



Testimony of
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Before the
Subcommittee on Health
of the House Committee on Energy and Commerce

**“The Future of Medicine:
Legislation to Encourage Innovation and Improve Oversight”**

March 17, 2022

Chairwoman Eshoo, Ranking Member Guthrie and Members of the Subcommittee:

Thank you for holding today's hearing, "The Future of Medicine: Legislation to Encourage Innovation and Improve Oversight." My name is David Gaugh and I am Senior Vice President for Sciences and Regulatory Affairs at the Association for Accessible Medicines (AAM). I am a licensed pharmacist with more than two decades of experience working in and around the generic drug industry. I also represented the industry in the initial development and in both subsequent renewals of the generic drug and biosimilar user fee agreements.

AAM and its Biosimilar Council are the nation's leading trade association for the manufacturers and distributors of FDA-approved generic and biosimilar prescription medicines. Today, generic and biosimilar medicines comprise 90% of prescriptions in the United States at only 18% of total drug spending.¹ AAM's members provide more than 52,000 jobs at nearly 150 facilities and manufacture more than 60 billion doses of generic medicines in the United States every year.² Our core mission is to improve lives by advancing timely access to high-quality, more affordable safe and effective generic and biosimilar medicines.

In today's testimony, I will highlight the 10-year success of the FDA's GDUFA and BsUFA programs in significantly increasing patient access to lower-cost medicines and, in turn, dramatically lowering the cost of prescription drugs for America's patients and our health care system. I will also share AAM's perspectives on the additional proposals the Committee is considering today that are most relevant to generic and biosimilar developers.

GDUFA and BsUFA aim to put FDA's generic and biosimilar drug programs on stable financial footing by enabling FDA to assess user fees to supplement funding appropriated by Congress to fund critical and measurable enhancements, which provide greater predictability and efficiency to the review of applications. As a direct outcome, the generic and biosimilar drug programs have increased patient access to safe, effective and affordable quality medicines.

This year's reauthorization marks the 10-year anniversary of both GDUFA and BsUFA. Over the past decade, these programs have substantially increased resources available to FDA to review applications. More than \$4 billion in supplemental user fees

¹ AAM, "The U.S. Generic & Biosimilar Medicines Savings Report," October 2021, available at <https://accessiblemeds.org/sites/default/files/2021-10/AAM-2021-US-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>.

² AAM, "A Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain," October 2021, available at <https://accessiblemeds.org/sites/default/files/2020-04/AAM-Blueprint-US-Pharma-Supply-Chain.pdf>.

from generic and biosimilar developers was and will be provided as a result.³ With these resources, FDA and industry have been able to significantly increase access to more affordable generic and biosimilar medicines, resulting in more treatment options and savings for patients and the United States health care system. For example:

- FDA and developers of generic medicines were able to increase efficiencies, which increased the number of generic drug approvals, with full and tentative approvals exceeding 1,000 in fiscal years 2017, 2018 and 2019. The median number of Abbreviated New Drug Application (ANDA) approvals increased over time as a result of GDUFA I and GDUFA II.⁴
- FDA licensed the first biosimilar in 2015 and has now licensed a total of 34 biosimilars in the United States.⁵ Biosimilar medicines are safe, effective and more affordable treatment options for patients than their brand-name counterparts. Biosimilars are already delivering on their promise of lower costs and expanded patient access to care with average prices of more than 40% less than their reference biologics.
- Over the last 10 years, generics and biosimilars provided more than \$2 trillion in savings – including \$469 billion from new generics and more than \$12 billion from biosimilars – to patients and the health care system in the United States.⁶

Timely approval of the FDA user fee agreements is critical to ensuring the continued availability of lower-cost generic and biosimilar medicines. AAM and its Biosimilars Council therefore strongly support congressional reauthorization of GDUFA and BsUFA as negotiated and without changes. The GDUFA III and BsUFA III commitment letters were carefully negotiated to balance program enhancements and resource requirements provided to FDA. The agreements include a year-over-year capacity planning adjuster (CPA) that allows FDA to automatically add additional full-time equivalent (FTE) resources when increased workload criteria exceed expectations. Therefore, AAM would have concerns about adding policies into the reauthorization package that require additional FTEs to implement if the package does not also include corresponding appropriations. Adding such policies would increase industry's year-over-year costs beyond what was negotiated and agreed to with FDA.

