Suspend the Rules and Pass the Bill, H.R. 1262, With an Amendment

(The amendment strikes all after the enacting clause and inserts a new text)

119TH CONGRESS
1ST SESSION

H. R. 1262

To amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 12, 2025

Mr. MCCAUL (for himself, Mr. BILIRAKIS, Mrs. DINGELL, Ms. SCHRIER, Mrs. HARSHBARGER, Ms. MATSUI, Mr. CRENSHAW, Ms. CASTOR of Florida, Mr. KELLY of Pennsylvania, Mrs. TRAHAN, and Mr. WEBER of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to molecularly targeted pediatric cancer investigations, and for other purposes.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Mikaela Naylon Give Kids a Chance Act''.

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

Sec. 1. Short title; table of contents.
Sec. 2. Research into pediatric uses of drugs; additional authorities of Food and Drug Administration regarding molecularly targeted cancer drugs.
Sec. 3. Ensuring completion of pediatric study requirements.
Sec. 4. FDA report on PREA enforcement.
Sec. 5. Extension of authority to issue priority review vouchers to encourage treatments for rare pediatric diseases.
Sec. 6. Limitations on exclusive approval or licensure of orphan drugs.
Sec. 7. Program for pediatric studies of drugs.
Sec. 8. Organ Procurement and Transplantation Network.
Sec. 9. Establishment of Abraham Accords Office within Food and Drug Administration.
Sec. 10. Increasing transparency in generic drug applications.
Sec. 11. Medicare Improvement Fund.

SEC. 2. RESEARCH INTO PEDIATRIC USES OF DRUGS; ADDITIONAL AUTHORITIES OF FOOD AND DRUG ADMINISTRATION REGARDING MOLECULARLY TARGETED CANCER DRUGS.

(a) IN GENERAL.—

(1) ADDITIONAL ACTIVE INGREDIENT FOR APPLICATION DRUG; LIMITATION REGARDING NOVEL-COMBINATION APPLICATION DRUG.—Section 505B(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(3)) is amended—

(A) by redesignating subparagraphs (B) and (C) as subparagraphs (C) and (D), respectively; and

(B) by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—For purposes of paragraph (1)(B), the investigation described in this paragraph is a molecularly targeted pediatric cancer investigation of—

''(i) the drug or biological product for which the application referred to in such paragraph is submitted; or

''(ii) such drug or biological product used in combination with—

''(I) an active ingredient of a drug or biological product—

''(aa) for which an approved application under section 505(j) under this Act or under section 351(k) of the Public Health Service Act is in effect; and

''(bb) that is determined by the Secretary, after consultation with the applicant, to be part of the standard of care for treating a pediatric cancer; or

''(II) an active ingredient of a drug or biological product—

''(aa) for which an approved application under section 505(b)

of this Act or section 351(a) of the Public Health Service Act to treat an adult cancer is in effect and is held by the same person submitting the application under paragraph (1)(B); and

''(bb) that is directed at a molecular target that the Secretary determines to be substantially relevant to the growth or progression of a pediatric cancer.

''(B) ADDITIONAL REQUIREMENTS.—

''(i) DESIGN OF INVESTIGATION.—A molecularly targeted pediatric cancer investigation referred to in subparagraph (A) shall be designed to yield clinically meaningful pediatric study data that is gathered using appropriate formulations for each age group for which the study is required, regarding dosing, safety, and preliminary efficacy to inform potential pediatric labeling.

''(ii) LIMITATION.—An investigation described in subparagraph (A)(ii) may be required only if the drug or biological

product for which the application referred to in paragraph (1)(B) contains either—

"(I) a single new active ingredient; or

"(II) more than one active ingredient, if an application for the combination of active ingredients has not previously been approved but each active ingredient is in a drug product that has been previously approved to treat an adult cancer.

