The Food and Drug Amendments of 2022 (FDA 2022)
Section by Section Summary

Title I: Fees Relating to Drugs

Sec. 101 – 107.
Reauthorizes prescription drug user fee program through 2027 to continue to expedite new drug development and review and fund postmarket drug safety activities. Prioritizes preparing the Food and Drug Administration (FDA) for development and innovation of cell and gene therapy products. Maintains existing fee structure and Congressional reporting requirements. FDA's commitments on product review timelines, hiring estimates, and program enhancements are contained in the performance goal letter.

Title II: Fees Relating to Devices

Sec. 201 – 209.
Reauthorizes medical device user fee program through 2027 to continue to expedite device development and review and assure the safety and effectiveness of devices. Generally maintains existing fee structure, but includes a new performance improvement adjustment provision, which provides for increased fees in later years if FDA meets review goal timelines. Maintains existing Congressional reporting requirements. Reauthorizes third party 510(k) review of certain devices and program for accreditation of testing laboratories to assess conformance of a device with certain recognized standards. FDA's commitments on product review timelines, hiring estimates, and program enhancements are contained in the performance goal letter.

Title III: Fees Relating to Generic Drugs

Sec. 301 – 306.
Reauthorizes generic drug user fee program through 2027 to continue to expedite generic drug development and review, increasing competition and lowering drug costs. Maintains existing fee structure and Congressional reporting requirements. FDA's commitments on product review timelines, hiring estimates, and program enhancements are contained in the performance goal letter.

Title IV: Fees Relating to Biosimilar Biological Products

Sec. 401 – 407.
Reauthorizes biosimilar user fee program through 2027 to continue to expedite biosimilar development and review and fund postmarket safety activities. Increases fees and maintains existing fee structure and Congressional reporting requirements. FDA's commitments on product review timelines, hiring estimates, and program enhancements are contained in the performance goal letter.

Title V: Improving Diversity in Clinical Trials

Sec. 501. Premarket reporting of diversity action plans for clinical trials and studies.
Requires a sponsor for a clinical investigation of a new drug or certain devices to submit a diversity action plan that includes the sponsor's goals for enrollment in the clinical trial or trials involved, the sponsor's rationale for such goals, and an explanation for how the sponsor intends to meet such goals. Also requires FDA to issue new draft guidance or update existing draft guidance within 12 months of enactment, and to finalize such guidance no later than six months after closing the comment period of such draft guidance. Requirements to submit a plan under Section 501 become effective six months after the guidance is finalized.

Sec. 502. Evaluation of the need for FDA authority to mandate postapproval studies or postmarket surveillance due to insufficient demographic subgroup data.
Requires FDA to evaluate, not later than two years after the publication of the final guidance referred to in Section 501, whether regulations should be issued, or additional authorities are needed, to collect data after approval in the event sponsors do not meet the enrollment goals included in the diversity action plans submitted under Section 501.

Sec. 503. Public workshops to enhance clinical trial diversity.
Requires FDA, in consultation with drug sponsors, medical device manufacturers, patients, and other stakeholders, not later than September 30, 2023, to convene one or more public workshops to solicit input from stakeholders on increasing the enrollment of historically underrepresented populations in clinical trials.

Sec. 504. Annual report on progress to increase diversity in clinical trials and studies.
Requires FDA, not later than two years after the enactment of the Food and Drug Amendments of 2022, and annually thereafter, to submit to Congress, and publish on the public website of FDA, a report that summarizes information related to the diversity action plans received pursuant to Section 501. Notes that nothing in this section shall be construed to authorize FDA to disclose any information that is a trade secret or confidential.

Sec. 505. Public meeting on clinical trial flexibilities initiated in response to COVID-19 pandemic.
Requires FDA, not later than 180 days after the date on which the COVID-19 public health emergency period ends, to convene a public meeting to discuss recommendations provided during the COVID-19 public health emergency to mitigate disruption of clinical trials. Such meeting shall discuss incorporating certain clinical trial disruption mitigation recommendations into current or additional guidance to improve clinical trial access and enrollment of diverse patient populations.

Sec. 506. Decentralized clinical trials.
Requires FDA, not later than 12 months after the enactment of the Food and Drug Amendments of 2022, to issue draft guidance that addresses considerations for decentralized clinical trials, including regarding the engagement, enrollment, and retention of a meaningfully diverse clinical

population, with respect to race, ethnicity, age, gender, and geographic location, when appropriate. FDA is required to finalize this guidance no later than six months after the public comment period for the draft guidance ends.