³ AAM Analysis of FDA's FY2014 – FY2020 GDUFA and BsUFA Financial Reports and Five-Year Financial Plans (2021 Update). FDA's reports are available at <https://www.fda.gov/about-fda/user-fee-reports/user-fee-financial-reports>.

⁴ AAM Analysis of the FDA Office of Generic Drug Annual Reports (2015-2020) and Activities Report of the Generic Drug Program (FY13-FY15, FY21). FDA's reports are available at <https://www.fda.gov/drugs/generic-drugs/annual-reports>.

⁵ Biosimilars Council, "FDA Biosimilars Approvals," March 2022, available at <https://biosimilarscouncil.org/resource/fda-biosimilars-approvals/>.

⁶ Ibid., AAM Generic & Biosimilar Savings Report.

With that context in mind, we appreciate the opportunity to respond to the Committee’s request for our perspective on additional proposals relevant to generic and biosimilar medicines.

Enhanced Access to Affordable Medicines Act (H.R. 6973)

The Federal Food, Drug and Cosmetic Act (FDCA) requires generic drug labeling to be the same as the brand-name reference listed drug. If brand-name drug labeling changes while the FDA is reviewing a generic drug application, approval of the generic application may be delayed until the applicant amends its labeling to conform to the updated brand-name drug labeling. Current GDUFA performance goals allow FDA to review generic drug application labeling amendments over a three-month timeframe. Thus, brand-name labeling changes, depending on how they are timed, can delay approval of generic medicines and accordingly delay patient access to more affordable FDA-approved generic alternatives. Even after the generic obtains approval, commercial launches may also be delayed and made more costly if the generic drug developer needs to reprint labeling and repackage the drug.

Brand-name drug manufacturers sometimes try to delay competition from more affordable generic medicines by initiating late-stage labeling changes. In the first six months of 2019 alone, changes to brand-name labeling appear to have occurred within 90 days of approval on 36 ANDAs.⁷ Late-stage labeling changes have also occurred on blockbuster medications, such as Advair®, resulting in significant lost savings to patients and the health care system. Findings from the U.S. Government Accountability Office (GAO) echo concerns that changes to brand-name labeling “may be strategically timed to delay approvals” or that labeling changes could be made frequently in an effort to complicate generic drug approvals.⁸

The Enhanced Access to Affordable Medicines Act (H.R. 6973), introduced by Rep. Buddy Carter (R-GA), would allow FDA to approve generic applications that would otherwise be eligible for approval but for a late-stage labeling change by the brand-name manufacturer. The generic drug applicant must agree to submit revised labeling no later than 60 days after approval. The bill also includes provisions that preclude use of the pathway if the labeling change relates to warnings. These commonsense guardrails would help ensure that the latest safety and warning information is readily available to physicians and patients. AAM believes this bill would help curb late-stage labeling changes that may be used as anticompetitive tactics to delay generic approvals. As a

⁷ AAM Analysis of labeling changes that occurred on FDA-approved drugs in 2019. FDA’s data are available at <https://www.accessdata.fda.gov/scripts/cder/daf/>.

⁸ GAO, “Generic Drug Applications: FDA Should Take Additional Steps to Address Factors That May Affect Approval Rates in the First Review Cycle,” August 2019, available at <https://www.gao.gov/assets/gao-19-565.pdf>.

result, the bill would help ensure that patients have more timely access to lower-cost generic medicines.

Increasing Transparency in Generic Drug Applications Act (H.R. 7032)

Certain generic medicines, including many complex generics, are required to demonstrate “Q1/Q2” sameness with the brand-name reference listed drug (RLD). A proposed generic formulation is Q1/Q2 to its RLD if it contains: (1) the same inactive ingredients (“qualitatively the same” or “Q1”); and (2) in the same concentrations (“quantitatively the same” or “Q2”). While a brand-name drug’s active ingredients are identified on the product’s labeling, information about inactive ingredients is not always readily available. Generic drug applicants therefore must run tests to try to decipher the components and concentrations in the brand-name drug before submitting proposed formulations to the FDA.

