Agenda

Process Update

• Background
• Usual Reauthorization Process

E&C Draft

• We have a draft!
• What’s in it?

Next Steps

• Expected House and Senate schedules
Process Update
FDA Drug and Medical Device User Fees Overview

FDA review of medical products is funded through a combination of annual discretionary appropriations from Congress and user fees collected from the industry.

- User fee amendment programs require Congressional reauthorization every five years.
  - UFAs expire at the end of September 2022, but Congress wants to finish work by end of July to avoid “pink slip” issue at FDA.

- Major user fee programs
  - **Prescription Drug User Fee Act (PDUFA)**
    - Seventh reauthorization
  - **Generic Drug User Fee Act (GDUFA)**
    - Third reauthorization
  - **Medical Device User Fee Act (MDUFA)**
    - Fifth reauthorization
  - **Biosimilar User Fee Act (BsUFA)**
    - Third reauthorization
**Usual FDA User Fee Reauthorization Legislative Process**

**HOUSE COMMITTEE ON ENERGY & COMMERCE**

- FDA commitment letters are transmitted to E&C
- E&C legislative hearings
- E&C Health Subcommittee Markup
- Full Committee Markup
- House Floor

**HELP Committee Markup**

- “Informal” Negotiations
- Senate Floor

- Senate Floor

**FDA**

- FDA commitment letters are transmitted to HELP
- HELP legislative hearings

**U.S. SENATE COMMITTEE ON Health, Education Labor & Pensions**
E&C Draft
FOR IMMEDIATE RELEASE
May 4, 2022

E&C Leaders Unveil FDA User Fees Legislative Package

Bipartisan Agreement Will Support Innovation, Lower Costs, and Improve People’s Lives

Washington, D.C. – Energy and Commerce Committee Chairman Frank Pallone, Jr. (D-NJ), Ranking Member Cathy McMorris Rodgers (R-WA), Health Subcommittee Chairwoman Anna G. Eshoo (D-CA), and Health Subcommittee Ranking Member Brett Guthrie (R-KY) today unveiled a comprehensive legislative package to reauthorize the Food and Drug Administration (FDA) user fee agreements. Eshoo and Guthrie will introduce the “Food and Drug Amendments of 2022” this week, which the Health Subcommittee intends to mark up next week.

The legislative package reauthorizes the Prescription Drug User Fee Act (PDUFA), the Generic Drug User Fee Act (GDUFA), the Biosimilar User Fee Act (BsUFA), and the Medical Device User Fee Act.
What’s in the Draft?

• User Fee Reauthorizations
  • PDUFA
  • MDUFA
  • GDUFA
  • BSUFA

• Riders
  • Accelerated Approval
  • Clinical trial diversity
  • Inspections
  • Policies included every five years
Next Steps
Next Steps

• E&C will move forward with markups, likely next week and the following week.

• HELP expected to move forward shortly.

• Great deal of work has been done already, but more work, negotiations, and potential hurdles ahead.

• Goal is to enact by August 1, if possible.