H.R. 2430, FDA Reauthorization Act of 2017	
Section 1. Short Title.	• This Act may be cited as the "FDA Reauthorization Act of 2017".
Section 2. Table of Contents	• Table of Contents
TITLE I: FEES RELATING TO DRUGS	
Sec. 101. Short title; finding.	• Establishes a short title – "Prescription Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward human prescription drug activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 102. Authority to assess and use drug fees.	• Reauthorizes the authority to collect fees at a higher level, and restructures the fees to reduce administrative burden and make funding more predictable. • Modernizes the fee structure. Historically, fees were derived one-third from facility fees, one-third from various application fees, and one-third from product fees. The new structure is derived from 20 percent application fees and 80 percent program fees for approved products. Supplemental application fees and facility fees are eliminated. • Updates the base fee amount. In fiscal year (FY) 2017, the base fee amount was $718,669,000, in FY2018, the base fee amount is $878,590,000. • Replaces the workload adjustment with a capacity planning adjuster so that fees more accurately reflect the workload and existing staff capacity at FDA. • Reauthorizes the authority to collect, and the availability and crediting, of fees.
Sec. 103. Reauthorization; reporting requirements.	• Maintains the existing reauthorization process and reporting requirements. The Secretary of Health and Human Services (HHS) is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 104. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 105. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 106. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE II: FEES RELATING TO DEVICES	
Sec. 201. Short title; finding.	• Establishes a short title – "Medical Device Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward medical device activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 202. Definitions.	• Adds the term "de novo classification request" to enable new fees specifically for de novo medical device reviews.

Sec. 203. Authority to assess and use device fees.	• Adds authority to collect fees for de novo classification request. • Updates the target base fee amounts for each year. FY2017 base is $130,184,348, the FY2018 base is increased to $183,280,756, ending at $213,687,660 in FY2022. • Updates the adjustment for inflation and allows the Secretary of HHS to, if necessary, increase the fees to meet the base target. • Reauthorizes the authority to collect, and the availability and crediting, of fees.
Sec. 204. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 205. Conformity assessment pilot program.	• Establishes a pilot to provide FDA the authority to audit and certify laboratories who conduct device conformance testing to a recognized standard, and also to withdraw the certification if necessary. • Requires FDA to evaluate the use of this scheme in at least five device types, or device parts that are found in multiple devices. • Requires FDA to obtain public input on the development of the pilot. • Sunsets the authority for the pilot in 2022.
Sec. 206. Reauthorization of review.	• Reauthorizes, and provides flexibility for the Secretary of HHS to better target which device types are most appropriate for, third party review. • Requires the Secretary of HHS to conduct a public guidance development process to identify the factors the Secretary of HHS will use to determine which devices are eligible for third party review.
Sec. 207. Electronic format for submissions.	• FDA currently receives both paper and electronic submissions. This provision requires all submissions to be in electronic format by October 1, 2021. The Secretary of HHS has the authority to extend the date as late as April 1, 2023.
Sec. 208. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
Sec. 209. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all medical device applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 210. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
TITLE III: FEES RELATING TO GENERIC DRUGS	
Sec. 301. Short title; finding.	• Establishes a short title – "Generic Drug User Fee Amendments of 2017" – and provides that the fees authorized in the title will go toward human generic drug activities, as set forth in the commitment letter submitted to the Congressional Record.

Sec. 302. Definitions.	• The definitions are amended to clarify that submissions by a State or Federal Government entity for drugs not intended for sale do not have to pay user fees. • Includes a definition for a contract manufacturing facility.

Sec. 303. Authority to assess and use human generic drug fees.	• Updates the fee structure to provide more predictability for FDA and flexibility for small businesses.
	• Removes the fees for prior approval supplements and establishes a generic drug applicant program fee.
	• Thirty-three percent of the total revenue will come from application fees, 20 percent of the revenue will come from generic drug facility fees, 7 percent will come from active pharmaceutical ingredient facility fees, and 35 percent will come from a new generic drug applicant program fee.
	• The generic drug applicant program fee is determined by how many applications the applicant has approved by the FDA:
	  • a manufacturer with 20 or more approved applications pays the full fee;
	  • a manufacturer with six-19 approved applications pays 40 percent of the full fee; and
	  • a manufacturer with five or fewer approved applications pays 10 percent of the full fee.
	• The base fee amount is updated from the FY2017 amount of $299,000,000 to $493,600,000 in FY2018.