Title VI: Generic Drug Competition

Sec. 601. Increasing transparency in generic drug applications.
Requires FDA to provide generic drug sponsors, upon request, information regarding any differences in ingredients between their generic drug and the reference listed drug to which they are compared, to facilitate generic drug development and review. Requires FDA to issue guidance explaining how it determines whether a generic drug is qualitatively and quantitatively the same as the listed drug.

Sec. 602. Enhanced access to affordable medicines.
Allows a generic drug to be approved even if its proposed labeling differs from that of the brand drug if the differences are limited to FDA approved changes made within 90 days of when the generic application is otherwise eligible for approval. The differences cannot be in the "Warnings" section of the labeling and the generic sponsor must submit revised labeling within 60 days of approval.

Title VII: Research, Development, and Supply Chain Improvements

Subtitle A—In General

Sec. 701. Animal testing alternatives.
Allows an applicant for new drug approval to use methods other than animal testing to support clinical testing and establish effectiveness in certain circumstances. Alternative methods may include cell-based assays, organ chips and microphysiological systems, sophisticated computer modeling, and other human biology-based test methods.

Sec. 702. Emerging technology program.
Authorizes the Emerging Technologies Program at FDA, a collaborative program where industry representatives, academics, and others can meet with FDA officials to support the adoption and improve the development of innovative approaches to drug design and manufacturing. Requires FDA to issue guidance regarding requirements related to such approaches and report to Congress regarding allocation of funds and staff utilization in this program. Authorizes FDA to make grants to carry out the program and authorizes $20 million each year for fiscal year (FY) 2023 through FY 2027 to carry out the program.

Sec. 703. Improving the treatment of rare diseases and conditions.
Requires the Secretary of Health and Human Services to submit a report summarizing FDA's activities relating to designating, approving, and licensing drugs used to treat rare diseases no later than four years after enactment. Requires FDA to study processes for evaluating drugs for rare diseases in the United States and the European Union. Requires FDA to convene one or more public meetings to solicit input from stakeholders regarding approaches to improving engagement with rare disease condition patients, patient groups, and experts. Incorporates

experts on the science of small population studies in FDA's existing list of external consultants on rare disease drugs and biologics.

Sec. 704. Antifungal research and development.
Requires the Secretary to issue draft guidance to industry and hold a public workshop to assist entities seeking approval or licensure for antifungal therapies intended to treat and preventative vaccines for coccidioidomycosis, commonly known as Valley Fever.

Sec. 705. Advancing qualified infectious disease product innovation.
Allows for biological products to qualify as Qualified Infectious Disease Product (QIDP) and allows for priority review of innovative biological antifungal such products if such products require clinical data to demonstrate safety or effectiveness. Does not extend QIDP exclusivity to biological products.

Sec. 706. Advanced manufacturing technologies designation pilot program.
Requires FDA to initiate a pilot program to designate an advanced manufacturing technology. A method of manufacturing is eligible for designation if such method incorporates a novel technology or uses an established technology in a novel way that will substantially improve the manufacturing process and maintain equivalent or superior drug quality. Designated technologies qualify for expedited application development and review and allow the designated technology application holder, or a person authorized by the application holder, to reference or rely upon data and information in a drug or biologic application about the advanced manufacturing technology in the same context of use. Requires FDA to hold a public meeting, issue guidance, and report to Congress regarding this pilot, which sunsets in 2029.

Sec. 707. Public workshop on cell and gene therapies.
Requires FDA to convene a public workshop on best practices on generating scientific data necessary to facilitate development of human cell-, tissue-, and cellular-based medical products, and the latest scientific information about such products.

Sec. 708. Reauthorization of best pharmaceuticals for children.
Reauthorizes Best Pharmaceuticals for Children through 2027, which allows the National Institutes of Health to fund studies of off-patent drugs in children.

Sec. 709. Reauthorization for humanitarian device exemption and demonstration grants for improving pediatric availability.
Reauthorizes exemptions from certain requirements for devices designed to treat or diagnose a disease or condition that affects 8,000 or fewer individuals in the United States, if such device would not be available to patients without such exemption and probable benefits outweigh risk of injury or illness, through 2027. Reauthorizes demonstration grants for improving development of pediatric medical devices through 2027.