When FDA determines that a proposed generic formulation does not satisfy the Q1/Q2 sameness policies, the Agency informs the generic applicant of that determination, but FDA does not disclose the ingredient at issue or any details about deviations in concentration. As a result of this lack of transparency, the generic applicant must continue to submit multiple proposed formulations through the controlled correspondence process until the Q1/Q2 criteria are satisfied. This back-and-forth between the generic applicant and the FDA is often inefficient and lengthy, requiring substantial time and resources from both parties that could be dedicated to other important priorities. It also can also lead to significant delays in competition that benefits patients.

Part of the reason for this delay is that generic applicants are limited to three formulations per controlled correspondence, which can result in generics having to submit multiple controlled correspondences before the Q1/Q2 criteria are satisfied.⁹ For example, it took FDA 10 years to approve a generic competitor to AbbVie’s blockbuster drug Restasis® (cyclosporine), due in part to apparent Q1/Q2 issues reflected in its cyclosporine guidance.¹⁰ At least nine developers sought approval, with only one finally receiving approval in February 2022.

Generic approvals and launches have also been substantially delayed by late-stage reversals of Q1/Q2 determinations by FDA. Indeed, FDA has reversed previous Q1/Q2 determinations for a number of complex generic products, in some cases years after making the Q1/Q2 determination. The effects of such late-stage reversals are

⁹ FDA, “Controlled Correspondence Related to Generic Drug Development Guidance for Industry,” December 2020, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/controlled-correspondence-related-generic-drug-development-guidance-industry>.

¹⁰ FDA, “Draft Guidance on Cyclosporine,” October 2016, available at https://www.accessdata.fda.gov/drugsatfda_docs/psg/Cyclosporine_ophthalmic%20emulsion_RLD%20050790_RV09-16.pdf.

problematic for patients and the health system: generic developers generally must start from scratch and reformulate their complex products—sometimes long after commencing their development program—which ultimately delays patient access to a high-quality, low-cost complex generics.

The Increasing Transparency in Generic Drug Applications Act (H.R. 7032), introduced by Rep. Annie Kuster (D-NH), would clarify FDA’s authority to share information about ingredients and the nature of deviations in concentration with generic applicants. In doing so, it would reduce the burden on FDA and industry of compiling, reviewing and responding to controlled correspondence related to generic formulations. It would also limit FDA’s ability to reverse a previous Q1/Q2 determination that a generic developer reasonably relied on in making formulation decisions. For these reasons, codifying this process would help prevent delays in generic drug approvals and facilitate complex generic competition, thereby delivering significant savings to patients in therapeutic areas where it is critically needed.

INSPECTIONS Act (H.R. 7006)

Manufacturing facility inspections are an essential part of evaluating applications to market all FDA-approved pharmaceuticals, including brand-name, generic, and biosimilar medicines. When FDA does not conduct inspections in a timely manner, approvals and patient access to new treatments, as well as more affordable options, can be delayed.

During the last two years, there have been significant disruptions to the inspections program. In March 2020, FDA announced that it was suspending domestic and foreign inspections due to the COVID-19 pandemic. The Agency focused only on “mission-critical” inspections, a narrow category that does not include inspections tied to most drug applications. As the pandemic subsided in late 2021, FDA attempted to resume some domestic inspections. With the rise of the Omicron variant, however, FDA reverted to performing only mission-critical inspections and did not resume a normal domestic inspection schedule until February 2022.

These inspection disruptions have had a significant effect on our members’ ability to obtain timely approval of more affordable generics and biosimilars. By FDA’s account, as of the end of FY2021—the most recent data available to AAM at the time of this hearing—**52** human drug application decisions remain “delayed solely due to a pending inspection or facility assessment.”¹¹ The tally of 52 likely underestimates the extent of the delays, as it excludes applications that might have had a minor issue unrelated to an inability to inspect. Inspections for biosimilar applicants are also impacted, including

¹¹ FDA, “An Update to the Resiliency Roadmap for FDA Inspectional Oversight,” November 2021, available at <https://www.fda.gov/media/154293/download>.

biosimilars for brand-name biologics like Humira®.¹² Prompt inspection of such facilities is urgently needed.

