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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Comment on “Generic Drug User Fee Amendments” Docket No. FDA-2020-N-1459

To whom it may concern:

We, the undersigned unions and consumer and public interest groups,¹ are appreciative of the opportunity to provide comments on the Food and Drug Administration’s (“FDA”) “Generic Drug User Fee Amendments” Docket No. FDA-2020-N-1459. We work tirelessly to rein in excessive drug prices and write these comments because we are concerned about the lack of meaningful patient choice resulting from anticompetitive contracting practices along with formulary discrimination that restrict patients’ access to innovative therapies and lower cost alternatives.

Patients’ access to biosimilars and generic drugs is critically important to lowering overall drug spending. Indeed, the use of generic medicines saved government and private payors some \$2 trillion in the past ten years and \$293 billion in 2018 alone.² The savings from generic drugs are tremendous; unfortunately, many patients including seniors are not obtaining all of the savings that they should. Although there has been a record number of first generics approved by the FDA between 2016 and 2018, fewer than half are commercially available.³ Misaligned

¹ The groups are American Federation of State, County, and Municipal Employees, Alliance for Retired Americans, American Family Voices, Consumer Action, Coalition to Protect Patient Choice, Doctors for America, End AIDS Now, Services Employees International Union, Social Security Works, Treatment Action Group, UNITEHERE, and U.S. PIRG Education Fund.

² AAM 2019 Generic Biosimilars Access and Savings Report, p. 10, 16 available at <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>.

³ *Id.* at 15.

incentives in the drug supply chain and anticompetitive conduct by branded pharmaceutical manufacturers result in the lack of commercialization of FDA-approved biosimilars and authorized generics. Only about half of the generics that were commercially available between 2016 and 2018 were included on formularies of Medicare Part D plans during that time, which means that only 25 percent of newly approved generic drugs made it on to a Part D plan's formulary, so seniors were denied access to lower cost alternatives.⁴ Unfortunately, generics are not being covered in Medicare Part D plans because of “rebates” and flaws in the Part D plans' benefit design that have made it easier for plans to exclude them.⁵

We believe that the Generic Drug User Fee Amendments (“GDUFA”) should include policies to increase competition and incentivize new product development. We appreciate the FDA's commitment and efforts to address competition concerns and obstacles faced by biosimilars and generics. Earlier this year, the FDA and the Federal Trade Commission (“FTC”) jointly held a workshop on a competitive marketplace for biosimilars. In 2018, the FDA published the Biosimilars Action Plan (“BAP”)⁶ and in 2017, the FDA announced the Drug Competition Action Plan (“DCAP”) to encourage robust and timely market competition for generic drugs.⁷ The FDA's goal with the DCAP was to help remove barriers to generic drug development and market entry to spur competition so that consumers can get access to the medicines they need at affordable prices.⁸ Robust competition from generic manufacturers results in more substantial price concessions and drives the uptake of lower cost drugs. To that end, the third component of the DCAP was aimed at closing loopholes and reducing the ability of branded manufacturers from “gaming” FDA rules that delay generic drug approvals.

We would like to highlight how branded drug manufacturers use contracting strategies known as rebate walls, which work in conjunction with formulary placement to foreclose competition from biosimilars and generics because we do not believe that these strategies are getting enough attention from the FDA. According to the Association for Accessible Medicines (“AAM”), rebates paid by drug manufacturers to pharmacy benefit managers (“PBMs”) and health plans are slowing the introduction and adoption of biosimilars and authorized generics in the United States.⁹ There is increasing evidence that the rebates drug manufacturers offer commercial and Medicare payors to get expensive prescription drugs on their formularies actually raise the cost of prescription drugs and keep more affordable biosimilars, branded, and generic drugs out of a preferred position on the formulary.¹⁰

What is important to understand about these rebates is that they are not discounts for patients. Because the rebates go to PBMs and plans, rather than to consumers, payors have perverse incentives to negotiate higher list prices so they can secure higher rebates – without regard to

⁴ *Id.*

⁵ AAM White Paper Access Denied First Generics available at https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

⁶ FDA Biosimilar Action Plan: Balancing Innovation and Competition, July 2018 available at <https://www.fda.gov/media/114574/download>.

