Association for Accessible Medicines

Your Generics & Biosimilars Industry

TESTIMONY OF DAVID R. GAUGH, R.PH.

SENIOR VICE PRESIDENT FOR SCIENCES AND REGULATORY AFFAIRS

ASSOCIATION FOR ACCESSIBLE MEDICINES

EXAMINING FDA'S GENERIC DRUG AND BIOSIMILAR USER FEE PROGRAMS
HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON HEALTH

Good morning Chairman Burgess, Ranking Member Green, and Members of the Subcommittee on Health. First, let me thank you for asking me to participate in this timely and important hearing.

I am David Gaugh, Senior Vice President for Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM), formerly GPhA, and a licensed pharmacist. AAM represents the manufacturers and distributors of finished generic pharmaceuticals, bulk pharmaceutical chemicals, and the suppliers of other goods and services to the generic industry. Generics represent greater than 89% of all prescriptions dispensed in the U.S., but only 27% of expenditures on prescription drugs.

Introduction

I would like to begin today by commending the Committee for your continued focus on the important issues we will examine today. As someone who has worked in and around the generic drug industry for more than two decades, I have witnessed firsthand the industry's remarkable growth and the vital role it plays in the lives of Americans every day by providing access to affordable medicines.

This growth in the generic drug industry has also served to underscore the critically important role of the Food and Drug Administration (FDA). As I will highlight, the level of cooperation between industry and the FDA has never been greater, and it is our hope that this collaboration will continue throughout all of our interactions with the agency.

However, the agency remains underfunded, and the responsibility of ensuring access to safe, effective and affordable medicines is a shared one with the entire pharmaceutical industry. That is why the generic industry has stepped up to help provide the FDA with additional user fee resources to address the ongoing challenges caused by an increasingly global drug supply-chain.

Expedited Generic Access

I am here to discuss AAM's conviction that the best way of achieving the goal of providing patients access to generic alternatives is through the development of policies that promote robust, competitive markets.

Generic manufacturers make complex and highly confidential analysis when selecting which products to pursue. This analysis can include assessing the complexity in reverse engineering, the state of the intellectual property, the size of the market, the likely number of competitors, the product development and manufacturing capabilities and costs.

Because of these complexities, AAM believes that the best way to control drug costs generally, is through policies that incentivize competition and Generic Drug User Fee Amendment (GDUFA II) does just that.

GDUFA II builds on the experiences – both the successes and shortcomings – of GDUFA I. The priority of the generic drug industry in the GDUFA II negotiations was to

achieve a more effective and transparent generic drug review program. We believe that accomplishing this goal will improve the rate of first-cycle approvals on the earliest legally eligible date through greater transparency and communication during the review process. Greater communication and cooperation between FDA and generic drug sponsors benefits both parties by sharing knowledge and experiences throughout the review process. Our industry's goal was not merely a faster FDA review timeline, but a more effective review process – that enables more approvals during the first-review cycle. Similar to the goals of the branded drug user fee program, PDUFA, reducing multiple FDA review cycles is a critical component of increasing access to affordable generic alternatives. The fewer review cycles required to get to approval, the sooner patients and payors can experience the benefits of generic drug competition. We strongly believe GDUFA II is well positioned to achieve this goal.

A few key areas of focus in GDUFA II include:

Application Metrics – FDA will review and act on 90 percent of ANDAs within 10 months after the date of submission for standard applications and 8 months for priority applications. This includes the inspection components of the review process. Priority status will be provided by FDA for submissions affirmatively identified as eligible for expedited review pursuant to current CDER Prioritization Policies (MAPP 5240.3 Rev. 2[1]).

- Submissions containing patent certifications pursuant to 21 CFR 314.94(a)(12);

[1] Center For Drug Evaluation And Research, MaPP 5240.3 Rev. 2 , https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf

- Submissions related to drug shortages;
- Submissions that are subject to special review programs such as the President's Emergency Plan for AIDS relief;
- Submissions related to public health emergencies;
- Submissions related to certain government purchasing programs;
- Submissions subject to statutory mandates or other legal requirements;
- Supplements for which expedited review is requested under 21 CFR 314.70(b)(4); and
- Submission for "sole-source" drug products.

