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Senate HELP Committee Holds Hearing on Food and Drug Administration User Fee Agreements

On March 21, the Senate Health, Education, Labor and Pensions (HELP) Committee held its first hearing on the Food and Drug Administration (FDA) user fee agreements for prescription drugs (PDUFA), medical devices (MDUFA), generic drugs (GDUFA) and biosimilars (BsUFA). These four user fee agreements will expire on Sept. 30 absent congressional reauthorization.

Key themes from the hearing are summarized below:

- **American Health Care Act (AHCA):** In the days leading up to the hearing, the committee's Democrats sent a letter to HELP Committee Chairman Lamar Alexander, R-Tenn., requesting that he postpone the user fee agreement hearing and allow the committee to instead consider the AHCA. The Chairman declined, causing the committee's Democrats to voice their strong disappointment that the committee, which has jurisdiction over key parts of the Affordable Care Act, would not have the opportunity to debate the AHCA.
- **PDUFA:** Witnesses said that PDUFA supports innovation and fosters faster, more predictable review for innovative therapies, including for orphan conditions. The agreement will also support the breakthrough therapy program, surrogate end points and accelerated drug development tools including biomarkers and added support for complex clinical trial designs. In addition, PDUFA will support the evaluation of real-world evidence, which was included as part of the 21st Century Cures Act that former President Obama signed into law in December 2016.
- **BsUFA:** According to witnesses, BsUFA "established the biosimilar industry." A witness from the FDA said that the agency hopes the program will continue to grow. To date, the FDA has approved four biosimilar products, with an additional 64 in development programs.
- **GDUFA:** Witnesses said that the primary purpose of GDUFA is to support affordability and noted that GDUFA I saved Americans US$1.5 trillion over a 10-year span. The new GDUFA agreement, GDUFA II, will include provisions to advance priority review of generic drugs and provide for predevelopment activities with the industry for complex generic drugs.

- **MDUFA:** According to witnesses, MDUFA has led to a significant reduction in the amount of time it takes for the agency to approve applications for medical devices. The new MDUFA agreement, MDUFA IV, contains programmatic enhancements, allows the FDA to strengthen partnerships with patients and promotes patient-centered clinical trials.
- **Prescription Drug Prices:** Democratic members raised the issue of drug prices and asked the FDA witness to comment on the success of the generic drug program. Although 2,300 generic drug applications are pending at the FDA, only six are for first type generics and only nine are generics for a sole-source drug.
- **Consequences of Failing to Reauthorize the User Fee Agreements:** Witnesses noted that failing to reauthorize the four expiring user fee agreements would trigger a notice process to alert "thousands" of FDA employees of potential termination. The agency would also be unable to hold meetings in a timely manner, and approval times for drugs and medical devices would be "severely adversely impacted."

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work or

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