Under existing authorities FDA has several alternatives to physically inspecting facilities, including: (1) obtaining inspection records remotely; (2) requesting information and records from applicants, facilities, and other inspected entities; (3) conducting remote interactive evaluations (real-time video interactions with facilities that cover the same ground as inspections); and (4) relying on inspections conducted by trusted foreign regulatory authorities under the Mutual Recognition Agreements (MRA). FDA, however, infrequently uses these alternatives. For example, FDA informed AAM that, as of December 2021, it had conducted **only five** remote interactive evaluations.

AAM recognizes the important role inspections play in FDA's ability to assess the overall quality of applications. Our members also share the Agency's concerns about public health and preventing the spread of COVID-19 among FDA and manufacturing facility employees. The interruptions caused by COVID-19, however, delayed and denied patients prompt access to new therapies and generic and biosimilar choices that would lower drug costs. If new COVID-19 variants emerge, or if there is a future pandemic, FDA's inspections could be paused again.

The Improving the Nation's Safe Pharmaceuticals and Excipients by Creating Tools for Inspecting and Overseeing Needed Supplies (INSPECTIONS) Act (H.R. 7006), introduced by Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT), would enhance FDA's oversight of facilities that manufacture prescription drugs and would help resolve some of the issues outlined above by:

- Adding the compliance history of a facility's home country to the list of factors determining a facility's risk level;
- Authorizing FDA to use certain records to satisfy requirements for pre-approval or risk-based surveillance inspections;
- Expressly empowering FDA to enter into MRAs that cover pre-approval inspections, rather than just risk-based surveillance inspections; and
- Calling for GAO oversight on the use of alternatives to in-person inspections.

AAM commends the bill sponsors' and Committee's ongoing attention to the inspections backlog. We agree that FDA should consider expanding its MRA with the European Union, where each jurisdiction recognizes and relies on the other's inspection reports, to cover pre-approval inspections and not just post-market surveillance inspections. We also believe FDA should expand use of remote interactive evaluations and use them more frequently in place of a physical inspection, in addition to using

¹² Center for Biosimilars, "FDA Delays Review of Alvotect's AVT02 Adalimumab Biosimilar Candidate," September 2021, available at <https://www.centerforbiosimilars.com/view/fda-delays-review-of-alvotect-s-avt02-adalimumab-biosimilar-candidate>.

alternative tools in place of an in-person inspection to verify corrective actions for a site that had received a warning letter. Some of the provisions in this bill may encourage the Agency to take those steps, which may help reduce the backlog and prevent the situation from worsening should there be future COVID-19 variants or other public health emergencies that may hinder in-person inspections.

Given the level of disruption caused by the pandemic, however, AAM recommends the bill be strengthened by requiring FDA to evaluate alternatives when an in-person inspection is not possible. Should FDA determine that an alternative to an in-person inspection cannot be used, the Agency would be required to inform the applicant which alternatives were considered and the reasons why an in-person inspection was deemed necessary. We believe this additional transparency and accountability will encourage FDA to perform its critical mission—without delay—while preserving the Agency’s discretion and judgment to require in-person inspections when necessary.

MADE in America Act (H.R. 3927)

AAM and its members agree that there is a role for Congress in enhancing domestic manufacturing and the security of the supply chain. While AAM shares many of the goals of the Manufacturing API, Drugs, and Excipients (MADE) in America Act (H.R. 3927), we are concerned that this proposal—without additional appropriations from Congress—would take away critical resources from FDA as negotiated in GDUFA III.

