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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 (MDUFA). In addition, the bipartisan agreement includes many provisions led by Energy and Commerce Committee members to support patients by lowering costs and providing a clear path for innovators, such as improvements and program integrity for Accelerated Approval, requirements regarding clinical trial diversity, policies to improve generic drug competition, and authorities to strengthen supply chains through accountability in FDA's inspections programs.

"The Food and Drug Amendments will allow FDA to continue its critical mission of reviewing and approving drugs and medical devices that save lives and improve the quality of life for Americans," Pallone, Rodgers, Eshoo, and Guthrie said. **"We are proud of this final agreement and the hard work by all our colleagues that went into building bipartisan consensus on a bill that achieves so much and can earn broad support in Congress.**

"In addition to providing FDA with authority to collect user fees to fulfill its mission, the bill includes new provisions that will strengthen the Accelerated Approval pathway and help ensure clinical trials better represent the diverse patients that need these products. The agreement will also lower drug costs through more competition and improve oversight of supply chains.

"We will continue to work together to finalize the bill in the weeks ahead, starting with a vote in the Health Subcommittee next week. We look forward to advancing this legislation out of the Committee soon so that we can send a final bill to the President's desk for signature before August," the four Committee leaders concluded.

The bipartisan Eshoo-Guthrie legislative package includes provisions that will:

- Make improvements to FDA's review for safety and efficacy of medical products, including cell and gene therapies, drugs for rare diseases, and novel medical devices;
- Strengthen program integrity for the Accelerated Approval pathway and preserve patient access to approved treatments by ensuring that drugs show clinical benefit through post-approval studies in a timely manner and streamlining the process for withdrawing approvals for drugs that fail to show a clinical benefit;

- Ensure clinical trials are representative of diverse populations by requiring drug and medical device manufacturers to submit clinical trial diversity action plans to FDA early in their development process;
- Bring down drug costs by making it easier for generic competition to enter the market; and
- Provide FDA tools to ensure the agency can conduct thorough safety inspections efficiently.

Legislative text is available HERE.

A Section-by-Section is available HERE.

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