Sec. 710. Reauthorization of provision related to exclusivity of certain drugs containing single enantiomers.
Reauthorizes provisions granting exclusivity to certain single enantiomer drugs under certain conditions through 2027.

Sec. 711. Reauthorization of the critical path public-private partnership program.
Reauthorizes the Critical Path Public-Private Partnership at $10 million annually through 2027.

Sec. 712. Reauthorization of orphan drug grants.
Reauthorizes orphan drug grants through 2027 and expands uses of such grants to include the development of regulatory science and manufacturing and controls related to individualized medical products to treat those with rare diseases or conditions.

Subtitle B—Inspections

Sec. 721. Factory inspection.
Authorizes inspection of records for non-restricted devices and records requests in advance or in lieu of inspections of device establishments. Requires FDA to provide a rationale for any records requested and issue guidance regarding such requests. Codifies and clarifies FDA authority to inspect clinical study sites, also known as bioresearch monitoring inspections. Requires FDA to review its processes and practices applicable to such inspections in the United States and in foreign countries, evaluate whether updates are needed to facilitate consistency, and issue guidance describing the conduct of such inspections.

Sec. 722. Uses of certain evidence.
Clarifies that the limitation on FDA's use of certain evidence regarding product movement in interstate commerce obtained from carriers and receivers does not apply to information obtained under other authorities such as those authorizing inspections.

Sec. 723. Improving FDA inspections.
Enhances FDA's inspection tools and requires study of when and how those tools are used. Allows FDA to consider the compliance history of establishments in a country or region as a factor when establishing a schedule for risk-based inspections. Allows the Secretary to use any records or other information collected for the purposes of or in lieu of an inspection to satisfy requirements that may pertain to a preapproval or risk-based surveillance inspection, and to resolve deficiencies found in such inspections, if applicable and appropriate. Allows the recognition of foreign government inspections as sufficient for preapproval inspections if the Secretary has entered into an agreement with that foreign government. Requires a periodic assessment of whether additional arrangements with foreign governments are appropriate.

Sec. 724. GAO report on inspections of foreign establishments manufacturing drugs.
Requires the Government Accountability Office (GAO) report on FDA inspections of foreign establishments manufacturing drugs.

Sec. 725. Unannounced foreign facility inspections pilot program.
Requires FDA to conduct a pilot program in which FDA increases the conduct of unannounced surveillance inspections of foreign drug establishments, evaluates the differences between such domestic and foreign establishments, including the impact of announcing such inspections, and post a report of its findings and recommendations on the FDA website.

Sec. 726. Reauthorization of inspection program.
Reauthorizes third party accreditation program for inspections for five years, until 2027.

Sec. 727. Enhancing intra-agency coordination and public health assessment with regard to compliance activities.
Amends section 506D to require FDA to ensure timely and effective internal coordination and alignment among field investigators and staff regarding the reviews of inspection reports and any feedback or corrective actions. Also updates reporting requirements with respect to communication between field investigators and staff, including on procedures for enabling and ensuring such communication

Sec. 728. Reporting of mutual recognition agreements for inspections and review activities.
FDA is required to publish a public report, no later than the end of calendar year 2022 and annually thereafter, on the utilization of agreements entered into pursuant to section 809 of the Federal Food, Drug, and Cosmetic Act or otherwise entered into to recognize inspections between drug regulatory authorities across countries and international regions with analogous review criteria to the FDA.

Sec. 729. Enhancing transparency of drug facility inspection timelines.
Requires FDA to publicly post, not later than 120 days after the end of each fiscal year, information related to inspections of facilities, including inspections that are necessary for approval of a drug or device. Such information shall include the median time following a request from FDA staff reviewing an application to the beginning of an inspection, as well as the median time from the sending of a warning letter, issuance of an import alert, or holding of a regulatory meeting to resolution of the actions indicated to address the conditions or practices observed during an inspection.

Title VIII: Transparency, Program Integrity, and Regulatory Improvements

Sec. 801. Prompt reports of marketing status by holders of approved applications for biological products.
Requires all holders of approved Biologics License Applications to conduct a one-time report to confirm that their products listed in the Purple Book are still available for sale. Requires approved BLA holders to report to the Secretary when withdrawing a product from the market. Similar requirements are already in place for small molecule drugs on an ongoing basis.

Sec. 802. Encouraging blood donation.
Exempts from Paperwork Reduction Act requirements FDA information collections to solicit patient perspectives during medical product development and to solicit information from blood donors and potential blood donors to inform recommendations regarding blood donation.