With that said, AAM believes there are important steps Congress can and should take to ensure uninterrupted patient access to life-saving medicines now and in the future as outlined in AAM’s “Blueprint for Enhancing the Security of the U.S. Pharmaceutical Supply Chain.”¹³ Creating the conditions that support and encourage further investment is vital to ensuring the most critical medicines—those most essential to our country’s health and security—are manufactured in the United States. In order to establish and maintain this environment, AAM’s Blueprint recommends the following:

- Creating new grant, tax and other incentives to support increased domestic production of medicines on the FDA’s Essential Medicines List (“essential medicines”);
- Supplying the Strategic National Stockpile, the Department of Veterans Affairs and other agencies with essential medicines on a long-term basis;
- Leveraging Medicare and Medicaid to support greater domestic production of essential medicines;
- Reducing regulatory inefficiencies to streamline the federal approval for U.S.-based facilities to manufacture essential medicines; and,
- Promoting a global, cooperative approach to diversifying the supply chain.

¹³ Ibid., AAM Blueprint.

The Blueprint includes actionable, short-term steps to expedite more domestic production of essential medicines, while putting in place a series of incentives to enhance the security of the pharmaceutical supply chain. Global coordination across a resilient, high-quality and reliable supply chain is an important element in ensuring the ability to respond to public health challenges and natural disasters. Modern manufacturing facilities can take five to seven years and cost up to \$1 billion to build. Thus, a long-term, consistent commitment from the federal government is critical to harnessing existing manufacturing and building an expanded domestic manufacturing base in the United States.

The MADE in America Act seeks to mitigate drug shortages while incentivizing the domestic manufacturing of drugs, active pharmaceutical ingredients (API), personal protective equipment (PPE) and diagnostics by:

- Identifying barriers to domestic manufacturing;
- Enhancing intra-agency coordination with regard to compliance activities;
- Requiring comprehensive reporting on FDA's utilization of MRAs;
- Enhancing transparency of drug facility inspection timelines by building on FDA's annual facilities inspection reports; and
- Creating a new pathway for FDA to evaluate advanced manufacturing technologies.

AAM shares many of the goals of this legislation, including increasing the efficiency of FDA's regulatory and approval processes, removing redundancies and reducing the time for approvals across the board. Instead of waiting until after a facility is built and equipment is installed and validated, FDA should expand cooperation with the manufacturer, working collaboratively to evaluate and approve the facility and the tech transfer processes concurrently. To accomplish these goals, AAM believes that the creation of an FDA intra-agency working group focused on helping expedite reviews and approvals to domestic pharmaceutical manufacturing would be helpful. This working group would focus on reviewing for approval the transfer of production back into either U.S.-approved facilities or newly constructed facilities at new or existing sites, including those utilizing advanced manufacturing technology.

AAM also supports continued exploration and study of advanced manufacturing technologies, including continuous manufacturing. These technologies, however, are still relatively new and may not be viable options for all product lines and all medicines. FDA's review and validation of these technologies could be helpful in building stronger evidence for adoption in addition to increasing the efficiency of the regulatory review process. Because advanced manufacturing technologies are not always appropriate or the best option for all products, we encourage policymakers and regulators to consider the potential unintentional consequences—such as slowing down or decreasing the amount of generic competition and creating or exacerbating drug shortages—that would result

from preferencing or unintentionally steering toward manufacturing methods that may not be appropriate or feasible for various types of drugs.

While AAM shares many of the goals of H.R. 3927, we believe this legislation would require a significant increase in resources and FTEs for FDA to implement. The resource and FTE commitments under GDUFA III and BsUFA III were very carefully negotiated, with industry providing sufficient funds to implement the commitments outlined in the agreements. Enactment of these additional provisions without additional appropriations from Congress could pull from these resources, placing a strain on the remaining resources available to FDA. We encourage Congress to carefully consider imposing new requirements on FDA that would impede its ability to fulfill the negotiated commitments under GDUFA III.

Drug Manufacturing Innovation Act (H.R. 6988)

AAM supports the continued exploration and study of advanced manufacturing technologies. While these technologies may hold promise, their adoption requires substantial investments in specialized chemistry and engineering expertise, the acquisition of new facilities or the conversion of existing facilities, and the potential abandonment of existing manufacturing capital that is still within its useful life. Generic developers operate in competitive and often low-margin markets. While some generic developers are exploring the costs and benefits of using advanced manufacturing technologies, these technologies may not be viable or sustainable options for certain product lines, especially for low-volume medicines.