"(iii) RESULTS OF ALREADY-COMPLETED PRECLINICAL STUDIES OF APPLICATION DRUG.—With respect to an investigation required pursuant to paragraph (1)(B), the Secretary may require the results of any completed preclinical studies relevant to the initial pediatric study plan be submitted to the Secretary at the same time that the initial pediatric study plan required under subsection (e)(1) is submitted.

"(iv) RULE OF CONSTRUCTION REGARDING INACTIVE INGREDIENTS.—With respect to a combination of active ingredi-

ents referred to in subparagraph (A)(ii), such subparagraph shall not be construed as addressing the use of inactive ingredients with such combination.''.

(2) DETERMINATION OF APPLICABLE REQUIREMENTS.—Section 505B(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(e)(1)) is amended by adding at the end the following: ''The Secretary shall determine whether subparagraph (A) or (B) of subsection (a)(1) applies with respect to an application before the date on which the applicant is required to submit the initial pediatric study plan under paragraph (2)(A).''.

(3) CLARIFYING APPLICABILITY.—Section 505B(a)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)(1)) is amended by adding at the end the following:

''(C) RULE OF CONSTRUCTION.—No application that is subject to the requirements of subparagraph (B) shall be subject to the requirements of subparagraph (A), and no application (or supplement to an application) that is subject to the requirements of subparagraph (A) shall be subject to the requirements of subparagraph (B).''.

(4) CONFORMING AMENDMENTS.—Section 505B(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(a)) is amended—

(A) in paragraph (3)(C), as redesignated by paragraph (1)(A) of this subsection, by striking ''investigations described in this paragraph'' and inserting ''investigations referred to in subparagraph (A)''; and

(B) in paragraph (3)(D), as redesignated by paragraph (1)(A) of this subsection, by striking ''the assessments under paragraph (2)(B)'' and inserting ''the assessments required under paragraph (1)(A)''.

(b) GUIDANCE.—The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall—

(1) not later than 12 months after the date of enactment of this Act, issue draft guidance on the implementation of the amendments made by subsection (a); and

(2) not later than 12 months after closing the comment period on such draft guidance, finalize such guidance.

(c) APPLICABILITY.—The amendments made by this section apply with respect to any application under section

505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and any application under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), that is submitted on or after the date that is 3 years after the date of enactment of this Act.

(d) REPORTS TO CONGRESS.—

(1) SECRETARY OF HEALTH AND HUMAN SERVICES.—Not later than 6 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the Secretary's efforts, in coordination with industry, to ensure implementation of the amendments made by subsection (a).

(2) GAO STUDY AND REPORT.—

(A) STUDY.—Not later than 8 years after the date of enactment of this Act, the Comptroller General of the United States shall conduct a study of the effectiveness of requiring assessments and investigations described in section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c), as amended by subsection (a), in the development of drugs and

biological products for pediatric cancer indications, including consideration of any benefits to, or burdens on, pediatric cancer drug development.

(B) FINDINGS.—Not later than 10 years after the date of enactment of this Act, the Comptroller General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under subparagraph (A).

SEC. 3. ENSURING COMPLETION OF PEDIATRIC STUDY REQUIREMENTS.

(a) EQUAL ACCOUNTABILITY FOR PEDIATRIC STUDY REQUIREMENTS.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)) is amended—

(1) in paragraph (1), by striking ''Beginning 270'' and inserting ''NONCOMPLIANCE LETTER.—Beginning 270'';

(2) in paragraph (2)—

(A) by striking ''The drug or'' and inserting ''EFFECT OF NONCOMPLIANCE.—The drug or''; and

(B) by striking ''(except that the drug or biological product shall not be subject to action under section 303)'' and inserting ''(except that the drug or biological product shall be subject to action under section 303 only if such person demonstrated a lack of due diligence in satisfying the applicable requirement)''; and

(3) by adding at the end the following:

''(3) LIMITATION.—The Secretary shall not issue enforcement actions under section 303 for failures under this subsection in the case of a drug or biological product that is no longer marketed.''.

