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May 20, 2022

The Honorable Patty Murray
Chair
Senate HELP Committee
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
Senate HELP Committee
217 Russell Senate Office Building
Washington, DC 20510

Re: Food and Drug Administration Safety and Landmark Advancements Act of 2022

Dear Chair Murray and Ranking Member Burr:

The Academy of Managed Care Pharmacy (AMCP) thanks the Senate Committee on Health, Education, Labor, and Pensions (HELP) for the opportunity to provide feedback in response to the discussion draft of the Food and Drug Administration Safety and Landmark Advancements (FDASLA) Act of 2022. AMCP supports the reauthorization of the Food and Drug Administration's (FDA) prescription drug, generic drug, biosimilar, and medical device user fee agreements, as well as the bill's provisions to strengthen oversight of cosmetics and dietary supplements, modernize the regulation of diagnostic tests, bring more competition to the market, and prepare the FDA for the next generation of medical products.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes, and ensuring the wise use of healthcare dollars. Through evidence and value-based strategies and practices, AMCP's over 7,000 pharmacists, physicians, nurses, and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models, and government health programs.

AMCP calls on the Senate HELP Committee to include pre-approval information exchange (PIE), an important practice that helps speed patient access to new, potentially lifesaving, treatments by reducing the time between FDA approval of a treatment and the beginning of coverage for that treatment, in the FDASLA Act of 2022.

Pre-approval information exchange is designed to allow drug and device manufacturers to proactively communicate certain economic and clinical information, such as clinical trial results and cost, to health payers regarding therapies or new indications of previously approved products in the FDA pipeline before they are approved. This allows payers to plan appropriately for the economic impact that a new treatment will have before the beginning of the plan year in which approval is anticipated. The information provided to payers by manufacturers prior to approval must meet

truthfulness and reliability standards. PIE includes safeguards to ensure that information is provided only to appropriate audiences, while empowering payers and manufacturers to begin developing purchasing agreements before FDA approval, which can significantly reduce the amount of time between approval and patient access.

Without access to pre-approval information, payers may be caught unaware by the cost of certain innovative therapies. An example of this is sofosbuvir, sold under the brand name Sovaldi, which was approved by FDA in 2013 as a first-in-class curative treatment for hepatitis C. In the year following approval, a full course of treatment cost between $84,000 and $168,000. Because payers were not aware of the treatment in advance, it caused a significant strain on their formularies and budgets. With the rise of even higher cost specialty drugs that can treat rare diseases, which can cost hundreds of thousands or even a million plus dollars for a course of treatment, pre-approval exchange of appropriate scientific and economic information is more important than ever.

The Pre-approval Information Exchange (PIE) Act of 2022 (H.R. 7008) was introduced in March 2022 by Representative Brett Guthrie (R-KY-02). After receiving and incorporating technical assistance from FDA, the PIE Act of 2022 was subsequently included as Section 809 in the bipartisan Food and Drug Amendments of 2022 (H.R. 7667), which was advanced favorably and unanimously by the House Energy & Commerce Committee on May 18, 2022.

FDA guidance initially drafted under Dr. Robert Califf's leadership in 2016 and finalized in 2018 permitted PIE but did not clarify if manufacturers can proactively share this information or are limited to providing it in response to a payer request for information. As a result, many manufacturers are hesitant to engage in PIE due to legal uncertainties, leading to preventable delays in access to new treatments. PIE seeks to clarify the circumstances under which pre-approval communications can occur and what types of information can be shared, while codifying the FDA's 2018 guidance.

Health care decision-makers find greater need for proactive PIE communication as the health care system evolves from a fee-for-service payment structure to a value-based model rewarding quality, improved patient outcomes, and cost-efficiency by facilitating more timely negotiations of value- and outcomes-based contracts. PIE is particularly important in fields with rapidly evolving therapeutic options, such as but not limited to oncology and the treatment of rare diseases. For example, many cancer treatments are approved only for one specific type of cancer but later found to be effective in treating other types as well. Cell and gene therapies, a growing class of treatments, are often used to treat rare diseases but have complex development processes and high list prices. Delays in patient access due to statutory barriers to timely exchange of information can have serious, life-threatening consequences. Publicly funded payers, like Medicare and Medicaid, have statutorily limited flexibility to change their prescription drug formularies during a plan year, which can lead to beneficiaries experiencing problems accessing or affording new treatments.

A legislative safe harbor for PIE will confirm that the proactive dissemination of certain clinical and economic information does not violate the prohibitions against pre-approval promotion and does not run afoul of the labeling, misbranding, and intended use provisions of the Federal Food, Drug, and Cosmetic Act and its implementation regulations. This will expedite coverage decisions for and patient access to emerging therapies, including those granted breakthrough designation.

As evidenced by the included letters, PIE is supported by a diverse and growing coalition of stakeholders representing the entirety of the healthcare continuum. AMCP implores the Senate HELP Committee to include pre-approval information exchange in the FDASLA Act of 2022. We appreciate your consideration and look forward to continued partnership to ensure patient access to affordable treatments, improved health outcomes, and the wise use of healthcare dollars. If you have any questions regarding PIE or would like further information, please see the attached Pre-approval Information Exchange Information Packet, visit AMCP's PIE Resource Center, or contact Jennifer Mathieu at 703.284.2654 or jmathieu@amcp.org.

Sincerely,

Susan A. Cantrell RPh, CAE
Chief Executive Officer

Attachment:
Pre-approval Information Exchange Information Packet_5.19.22