Sec. 304. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 305. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 306. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all human generic drug applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 307. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE IV: FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS	
Sec. 401. Short title; finding.	• Establishes a short title – "Biosimilar User Fee Amendments of 2017" – and that the fees authorized in the title will go toward biosimilar activities as set forth in the commitment letter submitted to the Congressional Record.
Sec. 402. Definitions.	• Technical update to the definition of the adjustment factor and biosimilar biological product to provide clarity.

Sec. 403. Authority to assess and use biosimilar biological product fees.	• Establishes an independent fee structure for biosimilars for the first time based on the following types of fees:
	  • Initial Biosimilar Development Fee for the first year once a sponsor begins clinical trials for a new biosimilar;
	  • Annual Biosimilar Development Fee for subsequent years a sponsor is developing a new biosimilar;
	  • Biosimilar Program Fee for sponsors of approved biosimilars; and
	  • Application Fee for new biosimilar applications.
	• Eliminates supplement and establishment fees.
	• Allows the Secretary of HHS to determine the appropriate percentage that will come from each of the fees, and each fee amount annually.
	• Updates the base fee amount from $20,000,000 to $45,000,000.

Sec. 404. Reauthorization; reporting requirements.	• Maintains the existing reauthorization and reporting requirements. The Secretary of HHS is required to provide recommendations to Congress by January 15, 2022, after an extensive process of public meetings. • Performance and financial reports continue to be due to Congress every year.
Sec. 405. Sunset dates.	• Sunsets the authority to collect fees on October 1, 2022, and the requirement to submit performance and financial reports on January 31, 2023.
Sec. 406. Effective date.	• Clarifies that the effective date is October 1, 2017, or date of enactment, whichever is later, and the fee structure and amount in this Act applies to all biosimilar applications received on or after October 1, 2017, regardless of the date of the enactment of this Act.
Sec. 407. Savings clause.	• Clarifies that submissions made prior to October 1, 2017, will continue to be reviewed and assessed fees based on the agreement for FY2012-2017.
TITLE V: PEDIATRIC DRUGS AND DEVICES	
Sec. 501. Best pharmaceuticals for children.	• Reauthorizes funding for National Institutes of Health to conduct pediatric trials not being conducted by drug sponsors, and makes technical corrections. • Requires the National Institutes of Health to post data, and FDA to link to that information, when opening a docket for comments on proposed pediatric labeling changes.
Sec. 502. Pediatric devices.	• Requires additional information in the annual report, including areas of pediatric need. • Reauthorizes rules regarding the development of devices for rare pediatric conditions until 2022. • Allows flexibility for the review of devices subject to the humanitarian device exemption by either Institutional Review Boards or other appropriate committees. • Reauthorizes the authority of FDA to issue grants to Pediatric Device Consortia working to develop devices for pediatrics at current law authorization levels until 2022 and requires FDA to provide regulatory consultation to grantees.

