Congress Begins Process of Reauthorizing Prescription Drug User Fee Act

March 16, 2017

Timely reauthorization of the Prescription Drug User Fee Act (PDUFA) was one of the hot issues discussed during the Legislative Conference during Rare Disease Week on Capitol Hill.

First enacted in 1992, PDUFA enables the Food and Drug Administration (FDA) to collect user fees from biopharmaceutical companies in order to enable the Agency to review the safety and efficacy of new medicines more quickly. According to PhRMA, it took FDA more than two years to review new medicines and more than 70% of medicines were approved outside of the U.S. before PDUFA.

Every five years, FDA and the biopharmaceutical industry negotiate a new user fee agreement, which Congress must enact in legislation. PDUFA was reauthorized in 2012 in the Food and Drug Administration Safety and Innovation Act, which also included provisions creating the Breakthrough Therapy designation as well as the Rare Pediatric Disease Priority Voucher program. PDUFA is due to be reauthorized this year, as the current user fee agreement expires on September 30th.

Released last year, the draft PDUFA VI agreement includes specific performance goals for drug review, proposed plans for enhanced use of biomarkers, expanded patient engagement, and improved specialization of reviewers for rare diseases.

The Senate Health, Education, Labor and Pensions Committee will convene a hearing on PDUFA reauthorization on March 21st at 10am ET with testimony from senior FDA leadership, and will be available by livestream. The House Energy and Commerce Subcommittee on Health will hold a hearing on PDUFA on March 22nd at 10:15am.

As discussed on the March webinar, it is important for PDUFA to be reauthorized by the end of July or FDA will need to send furlough notices to staff who review new medicines.

http://rareadvocates.org/congress-begins-process-of-reauthorizing-prescription-drug-user-fee-act/