American College of Physicians
Leading Internal Medicine, Improving Lives

May 20, 2022

The Honorable Patty Murray
Chair
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

Dear Chair Murray and Ranking Member Burr:

On behalf of the American College of Physicians (ACP), I am pleased to offer our views regarding the discussion draft of the ''Food and Drug Administration Safety and Landmark Advancements Act of 2022'' or the ''FDASLA Act of 2022'' released on May 17, 2022. This discussion draft would reauthorize the U.S. Food and Drug Administration's (FDA) user fee programs which will expire later this year without congressional action. Failure to reauthorize these agreements in a timely manner could lead to the FDA being unable to review and approve new prescription-drug medications. ACP therefore greatly appreciates that the Health, Education, Labor and Pensions (HELP) Committee has moved swiftly to release this discussion draft since holding the "FDA User Fee Agreements: Advancing Medical Product Regulation and Innovation for the Benefit of Patients" hearing on April 5, 2022. At that time, ACP offered our perspective on underlying policies as they pertain to brand name prescription drugs, generic drugs, and biosimilar drugs. ACP also shared these views with the Health Subcommittee of the House Committee on Energy and Commerce for a hearing entitled, "FDA User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics" held on February 3, 2022. Please find below ACP's feedback about specific sections of the FDASLA Act of 2022 discussion draft.

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.

Fees Relating to Generic Drugs

ACP policy supports encouragement of the use of lower-cost generic (or biosimilar drugs) by the Medicare program to achieve savings for Medicare and its beneficiaries, especially for low-income seniors by eliminating cost sharing for generics.[1] ACP also supports policies that increase competition for generic sole-source drugs and opposes extending market or data exclusivity periods beyond the current exclusivities granted to generic (and biologic) drugs. ACP also supports policies that would increase the number of generic drugs available.[2] Accordingly, ACP supports **Sec. 302**, which allows the FDA to use capacity planning adjustment (CPA) methodology—which is already used for prescription drug user fees—to adjust generic drug user fees more precisely when the need of greater FDA resources arises due to higher workload. ACP policy does generally support providing additional funding to the FDA to improve its ability to monitor and approve drugs. Utilizing CPA methodology for generic drugs would hopefully allow the FDA to approve generic drugs for market more efficiently.

ACP urges Congress to go even further in increasing competition in the marketplace, particularly by encouraging the introduction of multiple competitor products for lower-cost generic (or biosimilar) drugs as a cornerstone to controlling the increasing price of pharmaceuticals. Especially by eliminating anticompetitive pay-for-delay arrangements that curtail access to lower-cost alternative drugs. ACP strongly believes that applicable federal agencies should be empowered through guidance, congressional action, or additional resource support to address anticompetitive behaviors and gaming.[3]

Improving Regulation of Drugs and Biological Products

ACP supports a comprehensive national policy on prescription drug misuse, including proper disposal. Over the decade from 1999 to 2019, almost 247,000 people perished from opioid overdoses and these unfortunate deaths more than quadrupled during the same decade. Surplus medications, coupled with inadequate instructions for disposal, serve as a ready source for drugs to misuse or diversion. Consumer-friendly and environmentally responsible prescription drug disposal programs should be developed to reduce abuse of prescription drugs obtained from family and friends.[4] Therefore, ACP supports **Sec. 502** and the safer disposal of opioids and other drugs with serious risks by allowing the FDA to require these drugs be dispensed to patients with safe, in-home disposal systems.

ACP supports reducing 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.[5] Preventing lower-cost biosimilar (or generic) drugs from entering the market adds billions of dollars in costs to federal health care programs and affects the affordability and accessibility of drugs for patients who rely on them on a day-to-day basis. Reducing the exclusivity period from 12 to seven years, combined with provisions to prevent product hopping or evergreening of biologic drugs, could get biosimilar or interchangeable drugs to market faster and save the federal government and patients money. Aligning with ACP policy of removing additional barriers to biosimilar market entry is **Sec. 503's** clarification of the FDA's authority to tentatively approve a subsequent interchangeable biosimilar biological product while a first interchangeable product's period of exclusivity is pending. In addition, **Sec. 503** would give the FDA the authority to permit multiple interchangeable biosimilar biological

products share a period of first interchangeable exclusivity if they are approved on the same day and otherwise qualify for exclusivity.

Other Reauthorizations

ACP appreciates the discussion draft's reauthorization of the Orphan Drug Act in **Sec. 606.** However, ACP supports legislative reforms to the Orphan Drug Act (ODA) that realign incentives offered through the law to support increased innovation in rare disease drug development. Many gaps remain in availability of orphan drugs and the cost of these drugs remains high. ACP believes the ODA should be reformed to realign the incentives offered under the law to reward true innovation and drug discovery. One option to realign these incentives is to require the repayment of tax credits received by the manufacturer if an orphan drug achieves blockbuster status (≥$1 billion in annual revenue). Another option to realign incentives of the ODA is to increase scrutiny of orphan drug applications submitted to the FDA. By engaging in more thorough review of orphan drug applications and requesting additional information or justification for missing data as needed, the FDA will ensure that the law is being appropriately applied.[6]

Conclusion

We commend you and your colleagues for working in a bipartisan fashion to reauthorize the FDA's user agreements before they expire this fall. We appreciate this opportunity to offer our input to the Committee about the FDASLA Act of 2022 as released on May 17, 2022. Thank you for consideration of our recommendations that are offered in the spirit of ensuring that the patient's needs for safe and effective prescription drugs are met. Please contact Jared Frost, Senior Associate, Legislative Affairs, by phone at (202) 261-4526 or via email at jfrost@acponline.org with any further questions or if you need additional information.

Sincerely,

Ryan D. Mire, MD, FACP
President

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[1]Hilary Daniel, BS, Sue S. Bornstein, MD, for the Health Public Policy Committee of the American College of Physicians. Policy Recommendations for Public Health Plans to Stem the Escalating Costs of Prescription Drugs: A Position Paper From the American College of Physicians; https://doi.org/10.7326/M19-0013

[2]Hilary Daniel, BS, for the Health and Public Policy Committee of the American College of Physicians. Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians; https://doi.org/10.7326/M15-2768

[3]Hilary Daniel, BS, Josh Serchen, BA, and Thomas G. Cooney, MD, for the Health and Public Policy Committee of the American College of Physicians. Policy Recommendations to Promote Prescription Drug Competition: A Position Paper From the American College of Physicians; https://doi.org/10.7326/M19-3773

[4] Neil Kirschner, PhD, Jack Ginsburg, and Lois Snyder Sulmasy, JD, for the Health and Public Policy Committee of the American College of Physicians. Prescription Drug Abuse: Executive Summary of a Policy Position Paper From the American College of Physicians. https://doi.org/10.7326/M13-2209

[5] Hilary Daniel, BS, Josh Serchen, BA, and Thomas G. Cooney, MD, for the Health and Public Policy Committee of the American College of Physicians Policy Recommendations to Promote Prescription Drug Competition: A Position Paper From the American College of Physicians; https://doi.org/10.7326/M19-3773

[6] Hilary Daniel, BS, Josh Serchen, BA, and Thomas G. Cooney, MD, for the Health and Public Policy Committee of the American College of Physicians Policy Recommendations to Promote Prescription Drug Competition: A Position Paper From the American College of Physicians; https://doi.org/10.7326/M19-3773