PRESCRIPTION DRUG USER FEE ACT (PDUFA) BACKGROUND

BACKGROUND:

Under the Federal Food, Drug and Cosmetic Act, the Food and Drug Administration (FDA) has long had the critically important responsibility of evaluating the safety and efficacy of drugs before they are marketed. Over the years this task has become enormous, involving a great number of complex regulatory filings each year of increasing scientific complexity.

With the resources available to the agency in the early 1990s, FDA was unable to manage its mounting drug review workload in a timely manner. A consequence of this backlog was the alarming amount of time that it took new drugs to come to market. Although FDA was statutorily mandated to review most new drug applications (NDAs) within 180 days from time of submission, by 1992 the agency was averaging over three times as long. Since pharmaceutical companies are required to complete a much lengthier process of pre-clinical and clinical testing prior to submitting their application to FDA for marketing approval, patients were forced to wait an average of 12 years from the commencement of a drug's development to FDA approval, and many drugs were approved abroad before becoming available to U.S. patients. This "drug lag" became a significant concern for patients, Congress and the industry.

In order to make the drug approval process more efficient and get lifesaving medicines to patients faster, Congress worked on a bipartisan basis with the FDA, patient groups, and industry to craft a remedy that would bolster FDA resources while preserving agency fiscal and management discipline – and agency decision-making independence. The remedy was a framework for user fees, paid by pharmaceutical manufacturers, with funds dedicated to enlarging the FDA workforce and infrastructure committed to new drug reviews.

After some debate, strong bipartisan and industry support for drug user fees emerged when agreements were reached that: (1) the user fees must be reasonable; (2) revenues must be entirely dedicated to improvement of the review process; and (3) the user fees must be part of a broader, long-term commitment by the FDA to reform the approval process and meet specific drug review target goals.

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA I). Since then, PDUFA has been reauthorized six times, each time on a five-year cycle and each time with strong bipartisan support: by the Food and Drug Administration Modernization

Act of 1997 (PDUFA II); the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PDUFA III); the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (PDUFA IV); the Food and Drug Administration Safety and Innovation Act of 2012 ("FDASIA") (PDUFA V); the FDA Reauthorization Act of 2017 ("FDARA") (PDUFA VI); and most recently the FDA User Fee Reauthorization Act of 2022 (PDUFA VII). PDUFA VII governs fiscal years 2023 through 2027 and is scheduled to expire on September 30, 2027. FDA, industry, patient groups and other stakeholders are already engaged in the negotiations required to reauthorize the program as PDUFA VIII for fiscal years 2028 through 2032.

WHAT IS PDUFA?

PDUFA allows the FDA to collect user fees from the innovator pharmaceutical industry in order to hire additional drug reviewers and safety specialists and fund other efforts, such as upgrading drug safety surveillance and information technology, which in turn has improved the prescription drug review process and enhanced safety. User fees do not substitute for Congressional appropriations and therefore increase the total resources available to FDA to conduct human drug reviews. User fees also do not change any safety standards or compel FDA to take any short cuts in conducting drug reviews. Successive reauthorizations have expanded the FDA's authority to use PDUFA funds for authorized regulatory activities throughout the life cycle of a drug or biologic, including post-market drug safety activities such as adverse event data collection; the development of improved tools for assessing potential safety problems; and implementing and enforcing requirements for post-approval safety studies, new clinical trials, labeling changes, and Risk Evaluation and Mitigation Strategies (REMS).

WHY WAS PDUFA ENACTED?

PDUFA was enacted to bring new medicines to Americans more quickly. With the resources available to the FDA when PDUFA was first enacted — more than 30 years ago — FDA was unable to manage its mounting drug review workload in a timely fashion. In the late 1980s, just prior to the enactment of PDUFA I, drug reviews took a median time of 29 months. As a result, over 70 percent of all new medicines were first marketed overseas, and almost 60 percent were on the market abroad for more than one year before being approved in the U.S.