The Drug Manufacturing Innovation Act (H.R. 6988), introduced by Reps. Mike Levin (D-CA) and John Joyce (R-PA), would establish a program to support the adoption of, and improve the development of, innovative approaches to drug product design and manufacturing. It would also require FDA to issue guidance on regulatory requirements related to the development of such technologies and the data required to support approval of drugs made pursuant to their use.

While guidance providing clear expectations for the adoption and regulatory requirements related to advanced manufacturing technologies would be helpful, preferencing the use of advanced manufacturing technologies over other methods could have a negative impact on patient access to medicines. It could have significant unintended consequences, such as creating drug shortages, increasing prices and driving generic competition out of the market. We therefore encourage any programs, working groups and guidances contemplated by this legislation to focus on increasing the knowledge base and evidence supporting use of advanced manufacturing technologies and providing direction and other helpful information to drug developers who choose to implement these technologies.

Biosimilar Interchangeability Determinations (H.R. 7047)

Biosimilars—and, by extension, interchangeables—must have the same strength as the reference product under the *Biologics Price Competition and Innovation Act* (BPCIA).¹⁴ FDA has historically defined “strength” for parenteral solutions to mean both total drug content and concentration.¹⁵ When FDA determines a biosimilar is interchangeable with its reference product, it may be substituted for that brand-name product under the applicable state law. To incentivize the development of interchangeable biosimilars, the BPCIA awards a period of exclusivity to the first interchangeable biosimilar for the same reference product.

H.R. 7047, introduced by Rep. Kurt Schrader (D-OR), would provide FDA with the discretion to waive the same strength requirement for biosimilars in certain cases.¹⁶ Because biosimilarity is a prerequisite for interchangeability, this would potentially result in a biosimilar with a different concentration and a different volume than the reference product being interchangeable—and therefore eligible for substitution—with the reference product. In addition, if FDA determined a biosimilar with a different concentration from the reference product is interchangeable pursuant to this proposal, it could result in the first interchangeable biosimilar, to the extent it remains eligible for exclusivity, blocking another interchangeable product at the same concentration as the reference product from receiving interchangeable exclusivity.

We understand H.R. 7047 is trying to address short-term issues associated with product launches and anticompetitive tactics. AAM and its Biosimilars Council strongly share this goal, but we are concerned that this specific proposal does not represent the correct approach for addressing this key issue. In particular, AAM encourages the Committee to assess some of the implications from this proposal on the BPCIA as described below.

First, AAM is concerned that modifying strength and interchangeable exclusivity in this manner could lead to the gaming of exclusivity and potential dissemination of misinformation by brand-name companies to suggest that products are different. The bedrock principle underlying interchangeability—whether in the generic drug or biosimilar contexts—is that follow-on products are the same as their brand products in all ways that matter. This ensures a follow-on product can be confidently used in place of a brand without the intervention of a health care provider.

¹⁴ PHS Act § 351(k)(2)(A)(i)(IV); PHS Act § 351(k)(4)(A)(i).

¹⁵ FDA, “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),” December 2018, available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/new-and-revised-draft-qas-biosimilar-development-and-bpci-act-revision-3>, pp. 5-6 (“[A] sponsor of a proposed biosimilar product or proposed interchangeable product with an ‘injection’ dosage form (e.g., a solution) can demonstrate that its product has the same strength as the reference product by demonstrating that both products have the same total content of drug substance (in mass or units of activity) and the same concentration of drug substance (in mass or units of activity per unit volume).”).

¹⁶ PHS Act § 351(k)(2)(A)(i)(IV).

Second, if this proposal is added to the user fee reauthorization, it would likely be enacted right on the cusp of biosimilar competition for Humira. As AAM understands the proposal, it would result in one interchangeable for Humira—to the extent that the sponsor has not lost exclusivity—rather than two potentially simultaneous interchangeables at different strengths. Indeed, Boehringer Ingelheim currently has an interchangeability determination for its low-concentration adalimumab biosimilar¹⁷ and Alvotech is seeking a separate interchangeability determination for a high-concentration adalimumab biosimilar.¹⁸ As AAM understands this proposal, it could likely preclude such a second, simultaneous interchangeability determination because all strengths of Humira would be considered the same reference product for interchangeable exclusivity purposes. This may be problematic for patients: two or more simultaneous interchangeables could lead to additional competition that benefits patients and the health care system. More importantly, these potentially negative effects on competition would apply to future biologics and would not be limited to Humira.