⁷ FDA Drug Competition Action Plan available at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan#:~:text=In%202017%2C%20FDA%20announced%20the,underlying%20our%20generic%20drug%20program>.

⁸ *Id.*

⁹ See AAM White Paper Access Denied First Generics, *supra* note 5.

¹⁰ *Id.*

patient wellbeing or patient cost.¹¹ These rebates actually increase patients' costs because the patients' coinsurance is based on the inflated list price of the drug. If the patients had access to lower cost biosimilars, branded drugs, or generics, their coinsurance costs would go down.

How does the rebate wall work? A rebate wall or trap is erected when an incumbent manufacturer uses existing market power to secure preferred formulary access for its drug by offering volume-based rebates to PBMs and plans, on the condition that they deny or limit the formulary access of rival drugs.¹² The rebate may be bundled across multiple products, indications, and/or therapeutic specialties, the breadth of which cannot be matched by a new biosimilar, branded medicine, or generic.¹³ Through a rebate wall, a manufacturer with a dominant incumbent drug can prevent a newly launched biosimilar, branded drug, or generic drug from a preferred position even if the new drug is offered at a lower price. This is possible because the new drug has few prescriptions, if any, so even a larger rebate will not overcome the potential loss of the rebate dollars from the market-leading product. Newly launched drugs lose because offering them at a lower price does not guarantee them a preferred position on a plan's formulary.¹⁴ Patients lose because they do not have access to more affordable drugs.

Historically, a plan's formulary would cover a new generic medicine because the generic enters at a significantly discounted price from a branded product. Since 2017, the Centers for Medicare and Medicaid Services ("CMS") Part D formulary guidelines started to allow the Part D plans to place generics on branded tiers.¹⁵ The CMS change provided Part D plans with a lot of flexibility to design drug formularies and tier structure, and emboldened them to place first generics on branded drug tiers rather than on generic tiers. The change to formulary structure is costly enough, but matters are worse when PBM and plan incentives are considered. Branded manufacturers started providing rebates to Medicare Part D plans on the condition that first generics be kept off their formularies.¹⁶ Unfortunately, the PBMs and plans are incentivized to implement formularies that are designed to steer seniors from lower cost generics to branded drugs by comingling them on the same formulary tier. CMS also created a specialty tier intended for higher-priced brand products, however, new lower priced generic competitors to specialty drugs are only available on the same specialty tier, which means that the same problem exists for higher priced specialty drugs as well.¹⁷

¹¹ Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed*, *Washington Post*, November 26, 2018.

¹² The competitive concerns in these practices are described in David Balto, *FTC Must Tackle Anti-Competitive Drug Rebate Practices*, *Law360*, May 17, 2019; Robin Feldman, *Why Prescription Drug Prices Have Skyrocketed*, *Washington Post*, November 26, 2018. According to Professor Robin Feldman, law professor at University of California Hastings Law and an expert on drug pricing, "the name of the game is volume. The more volume a drug company has with a particular PBM or hospital, the better deal it can offer as a temptation to exclude rival drugs." Former FDA Chairman Scott Gottlieb has recognized that volume-based rebates on biologics allow the manufacturers and middlemen to split the monopoly profits. Speech, Brookings Institute, available at <https://www.brookings.edu/events/u-s-market-for-biosimilars-fda-scott-gottlieb/>

¹³ See, e.g., Aaron Hakim and Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, *Journal of the American Medical Association*, May 2, 2017.

¹⁴ Jay Hancock and Sydney Lupkin, *Secretive Rebate Trap Keeps Generic Drugs for Diabetes and Other Ills Out of Reach*, *Kaiser Health News*, January 18, 2019.

¹⁵ AAM White Paper Access Denied First Generics available at https://accessiblemeds.org/sites/default/files/2019-09/AAM-White-Paper-Access-Denied-First-Generics-web_0.pdf.

¹⁶ *Id.* at 12-13.

¹⁷ *Id.* at 13.