Congress enacted PDUFA I with the full support of FDA and industry to provide FDA with the necessary funds to review NDAs and biologics license applications (BLAs) more

quickly and efficiently. Congress has continued to amend PDUFA to further improve drug review times and, based upon specific performance goals, to get drug products to patients faster. Each subsequent reauthorization has refined those performance goals and broadened the program's mission. Over more than three decades, that structure has produced a dramatic and durable turnaround: the "drug lag" has been substantially eliminated, and the United States is now routinely among the first countries in the world to approve new medicines.

HOW IS PDUFA REAUTHORIZED?

PDUFA operates on a five-year cycle and must be periodically reauthorized by Congress; the current authorization, PDUFA VII, expires on September 30, 2027. The reauthorization of PDUFA is necessary to ensure that this successful program continues without interruption or delay and to ensure continued access to critical new medicines for the American public.

As a practical matter, if PDUFA is not reauthorized before it expires, FDA loses its authority to collect the user fees that fund a substantial share of the human drug review program. In past reauthorization cycles, the approach of the expiration date has meant that layoff notices were prepared for thousands of FDA drug reviewers, threatening to disrupt the drug approval process. Departures of FDA employees in the face of impending layoffs could significantly disrupt Agency operations — thereby increasing the amount of time that American patients must wait for new medicines to be approved.

HOW HAS PDUFA CHANGED SINCE IT WAS FIRST ENACTED?

PDUFA I (FY 1993–1997):

PDUFA I was enacted on October 29, 1992. The program was set to expire on September 30, 1997. PDUFA I was expected to raise $327 million over five years, with one-third of the total annual revenue coming from each of the following fees:

- **Application Fees:** Fees paid at the time of submission for a NDA, BLA, or supplement.
- **Establishment** Fees: Fees paid annually by companies that manufacture at least one approved prescription drug for which no generic versions are available. Such fees are levied for each manufacturing site producing prescription drug products in final dosage form.
- **Product Fees:** Annual fees for marketed drugs for which no generic versions are available.

FDA claimed that PDUFA would enable the agency to reduce new drug approval times from 20 months to 12 months and permit it to institute a priority review for drugs that would take as little as 6 months. By 1996, review times for drug applications had fallen to 15 months, a considerable improvement.

PDUFA II (FY 1998–2002):

In 1997, the Food and Drug Modernization Act (FDAMA) incorporated PDUFA II. FDAMA reauthorized PDUFA for an additional five years, with PDUFA II expiring on September 30, 2002.

The Congressional Budget Office (CBO) estimated that the additional increase in fees under PDUFA II (user fees were increased by 21 percent) would bring in $601 million over five years. FDA staff dedicated to reviews increased by over 85 percent during the 10 years since PDUFA was enacted, from 1,277 full time equivalents (FTEs) in 1992 before PDUFA was enacted to 2,365 FTEs by 2002.

PDUFA III (FY 2003–2007):

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 extended PDUFA through September 30, 2007 (PDUFA III).

PDUFA III placed great emphasis on ensuring that user fees provide a sound financial footing for FDA's new drug and biologic review process and, for the first time, gave FDA authority to expend PDUFA resources on risk management and drug safety activities during the approval process and during the first two to three years following drug approval. Beginning with PDUFA III, for drugs approved after October 1, 2002, the FDA could spend PDUFA resources on "collecting, developing, and reviewing safety information on drugs, including adverse event reports" for up to three years after the date of approval.

The planned fee collections and spending over the five-year period covering PDUFA III totaled a little over $1.25 billion. Funding from PDUFA III was sufficient to sustain the staff years supported in FY 2002 and to add several hundred additional FTEs. Because of the additional resources and process improvements implemented, the average FDA drug review time continued to decline.

PDUFA IV (FY 2008–2012):

The Food and Drug Administration Amendments Act of 2007 ("FDAAA") reauthorized PDUFA for an additional five years, with PDUFA IV expiring on September 30, 2012.

Under PDUFA IV, user fees were increased to ensure adequate funding for drug review; the planned fee collections and spending over the five-year period totaled over $1.96 billion, including $225 million designated specifically for post-market drug safety activities. PDUFA IV significantly expanded the FDA's authority to use PDUFA funds for post-market drug safety activities throughout the life cycle of a drug or biologic. It expanded the range of those activities to include improved adverse-event data collection systems and analytical tools to assess potential safety problems, and it provided resources to implement new requirements regarding post-market studies and clinical trials, safety labeling changes, and Risk Evaluation and Mitigation Strategies (REMS). PDUFA IV also provided substantial funding for drug safety initiatives, including the Sentinel Initiative.