(b) DUE DILIGENCE.—Section 505B(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c(d)), as amended by subsection (a), is further amended by adding at the end the following:

''(4) DUE DILIGENCE.—Before the Secretary may conclude that a person failed to submit or otherwise meet a requirement as described in the matter preceding paragraph (1), the Secretary shall—

''(A) issue a noncompliance letter pursuant to paragraph (1);

''(B) provide such person with a 45-day period beginning on the date of receipt of such

noncompliance letter to respond in writing as set forth in such paragraph; and

''(C) after reviewing such written response, determine whether the person demonstrated a lack of due diligence in satisfying such requirement.''.

(c) CONFORMING AMENDMENTS.—Section 303(f)(4)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(4)(A)) is amended by striking ''or 505–1'' and inserting ''505–1, or 505B''.

(d) TRANSITION RULE.—The Secretary of Health and Human Services may take enforcement action under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333) only for failures described in section 505B(d) of such Act (21 U.S.C. 355c(d)) that occur on or after the date that is 180 days after the date of enactment of this Act.

SEC. 4. FDA REPORT ON PREA ENFORCEMENT.

Section 508(b) of the Food and Drug Administration Safety and Innovation Act (21 U.S.C. 355c–1(b)) is amended—

(1) in paragraph (11), by striking the semicolon at the end and inserting '', including an evaluation of compliance with deadlines provided for in deferrals and deferral extensions;'';

(2) in paragraph (15), by striking ''and'' at the end;

(3) in paragraph (16), by striking the period at the end and inserting ''; and''; and

(4) by adding at the end the following:

''(17) a listing of penalties, settlements, or payments under section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) for failure to comply with requirements under such section 505B, including, for each penalty, settlement, or payment, the name of the drug, the sponsor thereof, and the amount of the penalty, settlement, or payment imposed.''.

SEC. 5. EXTENSION OF AUTHORITY TO ISSUE PRIORITY REVIEW VOUCHERS TO ENCOURAGE TREATMENTS FOR RARE PEDIATRIC DISEASES.

(a) EXTENSION.—Paragraph (5) of section 529(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(b)) is amended by striking ''December 20, 2024, unless'' and all that follows through the period at the end and inserting ''September 30, 2029.''.

(b) USER FEE PAYMENT.—Section 529(c)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff(c)(4)) is amended by striking subparagraph (A) and inserting the following:

''(A) IN GENERAL.—The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 505(b)(1) or section 351(a) of the Public Health Service Act for which the priority review voucher is used. All other user fees associated with the human drug application shall be due as required by the Secretary or under applicable law.''.

(c) GAO REPORT ON EFFECTIVENESS OF RARE PEDIATRIC DISEASE PRIORITY VOUCHER AWARDS IN INCENTIVIZING RARE PEDIATRIC DISEASE DRUG DEVELOPMENT.—

(1) GAO STUDY.—

(A) STUDY.—The Comptroller General of the United States shall conduct a study of the effectiveness of awarding rare pediatric disease priority vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff), as amended by subsection (a), in the development of human drug products that treat or prevent rare pediatric diseases (as defined in such section 529).

(B) CONTENTS OF STUDY.—In conducting the study under subparagraph (A), the Comptroller General shall examine the following:

(i) The indications for each drug or biological product that—

(I) is the subject of a rare pediatric disease product application (as defined in section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff)) for which a priority review voucher was awarded; and

(II) was approved under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

(ii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval or licensure of such a drug or biological product.

(iii) The size of the company to which a priority review voucher was awarded under section 529 of the Federal Food,

Drug, and Cosmetic Act (21 U.S.C. 360ff) for such a drug or biological product.

(iv) The value of such priority review voucher if transferred.

(v) Identification of each drug for which a priority review voucher awarded under such section 529 was used.

(vi) The size of the company using each priority review voucher awarded under such section 529.

(vii) The length of the period of time between the date on which a priority review voucher was awarded under such section 529 and the date on which it was used.

