

May 18, 2022

The Honorable Frank Pallone  
Chairman  
Energy & Commerce Committee  
2107 Rayburn HOB  
Washington, DC 20515

The Honorable Cathy McMorris Rodgers  
Ranking Member  
Energy & Commerce Committee  
1035 Longworth HOB  
Washington, DC 20515

***Re: H.R. 7667 – Food and Drug Amendments of 2022***

Dear Chairman Pallone and Ranking Member McMorris Rodgers:

The undersigned organizations, representing a diverse coalition of stakeholders in American healthcare, write to express their support for section 809 of the *Food and Drug Amendments of 2022* (H.R. 7667) on pre-approval information exchange (PIE). This important provision will help speed patient access to new, potentially lifesaving, treatments by reducing the time between Food & Drug Administration (FDA) approval of a treatment and the beginning of coverage for that treatment.

As the Subcommittee on Health of the Committee on Energy and Commerce heard during the March 17 hearing entitled “The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight” and during the May 11 markup entitled “Markup of 6 Bills, Health Subcommittee,” pre-approval information exchange is the practice of drug and device manufacturers communicating certain truthful and non-misleading economic and clinical information 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 a new treatment will have before the beginning of the plan year in which approval is anticipated. The language includes provisions to ensure that information is provided only to appropriate audiences. Section 809 also empowers payers and manufacturers to begin developing purchasing agreements before approval, which can significantly reduce the amount of time between approval and patient access.

FDA guidance initially drafted under Dr. 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, leading to preventable delays in access to new treatments.

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, sometimes ranging from hundreds of thousands of dollars to more than a million. Delays in patient access due to statutory

barriers to timely exchange of information can have serious 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.

The undersigned support the creation of a legislative safe harbor for PIE and strongly encourage the House Energy & Commerce Committee to support the inclusion of section 809 on pre-approval information exchange when advancing the *Food and Drug Amendments of 2022* (H.R. 7667). PIE will improve patient access to care by ensuring that the proactive provision of truthful and non-misleading economic and clinical information to payers prior to FDA approval does not run afoul of FDA labeling guidelines and prohibitions against off-label commercial marketing.

Sincerely,

Academy of Managed Care Pharmacy  
Alliance of Community Health Plans  
American College of Apothecaries  
American College of Clinical Pharmacy  
American Society of Health-System Pharmacists  
Astellas Pharma US, Inc.  
Aventine Consulting  
Blue Cross Blue Shield Association  
Calliditas Therapeutics  
Coherus BioSciences  
Council for Affordable Health Coverage  
Healthcare Leadership Council  
Humana  
Little Hercules Foundation  
Magellan Rx Management  
National Alliance of State Pharmacy Associations  
Parent Project Muscular Dystrophy  
Prime Therapeutics  
Xcenda/AmerisourceBergen