HR 2430

FDA Reauthorization Act of 2017

Congress: 115 (2017–2019, Ended)
Chamber: House
Policy Area: Health
Introduced: May 16, 2017
Current Status: Became Public Law No: 115-52.
Latest Action: Became Public Law No: 115-52. (Aug 18, 2017)
Law: 115-52 (Enacted Aug 18, 2017)
Official Text: https://www.congress.gov/bill/115th-congress/house-bill/2430

Sponsor

Name: Rep. Walden, Greg [R-OR-2]
Party: Republican • **State:** OR • **Chamber:** House

Cosponsors (3 total)

Cosponsor	Party / State	Role	Date Joined
Rep. Burgess, Michael C. [R-TX-26]	R · TX		May 16, 2017
Rep. Green, Gene [D-TX-29]	D · TX		May 16, 2017
Rep. Pallone, Frank, Jr. [D-NJ-6]	D · NJ		May 16, 2017

Committee Activity

Committee	Chamber	Activity	Date
Energy and Commerce Committee	House	Reported by	May 18, 2017

Subjects & Policy Tags

Policy Area:

Health

Related Bills

Bill	Relationship	Last Action
115 S 934	Related bill	**May 11, 2017:** Placed on Senate Legislative Calendar under General Orders. Calendar No. 76.
115 S 1093	Related bill	**May 10, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1069	Related bill	**May 8, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 HR 2376	Related bill	**May 5, 2017:** Referred to the Subcommittee on Health.
115 S 1048	Related bill	**May 4, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 S 1062	Related bill	**May 4, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.
115 HR 1652	Related bill	**Mar 24, 2017:** Referred to the Subcommittee on Health.
115 S 670	Related bill	**Mar 21, 2017:** Read twice and referred to the Committee on Health, Education, Labor, and Pensions.

Summary (as of Aug 18, 2017)

(This measure has not been amended since it was passed by the House on July 12, 2017. The summary of that version is repeated here.)

FDA Reauthorization Act of 2017

TITLE I--FEES RELATING TO DRUGS

Prescription Drug User Fee Amendments of 2017

(Sec. 102) This bill amends the Federal Food, Drug, and Cosmetic Act to extend through FY2022 and revise Food and Drug Administration (FDA) user fees for brand name drugs. User fees are eliminated for supplemental new drug applications and drug manufacturing facilities.

A prescription drug program fee replaces the prescription drug product fee. This annual fee is assessed on a new drug application holder for each approved drug for up to five drugs.

The total user fee revenue amount is adjusted annually for changes in review process capacity needs, to provide for operational reserves, and for additional direct costs. Eighty percent of revenues must be generated by prescription drug program fees, with the remainder from application fees.

(Sec. 103) The bill extends through FY2022 requirements for annual reports and consultation by the FDA on reauthorization of brand name drug user fees.

TITLE II--FEES RELATING TO DEVICES

Medical Device User Fee Amendments of 2017

(Sec. 203) The bill extends through FY2022 and revises FDA user fees for medical devices. A user fee is established for requests to classify devices that are not substantially equivalent to marketed devices. The FDA’s authority to waive or reduce device user fees in the interest of public health is eliminated.

(Sec. 204) The bill extends through FY2022 requirements for annual reports and consultation by the FDA on reauthorization of user fees for medical devices.

(Sec. 205) The FDA must establish a pilot program to accredit testing laboratories to determine whether medical devices conform to performance standards.

(Sec. 206) The bill extends through FY2022 the FDA's authority to accredit third parties to review premarket notifications for medical devices. The bill revises the types of devices that third parties may review.

(Sec. 207) Submissions to the FDA regarding medical devices must be solely in electronic format.

TITLE III--FEES RELATING TO GENERIC DRUGS

Generic Drug User Fee Amendments of 2017

(Sec. 302) Generic drug applications submitted by government entities for non-commercial drugs are not subject to user fees.

(Sec. 303) The bill extends through FY2022 and revises FDA user fees for generic drugs. User fees are eliminated for supplements to generic drug applications.