(viii) Whether, and to what extent, an unmet need related to the treatment or prevention of a rare pediatric disease was met through the approval under section 505 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 355) or licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) of a drug for which a priority review voucher was used.

(ix) Whether, and to what extent, companies were motivated by the availability of priority review vouchers under section 529 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360ff) to attempt to develop a drug for a rare pediatric disease.

(x) Whether, and to what extent, pediatric review vouchers awarded under such section were successful in stimulating development and expedited patient access to drug products for treatment or prevention of a rare pediatric disease that wouldn't otherwise take place without the incentive provided by such vouchers.

(xi) The impact of such priority review vouchers on the workload, review process, and public health prioritization efforts of the Food and Drug Administration.

(xii) Any other incentives in Federal law that exist for companies developing drugs or biological products described in clause (i).

(2) REPORT ON FINDINGS.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing the findings of the study conducted under paragraph (1).

SEC. 6. LIMITATIONS ON EXCLUSIVE APPROVAL OR LICENSURE OF ORPHAN DRUGS.

(a) IN GENERAL.—Section 527 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc) is amended—

(1) in subsection (a), in the matter following paragraph (2), by striking ''same disease or condition'' and inserting ''same approved use or indication within such rare disease or condition'';

(2) in subsection (b)—

(A) in the matter preceding paragraph (1), by striking ''same rare disease or condition'' and inserting ''same approved use or indication for which such 7-year period applies to such already approved or licensed drug''; and

(B) in paragraph (1), by inserting '', relating to the approved use or indication,'' after ''the needs'';

(3) in subsection (c)(1), by striking ''same rare disease or condition as the already approved drug'' and inserting ''same use or indication for which the already approved or licensed drug was approved or licensed''; and

(4) by adding at the end the following:

''(f) APPROVED USE OR INDICATION DEFINED.—In this section, the term 'approved use or indication' means the use or indication approved under section 505 of this Act or licensed under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition.''.

(b) APPLICATION OF AMENDMENTS.—The amendments made by subsection (a) shall apply with respect to any drug designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb), regardless of the date on which the drug was so designated, and regardless of the date on which the drug was approved under section 505 of such Act (21 U.S.C. 355) or licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).

SEC. 7. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS.

Section 409I(d)(1) of the Public Health Service Act (42 U.S.C. 284m(d)(1)) is amended by striking ''section,'' and all that follows through the period at the end and

inserting ''section, $25,000,000 for each of fiscal years 2026 through 2028.''.

SEC. 8. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK.

Section 372 of the Public Health Service Act (42 U.S.C. 274) is amended—

(1) in subsection (b)(2)—

(A) by moving the margins of subparagraphs (M) through (O) 2 ems to the left;

(B) in subparagraph (A)—

(i) in clause (i), by striking '', and'' and inserting ''; and''; and

(ii) in clause (ii), by striking the comma at the end and inserting a semicolon;

(C) in subparagraph (C), by striking ''twenty-four-hour telephone service'' and inserting ''24-hour telephone or information technology service'';

(D) in each of subparagraphs (B) through (M), by striking the comma at the end and inserting a semicolon;

(E) in subparagraph (N), by striking ''transportation, and'' and inserting ''transportation;'';

(F) in subparagraph (O), by striking the period and inserting a semicolon; and

(G) by adding at the end the following:

''(P) encourage the integration of electronic health records systems through application programming interfaces (or successor technologies) among hospitals, organ procurement organizations, and transplant centers, including the use of automated electronic hospital referrals and the grant of remote, electronic access to hospital electronic health records of potential donors by organ procurement organizations, in a manner that complies with the privacy regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, at part 160 of title 45, Code of Federal Regulations, and subparts A, C, and E of part 164 of such title (or any successor regulations); and

''(Q) consider establishing a dashboard to display the number of transplants performed, the types of transplants performed, the number and types of organs that entered the Organ Procurement and Transplantation Network system and failed to be transplanted, and other

appropriate statistics, which should be updated more frequently than annually.''; and

(2) by adding at the end the following:

''(d) REGISTRATION FEES.—

''(1) IN GENERAL.—The Secretary may collect registration fees from any member of the Organ Procurement and Transplantation Network for each transplant candidate such member places on the list described in subsection (b)(2)(A)(i). Such registration fees shall be collected and distributed only to support the operation of the Organ Procurement and Transplantation Network. Such registration fees are authorized to remain available until expended.