	• Requires a public meeting and report regarding the opportunities and barriers to the development, approval, and labeling of pediatric medical devices.
Sec. 503. Early meeting on pediatric study plan.	• Requires FDA to conduct earlier meeting with product sponsors regarding pediatric study plans for serious or life-threatening diseases upon request.
Sec. 504. Development of drugs and biological products for pediatric cancers.	• Provides FDA the authority to require adult cancer drugs that share a common target with a pediatric cancer to be studied in children to find out information about dosing, safety, and efficacy starting 3 years after the date of enactment, after a public meeting and guidance is available. • FDA will be required to publish and maintain a list of molecular targets, and cancers for which the requirement will be automatically waived. • GAO is required to issue a report, beginning 5 years from enactment, on the effectiveness of requiring pediatric assessments of adult oncology drugs
Sec. 505. Additional provisions on the development of drugs and biological products for pediatric use.	• Ensures responses to written requests are shared with the Pediatric Review Committee and that the Committee has expertise in rare diseases. • Requires FDA to act on pediatric study requests and proposed amendments to written request within 120 days of receipt. • Requires the Pediatric Review Committee to implement a plan to help achieve earlier submission of pediatric studies by drug sponsors. • Creates a permanent position for a neonatologist in the Office of Pediatric Therapeutics. • Requires FDA to issue a guidance on drug development for neonates • Requires non-compliance letters under the Pediatric Research and Equity Act (PREA) to be shared with the Pediatric Advisory Committee. • Expands the yearly FDA pediatric report to include information regarding the duration of studies conducted under PREA, and details of the written request process. • Requires FDA to submit a report on the lack of pediatric information in the labeling of orphan drugs.
TITLE VI: REAUTHORIZATIONS AND IMPROVEMENTS RELATED TO DRUGS	
Sec. 601. Reauthorization of provision relating to exclusivity of certain drugs containing single enantiomers.	• Reauthorizes section 505(u), which provides the Secretary of HHS the authority to grant exclusivity for drugs containing single enantiomers, until 2022.
Sec. 602. Reauthorization of the critical path public-private partnerships.	• Reauthorizes the Critical Path public-private partnership for an additional 5 years at current law authorization levels.
Sec. 603. Reauthorization of orphan grants program.	• Reauthorizes the authority of FDA to issue grants for orphan drug development until 2022.

Sec. 604. Protecting and strengthening drug supply chain.	• Clarifies that a prescription drugs manufactured and labeled for non-U.S. markets shall not be diverted into the U.S., unless legally imported by individuals or in a shortage situation. • Increases the penalties for counterfeit drugs.
Sec. 605. Patient experience data.	• Expands the definition of patient experience data to include both physical and psychosocial impacts of the disease or participation in clinical trials for a therapy to treat such disease.
Sec. 606. Communication plan.	• Clarifies that FDA has the authority to require companies to communicate with physicians about the formulations of their products.
Sec. 607. Orphan drugs.	• Requires drug manufacturers seeking approval of an orphan drug that has the same active ingredient as a drug on the market to demonstrate clinical superiority to that drug to get orphan drug exclusivity.
Sec. 608. Pediatric information added to labeling.	• Clarifies when pediatric information is required to be on labeling and when such information can be left out of labeling to improve generic access.
Sec. 609. Sense of Congress on lowering the cost of prescription drugs.	• Emphasizes that the Secretary of HHS should work with Congress on legislation that will: lower the cost of prescription drugs, encourage innovation in drug payment and biomedical research, and increase competition within the pharmaceutical industry.
Sec. 610. Expanded access.	• Requires FDA to conduct a public meeting on clinical trial inclusion criteria and issue a report about barriers to patients participating in clinical trials and potential solutions to include more populations. • Requires FDA to issue guidance to medical product developers for how to expand clinical trials to broader populations and improve access to treatments for people who do not qualify for clinical trials. • Requires FDA to issue guidance or regulations to streamline the institutional review board review for individual patient expanded access protocols.
Sec. 611. Tropical disease product application.	• Ensures that priority review vouchers for neglected tropical diseases reward innovation conducted since the start of the program and that innovation was essential to FDA approval.
TITLE VII: DEVICE INSPECTION AND REGULATORY IMPROVEMENTS	
Sec. 701. Risk-based inspections for devices.	• Establishes a risk-based inspection paradigm for medical devices analogous to the paradigm for drugs so FDA has more flexibility to see facilities that have higher risk.
Sec. 702. Improvements to inspections process for device establishments.	• Establishes standards to improve predictability for scheduled (not for-cause) inspections for device facilities.
Sec. 703. Reauthorization of inspection program.	• Reauthorizes the authority of FDA to conduct inspections via accredited organizations.
Sec. 704. Certificates to foreign governments for devices.	• Clarifies the process for issuance of foreign export certificates for medical devices. Establishes a pathway by which manufactures denied a certificate can present information and work with FDA to correct any outstanding issue.