An annual generic drug applicant program fee is assessed on holders of approved generic drug applications. The amount of the fee is based on the number of applications held. Of total user fee revenue, 35% must be generated from this fee. Application holders who do not pay this fee may not market their drugs.

(Sec. 304) The bill extends through FY2022 requirements for annual reports and consultation by the FDA on reauthorization of user fees for generic drugs.

TITLE IV--FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS

Biosimilar User Fee Amendments of 2017

(Sec. 403) The bill extends through FY2022 and revises FDA user fees for biosimilars. (Biosimilars are biological products approved by the FDA based on their similarity to an already-approved biological product.) User fees are eliminated for supplemental biosimilar applications and biosimilar manufacturing facilities.

An annual biosimilar biological product program fee is assessed on biosimilar application holders for each approved biosimilar for up to five biosimilars.

The bill sets the annual amount of revenue that must be generated by user fees. The FDA must determine the percentage of revenue generated by each fee. The total fee revenue amount is adjusted annually for changes in review process capacity needs and to provide for operational reserves.

TITLE V--PEDIATRIC DRUGS AND DEVICES

(Sec. 501) The bill extends through FY2022 and revises the National Institutes of Health (NIH) program to conduct pediatric studies of drugs. The NIH, in developing its list of priority issues in pediatric therapeutics, must consider identification of biomarkers for pediatric conditions.

(Sec. 502) The bill revises requirements for the FDA to report on pediatric use of medical devices.

The bill extends and revises the authorization for certain medical devices for pediatric patients to be sold above cost under the humanitarian device exemption.

The bill extends and revises grants for consortia to facilitate development of pediatric medical devices.

The FDA must convene a meeting on the development, approval, and labeling of pediatric medical devices.

(Sec. 503) The FDA must meet with applicants for approval of new drugs or biological products to discuss, upon request, the initial pediatric study plan for medications to treat serious conditions and to discuss deferral or waiver of pediatric assessments.

(Sec. 504) The bill revises the requirement for pediatric assessments to be submitted with applications for FDA approval of new medications. Sponsors of new medications for adult cancer, including orphan drugs, that target a molecule relevant to pediatric cancer must complete an investigation to yield pediatric study data to inform potential pediatric labeling of the medication. (Orphan drugs are medications for rare conditions.)

The FDA must publish a list of target molecules considered relevant to pediatric cancer and a list of molecules for which

pediatric study requirements are waived.

The FDA must convene a meeting regarding the lists and the revisions to the pediatric assessment requirement.

The bill revises FDA reporting requirements regarding pediatric studies and assessments.

The Government Accountability Office (GAO) must report on the effectiveness of requiring pediatric assessments and investigations in the development of medications for pediatric cancer.

(Sec. 505) The FDA must provide additional information to the internal committee that reviews requests for pediatric studies. (Currently, completion of pediatric clinical studies requested by the FDA extends the patents or marketing exclusivity period for a medication by six months, with exceptions.) This committee must develop and implement a plan to achieve earlier submission of pediatric studies.

The FDA must: (1) act within 120 days on proposed pediatric study requests and proposed amendments to requests, and (2) report on the lack of pediatric labeling for orphan drugs.

The FDA's Office of Pediatric Therapeutics must have a staff member with expertise in neonatology.

TITLE VI--REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS

(Sec. 601) The bill extends through FY2022: (1) marketing exclusivity for certain chemical variants of approved drugs; (2) Critical Path Public-Private Partnerships; and (3) support to defray the costs of developing drugs, devices, and medical food for rare conditions.

(Sec. 604) Except in cases of a drug shortage or certain importation of drugs from Canada, prescription drugs manufactured outside the United States may only be imported if authorized by the manufacturer and appropriately labeled.

The bill establishes a penalty for manufacturing, dispensing, or selling a counterfeit drug.

(Sec. 605) The bill revises the definition of patient experience data, for purposes of collecting such data as part of the medical product development process, to specifically include physical and psychosocial impacts of a condition, therapy, or clinical investigation.

