**Statement for the Record**
**American College of Physicians**
**Hearing before the House Energy and Commerce Subcommittee on Health**
**"FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics"**
**February 3, 2022**

The American College of Physicians (ACP) is pleased to submit this statement and appreciates that Chairman Pallone and Chairwoman Eshoo are holding this hearing to examine legislation reauthorizing user fee agreements, which allow for the timely review and approval of medications by the U.S. Food and Drug Administration (FDA). These agreements are set to expire this year and they are vital to ensuring the safety and efficacy of medications in this country. We hope that this important hearing will lead to broader bipartisan discussions to increase access to necessary and often life-saving prescription drugs and treatments for patients at an affordable cost. We are pleased to offer our perspective on underlying policies applicable to the three legislative proposals under consideration today, as they pertain to brand name prescription drugs, generic drugs, and biosimilar drugs.

The American College of Physicians is the largest medical specialty organization and the second-largest physician membership society in the United States. ACP members include 161,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. Internal medicine specialists treat many of the patients at greatest risk from COVID-19, including the elderly and patients with pre-existing conditions like diabetes, heart disease and asthma.

**ENSURING SAFE AND EFFECTIVE MEDICATIONS**

Prescription drug development is a complex process that includes the discovery and development of new drug compounds, research, testing, review, approval, and post marketing surveillance. According to the Biotechnology Innovation Organization, the United States produces more new drugs (57 percent) than the United Kingdom, Japan, Germany, and France combined (28 percent), as noted in ACP's 2020 position paper entitled, *Policy Recommendations to Promote Prescription Drug Competition.*

The FDA follows a very rigorous process to ensure that all medications are safe and effective for consumers, and this includes an accelerated approval process to bring innovative drugs and devices to market faster through user fee agreements with manufacturers. User fees are paid by biopharmaceutical and medical device companies to facilitate the agency's regulation and

review of prescription drugs, generic drugs, and medical devices. User fees have grown to provide the FDA with nearly half of its $6 billion budget. Without these resources, the FDA would be forced to significantly curtail the number of prescription drugs and other medical products it reviews each year.

Americans look to the FDA as the gold standard for getting life-sustaining and life-saving medications to consumers in a safe, effective, and timely way. This has never been more evident than during the global fight against the coronavirus and the development of vaccines and treatments to combat it. ACP believes it is vital to improve the FDA's ability to approve and monitor prescription drugs through increased funding and support efforts to regulate drugs manufactured outside the U.S. through both appropriations and user fees. ACP opposes any efforts to weaken FDA authority to demand rigorous evaluations of drugs and medical devices for both safety and effectiveness based on sound scientific and medical evidence and opposes legislative attempts to curtail FDA authority to establish and maintain standards of safety and effectiveness for approval of drugs and medical devices. We must realign incentives that reward true innovation, prevent manufacturers from exploiting loopholes, and address business practices that lead to increased costs to the health care system. This will increase the availability of lower-cost drugs in the marketplace, lower out-of-pocket costs for patients, and help drive down the price of prescription drugs.

**Prescription Drug User Fee Amendments of 2022 (PDUFA)**

PDUFA was created by Congress in 1992 and authorized the FDA to collect fees from companies that produce certain human drug and biological products. Since the passage of PDUFA, user fees have played an important role in expediting the drug approval process. On August 16, 2021, the FDA announced the Prescription Drug User Fee Rates for Fiscal Year 2022 in the Federal Register. These fees apply to the period from October 1, 2021, through September 30, 2022. The PDUFA of 2022 would reauthorize user fees for prescription drugs for an additional five years.

- **Transparency**: ACP urges the subcommittee to consider including in PDUFA Title IV of *the Elijah E. Cummings Lower Drug Costs Now Act* (H.R. 3). This title establishes mandatory reporting requirements applicable to manufacturers if they increase the price of a prescription drug by 10 percent or more over a 12-month period, or by 25 percent or more over a 36-month period, or if the estimated price of a qualifying drug for an applicable year per course of treatment is at least $26,000. ACP policy supports transparency in the pricing, cost, and comparative value of all pharmaceutical products. Pharmaceutical companies should disclose actual material and production costs to regulators, research and development costs contributing to a drug's pricing, including those drugs which were previously licensed by another company. Rigorous price transparency standards should be instituted for drugs developed from taxpayer-funded basic research.

- **Advertising**: ACP urges the subcommittee to consider including in PDUFA the *End Taxpayer Subsidies for Drug Ads Act* (S. 141). This legislation would prohibit a tax deduction for expenses for direct-to-consumer advertising of prescription drugs, thus eliminating the deduction that pharmaceutical companies use to pay for drug advertising. ACP believes that direct-to-consumer advertising of prescription drugs is an inappropriate practice that undermines the patient-physician relationship and often leaves patients confused and misinformed about medications. The FDA should play a stronger role in ensuring that complete, valid, and clear information is provided to the public and in making determinations about whether the commercial information in a DTC ad actually will educate and enhance the health of the public. Furthermore, Congress should give the FDA the authority to issue regulations that require review and approval of the content of any DTC advertisement prior to it being released to the public.