Sec. 803. Regulation of certain products as drugs.
Deems all contrast agents, radioactive drugs, and over-the-counter monograph drugs to be drugs and not medical devices.

Sec. 804. Postapproval studies and program integrity for accelerated approval drugs.
Requires FDA to specify conditions for required postapproval studies for drugs approved under accelerated approval, which may include enrollment targets and milestones, including the target date for study completion, by the time the drug is approved. Authorizes FDA to require postapproval studies, which may be supported by real world evidence, to be underway at the time of approval for such drugs and requires FDA to explain any instances where it does not require such studies. Clarifies that existing authority to withdraw approvals where sponsors fail to conduct studies with due diligence applies with respect to the approval conditions and streamlines procedures for withdrawal of approval. To withdraw an accelerated approval, the FDA is required to include an explanation for the withdrawal, an opportunity for written appeal, a meeting with the Commissioner or the Commissioner's designee, provide for public comment, and, upon request, an advisory committee meeting if there was not one previously on the withdrawal. Codifies labeling requirements for accelerated approval and information on surrogate endpoints and requires more frequent reports on postapproval study progress. Requires FDA to report to Congress on use of real world evidence in postapproval studies, issue guidance on novel surrogate endpoints and trial designs, and establish a rare disease endpoint advancement pilot program.

Sec. 805. Facilitating the use of real world evidence.
Requires FDA to issue guidance addressing the use of real world evidence and real world data, including that obtained for drugs and devices authorized for emergency use during the COVID-19 public health emergency, to support drug and device approvals and clearances. Requires FDA to report to Congress regarding the number of applications submitted for which an emergency use authorization was previously granted and, of such applications, how many included real world evidence and whether such evidence was sufficient to support a regulatory decision.

Sec. 806. Medical devices advisory committee meetings.
Requires the Medical Device Advisory Committee to meet at least once a year through 2027 to provide FDA advice on topics related to medical devices in pandemic preparedness and response, including issues related to in vitro diagnostics.

Sec. 807. Ensuring cybersecurity of medical devices.
Requires manufacturers of cyber devices to develop processes to ensure their devices are secure, have plans to identify and address cybersecurity vulnerabilities, provide a software bill of materials in their labeling, and submit this information to FDA in premarket submissions. Defines cyber devices as devices that have software, connect to the internet, or otherwise could be vulnerable to cybersecurity threats. Authorizes FDA to deny 510(k) clearance if cyber security information is inadequate and to exempt types of devices from these requirements. Makes failure to comply a prohibited act.

Sec. 808. Public docket on proposed modifications to approved strategies.
Requires FDA to provide a public comment period regarding patient access and provider administration when a proposed modification to an approved risk evaluation and mitigation strategy (REMS) is reviewed under section 505-1(h).

Sec. 809. Facilitating exchange of product information prior to approval.
Provides that no drug or device shall be considered misbranded as a result of the provision of information regarding investigational drugs or devices or uses to payors, formulary committees, or other similar entities under specified conditions. Requires the information to include a clear statement that the drug or device it discusses has not been approved, and that the safety and efficacy of the drug or device has not been established. Additional required disclosures include information about studies the drug or device is undergoing, how the studies relate to the overall plan for the development of the drug or device, and whether an application for the drug or device has been submitted to FDA and when such submission is planned.

Sec. 810. Bans of devices for one or more intended uses.
Clarifies that FDA is authorized to ban a particular use of a medical device. Also bans shock devices (electrical stimulation devices) intended for self-injurious and aggressive behavior.

Sec. 811. Clarifying application of exclusive approval, certification, or licensure for drugs designated for rare disease or conditions.
Amends section 527 of the Food, Drug, and Cosmetic Act, regarding orphan drugs, to provide clarity that exclusivity applies only to the specific indication or use approved by FDA under this section, not the entire rare disease or condition for which the drug was designated, consistent with FDA's long-held interpretation of the law.

Sec. 812. GAO report on third-party review.
Requires GAO to report on the program for accrediting third-party reviewers for medical devices.

Sec. 813. Reauthorization of device pilot projects.
Reauthorizes device pilots under section 519(i) of the Federal Food, Drug, and Cosmetic Act, which include pilots to generate safety surveillance data through 2027.

Sec. 814. Reporting on pending generic drug applications and priority review applications.
Reauthorizes reporting on pending generic drug applications and priority review applications through 2027.