(Sec. 606) The communication plan for a risk evaluation and mitigation strategy may include informing health care providers about drug formulations or properties and how those formulations or properties may be related to serious adverse drug events.

(Sec. 607) For a medication to be approved as an orphan drug with seven years of marketing exclusivity when it is the same medication for the same condition as an already approved orphan drug, the sponsor of the new medication must demonstrate that the new medication is clinically superior to the approved medication.

(Sec. 608) The bill expands to cover brand name drugs provisions that allow generic drugs to be approved and marketed without labeling for pediatric indications when the pediatric indications are protected by patent or marketing exclusivity.

(Sec. 610) The FDA, in coordination with the NIH, must convene a meeting to discuss clinical trial inclusion and exclusion criteria. The FDA must report on the meeting and issue guidance regarding eligibility criteria for clinical trials.

The GAO must report on individual access to investigational drugs through the expanded access program. (Expanded

access, also known as compassionate use, allows patients to be treated with an investigational drug outside of a clinical trial.)

The FDA must streamline review by institutional review boards of expanded access protocols for individual patients.

The manufacturer or distributor of an investigational drug for a serious condition must publish its expanded access policy not later than 15 days after the drug is designated a breakthrough therapy, fast track product, or regenerative advanced therapy.

(Sec. 611) The bill revises the priority review program for medications for tropical diseases to limit eligibility to applications that include new clinical investigations that were not submitted as part of an application in certain foreign countries.

TITLE VII--DEVICE INSPECTION AND REGULATORY IMPROVEMENTS

(Sec. 701) The bill revises provisions regarding FDA inspections of establishments that manufacture or process medical devices. The biannual inspection schedule for medical device establishments handling higher risk devices is replaced with a risk-based schedule. In establishing the risk-based schedule, the FDA must consider an establishment's participation in international medical device audit programs.

(Sec. 702) The FDA must adopt uniform processes and standards for inspections of domestic and foreign medical device establishments.

Upon request, the FDA must provide to the person in charge of a medical device establishment feedback regarding the person's proposals to address certain issues identified during an inspection.

(Sec. 703) The bill extends through FY2022 accreditation by the FDA of third parties to conduct inspections of medical device establishments.

(Sec. 704) The bill revises provisions regarding FDA certification of medical devices for export. The FDA must provide the basis for denying requests for certification of products for export as meeting FDA requirements for domestic products. A person denied such a certification may request supervisory review of that decision.

Products from a medical device establishment that an inspector found to be contaminated or insanitary may be certified for export if the person in charge of the establishment has agreed to a plan to correct the issues identified during the inspection.

(Sec. 705) The FDA may recognize auditing organizations that are recognized by organizations established by governments to facilitate international harmonization for purposes of inspecting medical device establishments.

(Sec. 706) The FDA may approve or classify a medical imaging device intended to be used with an approved contrast agent if differences from the approved use of the contrast agent do not adversely affect the safety and effectiveness of the contrast agent. (Contrast agents are substances used to enhance the visibility of body structures in medical imaging.) The FDA center that reviews medical devices has primary jurisdiction over such reviews.

After authorization of a medical imaging device that makes new use of a contrast agent, the sponsor of the approved contrast agent may submit a supplemental application for the new use of the contrast agent.

(Sec. 707) The bill revises how accessories to medical devices are classified. The FDA must classify accessories based

on the risks when used as intended and the level of regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.

Applications for approval or clearance of a medical device used with an unclassified accessory may request that the FDA classify the accessory. The FDA's response to the application must grant or deny the request for classification of the accessory.

The FDA must periodically classify suitable medical device accessories that have been approved for marketing as low risk devices. Manufacturers and importers of accessories approved for marketing may request classification of the accessories.

(Sec. 708) In order to provide timely and reliable information on the safety and effectiveness of medical devices that have been approved, cleared, or classified, the FDA must support pilot projects that use electronic health data to generate safety and active surveillance data and inform methods and programs to support safety and active surveillance activities.