''(2) COLLECTION.—The Secretary may collect the registration fees under paragraph (1) directly or through awards made under subsection (b)(1)(A).

''(3) DISTRIBUTION.—Any amounts collected under this subsection shall—

''(A) be credited to the currently applicable appropriation, account, or fund of the Department of Health and Human Services as discretionary offsetting collections; and

''(B) be available, only to the extent and in the amounts provided in advance in appropria-

tions Acts, to distribute such fees among awardees described in subsection (b)(1)(A).

''(4) TRANSPARENCY.—The Secretary shall—

''(A) promptly post on the website of the Organ Procurement and Transplantation Network—

''(i) the amount of registration fees collected under this subsection from each member of the Organ Procurement and Transplantation Network; and

''(ii) a list of activities such fees are used to support; and

''(B) update the information posted pursuant to subparagraph (A), as applicable for each calendar quarter for which fees are collected under paragraph (1).

''(5) GAO REVIEW.—Not later than 2 years after the date of enactment of this subsection, the Comptroller General of the United States shall, to the extent data are available—

''(A) conduct a review concerning the activities under this subsection; and

''(B) submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Com-

mittee on Energy and Commerce of the House of Representatives, a report on such review, including related recommendations, as applicable.

''(6) SUNSET.—The authority to collect registration fees under paragraph (1) shall expire on the date that is 3 years after the date of enactment of the Mikaela Naylon Give Kids a Chance Act.''.

SEC. 9. ESTABLISHMENT OF ABRAHAM ACCORDS OFFICE WITHIN FOOD AND DRUG ADMINISTRATION.

(a) IN GENERAL.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

''SEC. 1015. ABRAHAM ACCORDS OFFICE.

''(a) IN GENERAL.—The Secretary, acting through the Commissioner of Food and Drugs, shall establish within the Food and Drug Administration an office, to be known as the Abraham Accords Office, to be headed by a director.

''(b) OFFICE.—Not later than two years after the date of enactment of this section, the Secretary shall—

''(1) in consultation with the governments of Abraham Accords countries, as well as appropriate United States Government diplomatic and security personnel—

''(A) select the location of the Abraham Accords Office in an Abraham Accords country; and

''(B) establish such office; and

''(2) assign to such office such personnel of the Food and Drug Administration as the Secretary determines necessary to carry out the functions of such office.

''(c) DUTIES.—The Secretary, acting through the Director of the Abraham Accords Office, shall—

''(1) after the Abraham Accords Office is established—

''(A) as part of the Food and Drug Administration's work to strengthen the international oversight of regulated commodities, provide technical assistance to regulatory partners in Abraham Accords countries on strengthening regulatory oversight and converging regulatory requirements for the oversight of regulated products, including good manufacturing practices and other issues relevant to manufacturing medical products that are regulated by the Food and Drug Administration; and

''(B) facilitate interactions between the Food and Drug Administration and interested

parties in Abraham Accords countries, including by sharing relevant information regarding United States regulatory pathways with such parties, and facilitate feedback on the research, development, and manufacturing of products regulated in accordance with this Act; and

''(2) carry out other functions and activities as the Secretary determines to be necessary to carry out this section.

''(d) ABRAHAM ACCORDS COUNTRY DEFINED.—In this section, the term 'Abraham Accords country' means a country identified by the Department of State as having signed the Abraham Accords Declaration.

''(e) NATIONAL SECURITY.—Nothing in this section shall be construed to require any action inconsistent with a national security recommendation provided by the Federal Government.''.

