDERATIONS.—In developing and issuing the best practices under paragraph (3)(A), the working group shall consider—

(A) the use of—

(i) Braille;

(ii) auditory means, such as—

(I) "talking bottles" that provide audible container label information;

(II) digital voice recorders attached to the prescription drug container; and

(III) radio frequency identification tags;

(iii) enhanced visual means, such as—

(I) large font labels or large font "duplicate" labels that are affixed or matched to a prescription drug container;

(II) high-contrast printing; and

(III) sans-serf font; and

(iv) other relevant alternatives as determined by the working group;

(B) whether there are technical, financial, manpower, or other factors unique to pharmacies with 20 or fewer retail locations which may pose significant challenges to the adoption of the best practices; and

(C) such other factors as the working group determines to be appropriate.

(5) INFORMATION CAMPAIGN.—Upon completion of development of the best practices under subsection (a)(3), the National Council on Disability, in consultation with the working group, shall conduct an informational and educational campaign designed to inform individuals with disabilities, pharmacists, and the public about such best practices.

(6) FACA WAIVER.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the working group.

(b) GAO Study.—

(1) IN GENERAL.—Beginning 18 months after the completion of the development of best practices under subsection (a)(3)(A), the Comptroller General of the United States shall conduct a review of the extent to which pharmacies are utilizing such best practices, and the extent to which barriers to accessible information on prescription

drug container labels for blind and visually-impaired individuals continue.

(2) REPORT.—Not later than September 30, 2016, the Comptroller General of the United States shall submit to Congress a report on the review conducted under paragraph (1). Such report shall include recommendations about how best to reduce the barriers experienced by blind and visually-impaired individuals to independently accessing information on prescription drug container labels.

(c) Definitions.—In this section—

(1) the term "pharmacy" includes a pharmacy that receives prescriptions and dispenses prescription drugs through an Internet Web site or by mail;

(2) the term "prescription drug" means a drug subject to section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)(1)); and

(3) the term "prescription drug container label" means the label with the directions for use that is affixed to the prescription drug container by the pharmacist and dispensed to the consumer.