Committee on Energy and Commerce
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: Hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight"

March 17, 2022

Dear Chairwoman Eshoo and Ranking Member Guthrie,

The Generics Access Project (GAP) commends the House Energy and Commerce Committee for convening this hearing on "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." GAP represents a number of patient advocacy groups in a concerted effort to improve availability of generic medicines in the United States. We urge Congress to enact common sense legislation that will improve timely access to affordable medicines and expand access to the generic drugs that will help lower costs for America's patients.

The U.S. health care system and its patients have benefited significantly from increased access to generic drugs, which make up nearly 90% of all U.S. prescription volume, but account for only 22% of total prescription drug spending.[1] As a result of this growth, more patients have access to lower-cost medicines, which is driving large savings for the U.S. health care system, totaling $2.2 trillion in the last decade (2010-2019) and $313 billion in 2019 alone.[2]

Congress is presented with a unique opportunity as it continues to work towards lowering drug prices to make important refinements that will improve patient access to medicine. More can be done to increase the approval of both simple and complex generic medicines through an efficient, patient-focused regulatory structure. GAP was encouraged by the comments many members of this Committee raised during the "Food and Drug Administration (FDA) User Fee Reauthorization: Ensuring Safe and Effective Drugs and Biologics" hearing on February 3rd. Numerous Representatives recognized the importance that generic drugs play in our health care system, and we hope these comments will help guide the Committee as it seeks to shape the innovative future of medicine.

Ensuring Legislative Language Helps Achieve Goals of Generic Drug User Fee Agreement (GDUFA) III

Passed in 2012, Congress intended GDUFA to speed up FDA approval of generic drugs, stimulate competition for branded drugs, and reduce overall drug prices for American patients by collecting industry user fees to support the agency's regulatory review of new generic drug applications. Congress is

[1] IQVIA. (2019). Fact Sheet: Generic Drug and Biosimilar Access and Savings in the U.S. Report. https://accessiblemeds.org/sites/default/files/2019-12/AAM-2019-Generic-Biosimilar-Access-Savings-US-One-Pager.pdf

[2] The Association for Accessible Medicines, (October 2020) 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-Savings-Report-US-Web.pdf

now set to reauthorize the third iteration of this program, known as GDUFA III, following months of unprecedented engagement and input from patient groups.

Proposed GDUFA III improvements include:

- implementing better product guidance practices for new generic drug applicants
- expanding mid-cycle review meeting opportunities
- increasing opportunities for timely regulatory feedback
- focusing attention on first and second generation complex generic approvals

The FDA's GDUFA III commitment outlines needed improvements that will ultimately benefit patients by resulting in more affordable treatment options, increased access to complex therapies for serious and chronic conditions and generating savings for patients and the overall health care system. We urge Congress to enact recommendations that support the proposed goals outlined in the GDUFA III Commitment Letter.

Process Reforms to Address Regulatory Inefficiencies

Complex generic medicines are versions of some of the more complicated and innovative chemical-based medicines on the market. These drugs are considered "complex" due to their formulation, their unique drug-device delivery systems, or because of the complexity of their ingredients. These medicines treat some of the most serious diseases such as schizophrenia, metastatic breast cancer, osteoporosis, and diabetes. As innovative medicines become more complex, we will see more complex generics entering the FDA review process, helping patients have increased access to lower-cost alternatives to brand name drugs.

An area for improvement is to reform the FDA's regulatory program it uses to review and approve complex generics via the 505(b)(2) pathway. This pathway is well suited to review and approve complex medicines but the FDA's approach to issuing therapeutic equivalence (TE) ratings should be improved. When a simple generic drug is approved through the Abbreviated New Drug Application process they are deemed "therapeutically equivalent" to the brand drug and issued a corresponding TE rating that gives pharmacists the ability to substitute a lower-cost option at the pharmacy counter. Congress should consider adjusting the 505(b)(2) pathway to allow for manufacturers to request an automatic TE determination once a complex generic is approved.

Currently, it can take years for a TE rating to be obtained by an eligible complex generic applicant. The TE rating must be requested through an open-ended citizen petition process which has become far less predictable and timely in recent years. Sometimes a TE rating is never assigned, and the generic alternative to the brand name medicine never reaches market leaving patients, health care payers, and our society without access to competition.

S. 1463, the Modernizing Therapeutic Equivalence Rating Determination Act, would fix the process for assigning a TE rating by requiring the FDA to issue a TE rating within 30 days of the product's approval through the 505(b)(2) pathway, when a TE rating is requested by the applicant. This modification would help ensure more generics are able to compete, reduce shortages, and lower out-of-pocket costs in a time when so many patients are struggling to meet their healthcare costs.

We urge Congress to enact legislation that updates the FDA 505(b)(2) complex generic approval pathway so that TE ratings are assigned to applicants within 30 days of an applicant's request. Patients see cost savings when they substitute a high-priced brand-name drug for a less expensive, safe, and therapeutically equivalent alternative.

Conclusion

Thank you for the opportunity to share our comments regarding the important role generics and complex generics play when it comes to lowering costs for American patients. The Generics Access Project stands ready to work with Congress, the Administration, and other stakeholders to enhance the approval of generic drugs, increasing the competition they bring to the drug market, and improving access to lower-cost treatment options for patients. Should you have any questions, please contact Gavin Clingham at gavin@allianceforpatientaccess.org.

Sincerely,

Generics Access Project

Founding Members
Alliance for Patient Access
Allergy and Asthma Network
Asthma and Allergy Foundation of America
Color of Crohn's and Chronic Illness
International Cancer Advocacy Network