AAM recognizes and appreciates that H.R. 7047 is intended to address problematic, competition-stifling behavior. We would be glad to work with the Committee to directly address anticompetitive tactics and to help ensure that biosimilars and interchangeables are not harmed by last-minute changes to brand-name products. We would also welcome the opportunity to discuss how Congress could take steps to reduce the clinical burden on biosimilars and interchangeable manufacturers to ensure more timely patient access to low-cost medicines. However, making significant modifications to the BPCIA will likely lead to significant unintended and unpredictable consequences for competition and access to more affordable biosimilar options.

Biologics Marketing Transparency Act (H.R. 7035)

The FDA Reauthorization Act of 2017 (FDARA) included provisions requiring holders of approved brand-name and generic applications to notify FDA in advance of withdrawing a drug from the market or if a drug will not be available for sale. FDA uses these marketing status notifications to update drug information listed in the Agency's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book")—and, in particular, the discontinued section of the Orange Book. Inclusion of this information in the Orange Book can help abate confusion about the marketing status of various drugs. Accurate drug marketing information is also helpful to generic drug

¹⁷ Center for Biosimilars, "FDA Grants Interchangeable Status for Boehringer Ingelheim's Adalimumab Biosimilar (Cyltezo)," October 2021, available at <https://www.centerforbiosimilars.com/view/fda-grants-interchangeable-status-for-boehringer-ingelheim-s-adalimumab-biosimilar-cyltezo->.

¹⁸ JD Supra, "FDA Accepts Alvotech's BLA Supporting Interchangeability for ATV02, a High Concentration, Citrate-Free Biosimilar Candidate for Humira®," March 2022, available at <https://www.jdsupra.com/legalnews/fda-accepts-alvotech-s-bla-supporting-6313361/>.

developers because withdrawal of a brand-name drug from the market can complicate ANDA submissions and reviews, and it can delay ANDA approvals.

The Biologics Marketing Transparency Act (H.R. 7035), introduced by Reps. Kathy Manning (D-NC) and Richard Hudson (R-NC), would extend FDARA's marketing status notification requirements to biologic medicines licensed under the Public Health Service Act. This commonsense proposal will provide useful information to biosimilar developers through the Purple Book. AAM supported the 506l marketing status provision included in FDARA and we look forward to working with the Committee on this proposal to ensure that it is appropriately tailored to address biologics.

Conclusion

The proposed GDUFA III and BsUFA III performance goals presented to Congress represent a sustained collaboration among FDA, industry and other vested stakeholders. More than 14 months were spent negotiating the two packages. We are proud that the commitments reached will significantly benefit America's patients by increasing access to more affordable generic and biosimilar medicines. Many lessons have been learned from the prior two GDUFA and BsUFA agreements, and we feel strongly that, with GDUFA III and BsUFA III, we arrived at a thoughtful, carefully negotiated commitment that will help address complex issues for both the generic drug and biosimilar user fee programs. Throughout the negotiation process, we focused on increasing patient access to more affordable, high-quality generic and biosimilar medicines. We believe we were successful in that endeavor.

AAM understands that the legislative proposals under discussion today, and the reauthorization package Congress ultimately passes, could affect FDA's ability to implement the user fee agreements. It is important to balance how each of these policies may alter the allocation of resources between the negotiated user fees and the amounts appropriated by Congress each year to fund FDA's operations. Similarly, the timely approval of the user fee agreements is of paramount importance to ensuring that the generic drug and biosimilar review programs continue uninterrupted for the benefit of patient access to more affordable medicines. We look forward to working with members of both parties to ensure timely passage of GDUFA III and BsUFA III.

Thank you again for the opportunity to testify on these important proposals. I look forward to answering your questions.