Bridging (No ANDA Left Behind) – In GDUFA I, ANDA applications that were filed with the FDA prior to October 1, 2014, did not receive an official GDUFA I Goal Date. However, during early implementation phases of GDUFA I, the FDA agreed to assign Target Actions Dates (TADs) to those applications. These TADs would allow both the FDA and industry to better track the application status. During GDUFA II negotiations, it was agreed that ALL GDUFA I pending applications would be provided an official GDUFA II Goal Date. Therefore, prior to the completion of GDUFA I, all applications and supplements that have been assigned TADs by FDA will be converted to official GDUFA II Goal Dates. For all applications and supplements that were either (a) previously not assigned a TAD or (b) were previously assigned a TAD and the TAD was missed, at the time of GDUFA II commencement, these pending applications will be assigned a goal date by the FDA that shall not be later than July 31, 2018. This will provide for an official accountability for all pending application.

Complex Products – The GDUFA II agreement creates a pre-ANDA submission communication pathway for a subset of generic drug applications, complex products. Like the Breakthrough Therapies program initiated for certain high priority branded drug application, earlier interaction between the applicant and FDA is expected to enhance industry's ability to understand and anticipate FDA's expectations during the critical research and development phase of product development. We also believe that this early engagement between industry and FDA will significantly contribute to the applicant's ability to improve the overall submission quality of ANDA's which in turn will contribute to first-cycle approvals. FDA should consider how it can further enhance communication with generic drug sponsors to improve on its 9% first-cycle approval rate.

ANDA Review Transparency and Communications Enhancements – The agreement includes increased transparency and communication elements between FDA and ANDA applicants throughout the review process through liberal use of Information Requests (IRs) and Division Review Letters (DRLs). These enhancements are intended to decrease the number of review cycles from the 3-4 review cycles experienced today, and move them more towards first-cycle approvals.

Reporting and Accountability – FDA will conduct increased financial and performance reporting to maximize transparency to Congress, industry and the public. The GDUFA II agreement includes several new performance and financial reporting requirements to ensure transparency and efficiencies are maintained. The new reporting requirements

will allow Congress, generic drug sponsors and FDA to better assess FDA's resource management planning and processes to ensure the overall success of the GDUFA program. The quarterly and annual reporting requirements will also provide insight into the financial and performance efficiencies of the FDA, allowing for future program improvements and enhancements.

Small Business Consideration – The GDUFA II agreement supports small business by exempting them from a facility fee until the first ANDA in that facility is approved. The proposal also provides for tiering of the annual ANDA program fees based on small, medium and large companies. This tiering is based on the total number of approved ANDAs for each company.

It is paramount that, as we work to shape the future of our country's generic drug industry, we also work to bring the FDA into the 21st century and ensure that the agency's ability and readiness to achieve its mission in this global age are up-to-date. AAM strongly support the GDUFA II package as negotiated and agreed to with FDA as it provides critical steps in this direction.

By designing GDUFA II to spread fees across multiple stakeholders and sources to keep individual amounts as low as possible, the programs will help assure that patients continue to receive the significant cost savings from generics alternatives. It is important to emphasize that the funding provided by GDUFA II is in addition to, not a substitute for, Congressional appropriations.

Conclusion

In conclusion, Mr. Chairman, the GDUFA II user fee proposal is a culmination of months of negotiations between FDA and industry, and the final product as transmitted to Congress represents a careful balance among all the stakeholders involved. We respectfully urge the Committee to approve GDUFA II as negotiated and agreed by FDA and generic drug manufacturers, without any changes to the agreement. It is also vital that the agreement be approved in a timely manner so that patients, the FDA, and generic manufacturers can begin to see the many benefits. Nothing is more important to our industry than ensuring patients have access to the lifesaving generic medications they require, and GDUFA II provides a critical step toward accomplishing this goal. Thank you, and I would be happy to address any questions.