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March 15, 2017

House Health Subcommittee Holds Hearing on User Fee Program Reauthorizations and Generic Drug Competition Bill

The U.S. House of Representatives Energy and Commerce Health Subcommittee held a hearing March 2 to consider reauthorization of the Food and Drug Administration (FDA) generic drug and biosimilar user fee programs as well as H.R. 749, the Lower Drug Costs Through Competition Act, which was introduced Jan. 30 by Reps. Gus Bilirakis, R-Fla., and Kurt Schrader, D-Ore.

The generic drug and biosimilar user fee programs (GDUFA and BsUFA, respectively) as well as the prescription drug and the medical device user fee programs (PDUFA and MDUFA, respectively) are set to expire on Sept. 30, absent reauthorization. At the March 2 hearing, Subcommittee Chairman Michael Burgess, R-Texas, noted that all four user fee programs appear to be on track for timely reauthorization.

Key points made during the hearing included the following:

- **Reauthorization for the Generic Drug User Fee Amendments (i.e., GDUFA II):** GDUFA II includes new communication pathways for companies preparing applications for complex generics to improve the chance that a complex generic drug application is approved during the first cycle of review. The FDA witness at the hearing noted difficulties with meeting shorter review timelines, including the challenge of inspecting generic drug manufacturing facilities located around the world. Certain committee members and other witnesses also raised concerns about policies perceived as reducing the FDA's current safety and effectiveness standards.
- **H.R. 749, The Lower Drug Costs Through Competition Act:** This bill would establish a six-month priority review process for generic drug applications for drug products with limited supply and/or limited competition; it also would create a priority review voucher program for review of a second generic drug application. At the hearing, Rep. Bilirakis, a lead co-sponsor of the bill, expressed his hope that the committee would move the bill this month. The bill also would require a study of risk evaluation and mitigation strategy (REMS) programs. In discussing issues of potential abuse of REMS programs, as raised by several subcommittee members during the hearing, a panelist

from the Association for Accessible Medicines opined that the issue would be better addressed by a legislative fix rather than the current bill's requirement for another study. A witness from the Pew Charitable Trusts also questioned the practical benefit of a six-month priority review process for generic drug applications when other priority review programs are already available. The need for further development of the biosimilars market as a way to address drug costs was also discussed.

- **Concerns regarding pharmacy benefit managers (PBMs):** Rep. Buddy Carter, R-Ga., the only pharmacist in Congress and co-chair of the House Community Pharmacy Caucus, raised concerns about PBMs and their role in high drug prices. Rep. Carter specifically mentioned the lack of transparency in the negotiations and contracts and the lack of competition among PBMs.

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

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