**Generic Drug User Fee Amendments of 2022 (GDUFA)**

GDUFA was created by Congress in 2012 to ensure patients have access to safe, high-quality, and affordable generic drugs. GDUFA enables the FDA to assess industry user fees to bring greater predictability and timeliness to the review of generic drug applications. On July 28, 2021, the FDA announced the Generic Drug User Fee Rates for Fiscal Year 2022 in the Federal Register. These fees apply to the period from October 1, 2021, through September 30, 2022. The GDUFA of 2022 would reauthorize user fees for generic drugs for an additional five years.

ACP urges the subcommittee to consider including in GDUFA *the Protecting Consumer Access to Generic Drugs Act of 2021* (H.R. 153). This legislation would prohibit brand name drug manufacturers from compensating generic drug manufacturers to delay the entry of a generic drug into the market (pay-for-delay) and would prohibit biological product manufacturers from compensating biosimilar and interchangeable product manufacturers to delay entry of biosimilar and interchangeable products. ACP policy supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products. ACP believes applicable federal agencies should be empowered through guidance, congressional action, or additional resource support to address anticompetitive behaviors and gaming.

**Biosimilar User Fee Amendments of 2022 (BsUFA)**

BsUFA was created by Congress in 2012 and authorized the FDA to assess and collect fees from drug companies that submit marketing applications for certain biosimilar biological products. On July 28, 2021, the FDA announced the Biosimilar Drug User Fee Rates for Fiscal Year 2022 in the Federal Register. These fees apply to the period from October 1, 2021, through September 30, 2022. The BsUFA would reauthorize user fees for biosimilars for an additional five years.

Biosimilar drugs are products that have only minor variations in clinically inactive components versus biologic (reference) products and have no clinically meaningful differences in safety,

purity, or potency compared with a reference product. In a sense, they offer the same benefits of generic drugs. However, because they are developed from a biological source rather than a chemical entity, are not approved under an abbreviated new drug application (ANDA) and are not considered interchangeable unless they meet the additional criteria for interchangeability from the FDA, biosimilars are not considered "generics" of biologic reference products. The Affordable Care Act included provisions to encourage market competition for biosimilar drugs. As part of the ACA, biologic drugs are awarded 12 years of combined data and marketing exclusivity during which no biosimilar can enter the market.

ACP urges the subcommittee to consider including in BsUFA a provision to reduce the period of data and market exclusivity for biologic drugs from 12 years to seven years. ACP also supports removing additional barriers to biosimilar market entry, such as modifications to the current patent system that would reduce excessive patenting on brand-name and biologic drugs.

**STRENGTHENING THE SUPPLY CHAIN OF VITAL MEDICATIONS**

ACP also urges the subcommittee to consider additional measures germane to this hearing to help the federal government respond to future pandemics, including facilitating the procurement and availability of pandemic-related vaccines and other antiviral medications in the Strategic National Stockpile. The FDA has always played a central role in the federal response to public health emergencies.

ACP supports the national procurement of vaccines in an amount sufficient to protect the entire U.S. population and national procurement of antiviral medications to cover 25 percent of the U.S. population. ACP believes that additional courses of antiviral medications should be safeguarded in the Strategic National Stockpile for all public safety officers and health care workers with direct patient contact in amounts sufficient to provide prophylaxis. In the event of a pandemic, stockpiled vaccines and antivirals should be distributed equitably to all states' public health authorities based on the numbers of people in high-risk and high-priority groups.

ACP is encouraged by draft legislation currently under consideration in the Senate Health, Education, Labor & Pensions Committee entitled the PREVENT Pandemic Act that addresses the need for this improved readiness. Specifically, ACP supports the following provisions as outlined in that draft legislation:

- Title I would establish a 12-member ''National Task Force on the Response of the United States to the COVID–19 Pandemic'' that would review the United States' response to the COVID-19 pandemic. ACP believes it is essential that the commission include physicians with expertise in pandemic preparedness and response, including primary care physicians who have been on the frontlines of treating patients with COVID-19.
- Title IV would improve coordination and communication among private sector entities and the FDA to ensure that medical countermeasures can be rapidly manufactured when needed to respond to public health emergencies.

- Title V would clarify FDA's authority to consult with third parties to evaluate and make recommendations with respect to the validity, accuracy, and reliability of in vitro diagnostic tests for use during a public health emergency, which will enable the FDA to prioritize its response efforts where needed during future emergencies.
- Title V provides the FDA with authority to share more safety and effectiveness information with the public about products authorized for emergency use.

**CONCLUSION**

We appreciate this opportunity to offer our input on legislative proposals before this subcommittee to reauthorize user fee programs within the FDA. As lawmakers deliberate on these important policies, we urge you to keep in mind what is in the best interests of patients and their ability to access high quality, affordable medications. Should you have any additional questions, please contact Jonni McCrann at jmccrann@acponline.org.