(b) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the Abraham Accords Office, including—

(A) an evaluation of how the Office has advanced progress toward conformance with Food

and Drug Administration regulatory requirements by manufacturers in the Abraham Accords countries;

(B) a numerical count of parties that the Office has helped facilitate interactions or feedback pursuant to section 1015(c)(1)(B) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a));

(C) a summary of technical assistance provided to regulatory partners in Abraham Accords countries pursuant to subparagraph (A) of such section 1015(c)(1); and

(D) recommendations for increasing and improving coordination between the Food and Drug Administration and entities in Abraham Accords countries.

(2) ABRAHAM ACCORDS COUNTRY DEFINED.—In this subsection, the term ''Abraham Accords country'' has the meaning given such term in section 1015(d) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a)).

SEC. 10. INCREASING TRANSPARENCY IN GENERIC DRUG APPLICATIONS.

(a) IN GENERAL.—Section 505(j)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(3)) is amended by adding at the end the following:

''(H)(i) Upon request (in controlled correspondence or an analogous process) by a person that has submitted or intends to submit an abbreviated application under this subsection for a drug that is required by regulation to contain one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, or for which the Secretary determines there is a scientific justification for an approach that is in vitro, in whole or in part, to be used to demonstrate bioequivalence for a drug if such a drug contains one or more of the same inactive ingredients in the same concentrations as the listed drug referred to, the Secretary shall inform the person whether such drug is qualitatively and quantitatively the same as the listed drug. The Secretary may also provide such information to such a person on the Secretary's own initiative during the review of an abbreviated application under this subsection for such drug.

''(ii) Notwithstanding section 301(j), if the Secretary determines that such drug is not qualitatively or quantitatively the same as the listed drug, the Secretary shall identify and disclose to the person—

''(I) the ingredient or ingredients that cause such drug not to be qualitatively or quantitatively the same as the listed drug; and

''(II) for any ingredient for which there is an identified quantitative deviation, the amount of such deviation.

''(iii) If the Secretary determines that such drug is qualitatively and quantitatively the same as the listed drug, the Secretary shall not change or rescind such determination after the submission of an abbreviated application for such drug under this subsection unless—

''(I) the formulation of the listed drug has been changed and the Secretary has determined that the prior listed drug formulation was withdrawn for reasons of safety or effectiveness; or

''(II) the Secretary makes a written determination that the prior determination must be changed because an error has been identified.

''(iv) If the Secretary makes a written determination described in clause (iii)(II), the Secretary shall provide notice and a copy of the written determination to the person making the request under clause (i).

''(v) The disclosures authorized under clauses (i) and (ii) are disclosures authorized by law, including for purposes of section 1905 of title 18, United States Code. This

subparagraph shall not otherwise be construed to authorize the disclosure of nonpublic qualitative or quantitative information about the ingredients in a listed drug, or to affect the status, if any, of such information as trade secret or confidential commercial information for purposes of section 301(j) of this Act, section 552 of title 5, United States Code, or section 1905 of title 18, United States Code.''.

(b) GUIDANCE.—

(1) IN GENERAL.—Not later than one year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue draft guidance, or update guidance, describing how the Secretary will determine whether a drug is qualitatively and quantitatively the same as the listed drug (as such terms are used in section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a)), including with respect to assessing pH adjusters.

(2) PROCESS.—In issuing guidance under this subsection, the Secretary of Health and Human Services shall—

(A) publish draft guidance;

(B) provide a period of at least 60 days for comment on the draft guidance; and

(C) after considering any comments received and not later than one year after the close of the comment period on the draft guidance, publish final guidance.

(c) APPLICABILITY.—Section 505(j)(3)(H) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a), applies beginning on the date of enactment of this Act, irrespective of the date on which the guidance required by subsection (b) is finalized.

SEC. 11. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)) is amended by striking ''$1,403,000,000'' and inserting ''$2,622,000,000''.