(Sec. 709) The FDA must categorize certain hearing aids as over-the-counter hearing aids and issue regulations regarding those hearing aids. The regulations for over-the-counter hearing aids must: (1) provide reasonable assurances of safety and efficacy; (2) establish output limits and labeling requirements; and (3) describe requirements for the sale of hearing aids in-person, by mail, or online, without a prescription. The FDA must determine whether premarket notification is required for over-the-counter hearing aids to provide reasonable assurance of safety and effectiveness.

State and local governments may not establish or continue in effect requirements specifically applicable to hearing products that are not identical to FDA requirements and that restrict or interfere with the servicing or sale of over-the-counter hearing aids.

The FDA must update and finalize its draft guidance on hearing products. The guidance must clarify which products are medical devices.

(Sec. 710) The FDA must report on the continued quality, safety, and effectiveness of medical devices after servicing. The report must contain information including the current authority of the FDA to regulate medical device servicing and how the FDA could improve its regulation of servicing.

TITLE VIII--IMPROVING GENERIC DRUG ACCESS

(Sec. 801) The FDA must prioritize review of, and act within eight months of submission on, generic drug applications for drugs for which there is a shortage or for which there are not more than three approved products and no blocking patents or exclusivities.

To be eligible for priority review, an applicant must submit, at least 60 days in advance of the application, information to the FDA on facilities involved in the manufacturing and testing of the drug. The FDA may expedite inspection of such manufacturing facilities.

The FDA must publish a list of brand name drugs for which all patents and exclusivities have expired and no generic drug application has been approved.

(Sec. 802) Upon request, the FDA must provide review status updates to applicants with pending generic drug applications.

(Sec. 803) The FDA may, upon the request of an applicant for approval of a generic drug, designate a generic drug as a

competitive generic therapy and expedite the development and review of the application. A drug may be designated as a competitive generic therapy if there is not more than one approved, marketed drug that is the same drug.

(Sec. 804) Holders of approved brand name or generic drug applications must notify the FDA: (1) 180 days prior to withdrawing a drug from sale, or as soon as practicable, and provide specified information including the reason for withdrawal; (2) within 180 days of approval of a drug if the drug will not be available for sale within 180 days of approval and provide specified information including the reason the drug is not for sale; and (3) within 180 days of enactment of this bill of whether their drugs on the FDA's list of marketed drugs are marketed. The FDA must update its list of marketed drugs based on this information.

(Sec. 805) The FDA must annually report information regarding petitions for permission to seek approval for a generic drug application for a drug that differs from the brand name drug.

(Sec. 806) The FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain drug applications, including applications for drugs in a shortage or drugs for which approval is dependent on remediation of conditions identified in the inspection report.

(Sec. 807) The FDA must report quarterly on generic drug applications, including information regarding applications subject to priority review or expedited development and review and withdrawals of generic drug applications.

(Sec. 808) First approved applicants for a competitive generic therapy are granted a 180-day marketing exclusivity period. There may be only one such period for a drug. This exclusivity period is forfeited by an applicant if the applicant fails to market the drug within 75 days after approval.

(Sec. 809) For FY2013-FY2017, the GAO must report on the rate of approval of generic drug applications upon completion of the FDA's first review of an application. For years when the rate is below 20%, the GAO must report on the reasons for the low rate. The GAO must report on whether there are ways the generic drug review process could be improved to increase the rate of approvals upon first review.

TITLE IX--ADDITIONAL PROVISIONS

(Sec. 902) The FDA must annually publish information regarding the past year's inspections of drug or medical device facilities, including the amount of time between steps in the inspection process.

(Sec. 903) The bill revises requirements for performance reports under user fee provisions for prescription drugs, medical devices, generic drugs, and biosimilars, including to require quarterly publication of information regarding guidance and meetings. Performance reports must include: (1) an analysis of changes in the number of full time equivalents hired under user fee agreements and the number funded under the FDA budget, (2) an analysis of changes in user fee revenue amounts and review costs, and (3) the number of employees in specified FDA offices for whom time reporting is required and the number for whom it is not required.

