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House Energy and Commerce Subcommittee Holds Hearing on Food and Drug Administration Prescription Drug User Fees

On March 22, the U.S. House of Representatives Energy and Commerce Health Subcommittee held a hearing on the reauthorization of the Prescription Drug User Fee Act (PDUFA). The committee's leaders, Health Subcommittee Chairman Dr. Michael Burgess, R-Texas, and full committee Chairman Greg Walden, R-Ore., stated that they expect Congress will pass reauthorization legislation for the four expiring user fee agreements for prescription drugs, generic drugs, medical devices and biosimilars through regular order and in advance of the four programs' Sept. 30 expiration date.

Burgess noted that the new PDUFA agreement, PDUFA VI, contains many provisions complementary to policies in the 21st Century Cures Act, signed into law by former President Obama in December 2016, including a formalized structure to incorporate patient experience in the approval process, modernized clinical trials, the use of real-world evidence and biomarkers.

Key points made during the hearing include the following:

- **PDUFA VI Policy Proposals:** PDUFA VI will support biomarker qualification, encourage broader use of surrogate endpoints, advance clinical trial design and promote the use of real-world evidence in the drug approval process. The agreement will foster better communication with the industry during the drug development process and will make necessary administrative improvements, including additional oversight and reporting at the Food and Drug Administration (FDA).
- **Rare-Disease Therapies:** Witnesses said that PDUFA VI contains several key provisions that will benefit patients with rare diseases, including provisions to promote patient-centered drug development and an agency commitment to include rare-disease experts in drug review teams.
- **Administration Hiring Freeze:** Rep. Fred Upton, R-Mich., discussed a bipartisan letter that he and Rep. Diana DeGette, D-Colo., sent to the White House Office of Management and Budget regarding the impact of the administration's hiring freeze on the FDA. A witness from the FDA emphasized that the new focus on patient-centered drug development, the use of real-world evidence

as part of the approval process and the inclusion of rare-disease staff on review teams will require FDA to recruit different types of scientists and will require additional revenue.

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

Stephanie P. Hales
Partner
shales@sidley.com
+1 202 736 8349

Dora Hughes, M.D., M.P.H.
Senior Policy Adviser
dhughes@sidley.com
+1 202 736 8653

Laura R. Cohen
Policy Attorney
laura.cohen@sidley.com
+1 202 736 8127

Meghan F. Weinberg
Associate
mweinberg@sidley.com
+1 202 736 8129

Sidley Government Strategies Practice

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