PDUFA V (FY 2013–2017):

The Food and Drug Administration Safety and Innovation Act (FDASIA) reauthorized PDUFA for an additional five years, with PDUFA V expiring on September 30, 2017.

PDUFA V set FY 2013 fee revenue at a base of approximately $693 million — about a 6 percent increase over FY 2012 — adjusted annually for inflation and workload. Beyond funding, PDUFA V introduced significant program enhancements. It established a new review model for new molecular entity (NME) NDAs and original BLAs — known as "the Program" — featuring additional pre-submission and mid-cycle communication between FDA and sponsors to improve the efficiency, predictability and transparency of reviews. PDUFA V also formalized FDA's commitment to a structured benefit-risk assessment framework; launched the patient-focused drug development initiative, committing FDA to a series of disease-specific public meetings to systematically gather patient perspectives; strengthened FDA's regulatory science and drug safety capacity; and advanced the use of electronic submission standards.

PDUFA VI (FY 2018–2022):

The FDA Reauthorization Act of 2017 (FDARA) reauthorized for an additional five years, with PDUFA VI expiring on September 30, 2022.

PDUFA VI restructured the user fee system for the first time in the program's history. The three-fee model used since PDUFA I — application, establishment, and product

fees — was simplified to two fees: a one-time application fee paid when a marketing application is submitted (removing supplement fees), and an annual prescription drug program fee assessed on each approved prescription drug product. PDUFA VI set annual base revenue at approximately $878.6 million, adjusted for inflation, capacity planning, and an operating reserve. The agreement also enhanced FDA's capacity-planning and financial-transparency practices, modernized the agency's hiring and information-technology capabilities, and continued enhancements in patient-focused drug development, the use of real-world evidence, biomarker qualification, and the review of combination products.

PDUFA VII (FY 2023–2027):

The FDA User Fee Reauthorization Act of 2022 incorporated PDUFA VII, reauthorizing PDUFA for an additional five years, with PDUFA VII scheduled to expire on September 30, 2027.

The base revenue amount for FY 2026 is approximately $1.43 billion, adjusted for inflation and other factors. PDUFA VII focuses the program on the next generation of drug development. Key commitments include expanding FDA's capacity to review the rapidly growing pipeline of cell and gene therapies and other advanced biological products; advancing the use of real-world evidence and innovative clinical trial designs; supporting the development and qualification of biomarkers and other drug development tools; promoting manufacturing readiness and the adoption of innovative manufacturing technologies; strengthening rare disease drug development; and modernizing FDA's data and information technology infrastructure. PDUFA VII also extended the program to allergenic extract products licensed after October 1, 2022, and exempted certain skin-test diagnostic products from user fees.

PDUFA VIII (FY 2028–2032):

The next iteration of PDUFA is currently under development, with negotiations between FDA and industry occurring from November 2025 through May 2026. The PDUFA VIII draft commitment letter is expected to become public in late summer 2026. Following publication of the draft commitment letter, FDA will host a public meeting to receive stakeholder feedback. Congress will receive the final letter by January 15, 2027 and must pass authorizing legislation before PDUFA VII expires on September 30, 2027 so that PDUFA can continue and American patients can continue to reap the benefits.

HAS PDUFA BEEN A SUCCESS?

Over more than three decades, PDUFA has transformed FDA drug review from a process plagued by delay into one of the fastest and most predictable in the world. Standard applications are now reviewed within the 10-month goal and priority applications within the 6-month goal, measured from the 60-day filing date. The "drug lag" that once sent most new medicines to overseas markets first has been substantially eliminated, and the United States is now routinely the first country to approve new drugs for patients. In 2025, FDA approved 46 novel drugs, nearly half of them first-in-class therapies. User fees now provide over 75% of the funding for FDA's human drug review program.