(Sec. 904) User fee performance reports must include an analysis of: (1) the number of product applications filed and approved, (2) whether the relevant FDA review office has met performance enhancement goals, and (3) circumstances affecting the ability of the FDA to meet review time and performance enhancement goals.

The FDA must annually submit a corrective action report to Congress as part of user fee reporting. If the FDA determines that fiscal year goals were met, the report must include recommendations on ways to improve the product review process. If goals were not met, the report must include a description of the circumstances under which goals were missed

and efforts to improve the FDA's ability to meet the goals.

Each fiscal year, as requested, representatives of the FDA must meet with members of Congress and participate in a congressional hearing regarding user fee reports.

(Sec. 905) The GAO must report on FDA expenses related to facility maintenance and renovation for FY2012-FY2019. The report must include an analysis of the FDA's ability to further its public health mission and review medical products by incurring such expenses.

Beginning FY2024, the bill prohibits the use of user fees for: (1) maintenance, renovation, and repair of facilities; and (2) acquisition, maintenance, and repair of materials and supplies that are not necessary scientific equipment.

Actions Timeline

- **Aug 18, 2017:** Signed by President.
- **Aug 18, 2017:** Became Public Law No: 115-52.
- **Aug 7, 2017:** Presented to President.
- **Aug 3, 2017:** Motion to proceed to measure considered in Senate.
- **Aug 3, 2017:** Cloture on the motion to proceed to the measure invoked in Senate by Yea-Nay Vote. 96 - 1. Record Vote Number: 185. (CR S4787)
- **Aug 3, 2017:** Motion to proceed to consideration of measure agreed to in Senate by Unanimous Consent.
- **Aug 3, 2017:** Measure laid before Senate by motion. (consideration: CR S4782-4787)
- **Aug 3, 2017:** Passed/agreed to in Senate: Passed Senate without amendment by Yea-Nay Vote. 94 - 1. Record Vote Number: 187.
- **Aug 3, 2017:** Passed Senate without amendment by Yea-Nay Vote. 94 - 1. Record Vote Number: 187.
- **Aug 3, 2017:** Message on Senate action sent to the House.
- **Aug 1, 2017:** Motion to proceed to consideration of measure made in Senate. (CR S4663)
- **Aug 1, 2017:** Cloture motion on the motion to proceed to the measure presented in Senate. (CR S4663)
- **Jul 17, 2017:** Read the second time. Placed on Senate Legislative Calendar under General Orders. Calendar No. 174.
- **Jul 13, 2017:** Received in the Senate. Read the first time. Placed on Senate Legislative Calendar under Read the First Time.
- **Jul 12, 2017:** Mr. Walden moved to suspend the rules and pass the bill, as amended.
- **Jul 12, 2017:** Considered under suspension of the rules. (consideration: CR H5454-5483)
- **Jul 12, 2017:** DEBATE - The House proceeded with forty minutes of debate on H.R. 2430.
- **Jul 12, 2017:** Passed/agreed to in House: On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote.(text: CR H5454-5477)
- **Jul 12, 2017:** On motion to suspend the rules and pass the bill, as amended Agreed to by voice vote. (text: CR H5454-5477)
- **Jul 12, 2017:** Motion to reconsider laid on the table Agreed to without objection.
- **Jul 11, 2017:** Reported (Amended) by the Committee on Energy and Commerce. H. Rept. 115-201.
- **Jul 11, 2017:** Placed on the Union Calendar, Calendar No. 138.
- **Jun 7, 2017:** Committee Consideration and Mark-up Session Held.
- **Jun 7, 2017:** Ordered to be Reported (Amended) by the Yeas and Nays: 54 - 0.
- **May 18, 2017:** Subcommittee Consideration and Mark-up Session Held.
- **May 18, 2017:** Forwarded by Subcommittee to Full Committee (Amended) by Voice Vote .
- **May 16, 2017:** Introduced in House
- **May 16, 2017:** Referred to the House Committee on Energy and Commerce.
- **May 16, 2017:** Referred to the Subcommittee on Health.