Sec. 705. Facilitating international harmonization.	• Allows FDA to recognize auditors used by foreign governments to help improve international harmonization of inspection standards and increase FDA access to audit data.
Sec. 706. Fostering innovation in medical imaging.	• Allows FDA to approve a medical imaging device with the use of a contrast agent as long as the contrast agent is used at the same dose, in the same patient population, with the same type of imaging technology, and does not pose any additional safety risk.
Sec. 707. Risk-based classification of accessories.	• Clarifies a process by which FDA can implement the accessory classification provision of 21st Century Cures that required FDA to classify a device accessory independently based on the intended use of the accessory.
Sec. 708. Device pilot projects to generate reliable and timely safety and active surveillance data.	• Creates a new voluntary pilot program for device manufacturers who wish to meet reporting or post-market study requirements using active surveillance. Requires FDA to report safety data from the pilot consistent with current reporting.
Sec. 709. Regulation of over-the-counter hearing aids.	• Establishes a category of over-the-counter (OTC) hearing aids and subjects these devices to FDA regulation to ensure they are safe and effective for use and labeled appropriately for OTC sale.
Sec. 710. Report on servicing of devices.	• The Secretary of HHS shall post to the FDA website, within 270 days of enactment, a report on the quality and safety of devices with respect to servicing.
TITLE VIII: IMPROVING GENERIC DRUG ACCESS	
Sec. 801. Priority review of generic drugs.	• FDA should act within 8 months on any ANDA for a drug that has no more than three approved drugs and for which there is no blocking patents affecting its ability to come to market, or that is on the drug shortage list. • In order to receive an 8 month timeline for review, generic drug manufacturers are required to provide FDA information regarding facilities involved in the manufacturing process 60 days before submitting the application. • Requires FDA to maintain a list of drugs with limited competition.
Sec. 802. Enhancing regulatory transparency to enhance generic competition.	• Requires the Secretary to provide periodic updates to generic drug manufacturers about the status of the applications under review at FDA.
Sec.803. Competitive generic therapies.	• Authorizes FDA to expedite the review and development of certain generic drugs, including additional meetings and guidance about the development of such drugs.
Sec.804. Accurate information about drugs with limited competition.	• Requires drug manufacturers to notify and provide rationale to the Secretary when removing a drug from the market, or withdrawing or transferring an approved application.
Sec. 805. Suitability petitions.	• Increases transparency about pending suitability petitions, which FDA is required to act on within 90 days of receipt.
Sec. 806. Inspections.	• FDA is required to develop a protocol to expedite re-inspection where facility issues are the only thing delaying a generic application.
Sec. 807. Reporting on pending generic drug applications and priority review applications.	• Improves transparency about the number of applications at FDA pending for pending generic drugs and the inspection process,

	including how many have been prioritized under Section 801 and had expedited development under Section 803.
Sec. 808. Incentivizing competitive generic drug.	• Provides an incentive for companies to enter the market where only one generic drug exists that has no remaining patents and exclusivities.
Sec. 809. GAO study of issues regarding first cycle approvals of generic medicines.	• Requires a GAO report to study the rate of first cycle approvals between 2012 and 2017, including explanations for why, if any, of the rates of first cycle approval for those years was less than 20 percent, and what FDA could do to improve the first cycle approval rate.
TITLE IX – ADDITIONAL PROVISIONS	
Sec.901. Technical corrections.	• Makes technical corrections to the 21st Century Cures Act.
Sec. 902. Annual report on inspections.	• Improves transparency on facility inspections and requires FDA to publish information on the inspection process.
Sec. 903. Streamlining and improving consistency in performance rating.	• Requires FDA to provide additional metrics in the annual use fee report to increase transparency about whether FDA is meeting its user fee goals.
Sec. 904. Analysis of use of funds.	• Requires FDA to perform and analysis and propose a corrective action plan if user fee goals are missed. • Requires FDA representatives to testify before the HELP Committee at least once per year.
Sec. 905. Facilities management	• Limits the use of fees on maintenance, renovation, and repair of facilities, acquisitions, fixtures, and furniture beginning with next user fee agreement.