In short, the rebate wall and formulary design flaw are being used to limit patient choice, slow the adoption of less expensive new authorized generics, raise costs to patients, and reduce competition. The anticompetitive effect is that a new generic cannot get on the formulary or, at best, is on a tier with a branded drug and is being disadvantaged by the rebate wall. This result is extremely harmful to patients because it means that they miss out more affordable prescription medicines that they need in the short term as well as in the long term, if manufacturers of generics exit the market all together or decide not to launch at all.

The elimination of rebate walls should not be controversial. Indeed, Alex Azar, Secretary of Health & Human Services,¹⁸ and former Commissioner Scott Gottlieb have called for action to stop branded drug companies from using rebate walls that foreclose competition.¹⁹ Former FDA Commissioner Scott Gottlieb has argued for the need to “stop branded drug companies from using ‘rebates’ to squelch competition from biosimilars...If there’s one situation where rebates are anticompetitive, it’s when they’re being used to block competition from a low-cost generic.”²⁰ Eliminating the use of rebate walls in the prescription drug market will ensure that consumers benefit from and have access to new, lower cost, clinically effective prescription drugs. Formulary decisions should be based on efficacy, safety and lowest list price – not highest price concession based on a percentage of the list price.

Recommendations:

We believe that the FDA should use a portion of the generic drug user fees to fund initiatives that would result in patients and consumers having greater access to lower cost medicines that would incentivize new generic product development. Indeed, the FDA has an important role to play in ensuring that prescription drug markets are competitive and patients have access to low cost generic drugs as it seeks to “strike a careful balance between pharmaceutical innovation and access to lower cost generic products.”²¹ Here are three recommendations.

- First, the FDA should further coordinate with the FTC by proactively identifying anticompetitive business practices including rebate walls that prevent lower cost generics, biosimilars, and branded drugs from gaining formulary access. When announcing the DCAP and the BAP, Former FDA Commissioner Scott Gottlieb discussed the need for the FDA to work closely with the FTC regarding anticompetitive practices and the FDA should continue these efforts.²²

¹⁸ HHS Secretary Alex Azar Testimony to the Senate Health, Education, Labor and Pensions (HELP) Committee, June 12, 2018 (“I am very much aware that these rebate walls can prevent competition and new entrants into the system... I do not like that practice. I think it’s using their market power in ways that are not appropriate.”) available at <https://www.c-span.org/video/?446791-1/secretary-azar-testifies-prescription-drug-pricing-plan>.

¹⁹ Scott Gottlieb, *Don’t Give Up on Biosimilars—Congress Can Give Them a Boost*, Wall Street Journal, August 24, 2019.

²⁰ *Id.*

²¹ DCAP and Scott Gottlieb, FDA Working to Lift Barriers to Generic Drug Competition, FDA, June 21, 2017.

²² *Id.* (“We’re also going to be looking hard at how best to coordinate with the Federal Trade Commission in identifying and publicizing practices that the FTC finds to be anti-competitive.”); see also, The Brookings Institute. *Cultivating a Vibrant U.S. Market for Biosimilars: A Conversation with the FDA’s Scott Gottlieb*. July 18, 2018. Available at: https://www.brookings.edu/wp-content/uploads/2018/07/es_20180718_biosimilars_transcript.pdf. Mr. Gottlieb stated that “[a]s far as the partnership with the FTC, we have worked with them to provide information where we think that there's anti-competitive behavior as well as -- I don't want to say instigate certain scenarios -- but certainly when certain scenarios seem to be unfolding, working in concert with them through the activity to make sure that they have transparency on what's going on. And I think we've handed them some pretty good set of

- Second, the FDA should establish a more formal process to relay competition, access, and coverage concerns to the FTC and CMS.²³ The FDA is uniquely situated to engage with these agencies to promote competition that would result in lower prices and greater access to affordable drugs. The FDA should collaborate with the FTC and CMS to learn more about how rebate walls impact the availability of biosimilars and generics in the Medicare Part D market. Coordination between the three agencies could be very useful as CMS plays a central role in overseeing the Medicare program, making formulary and tiering decisions, and addressing rebates through rule making.
- Third, the FDA, FTC, and CMS should hold a public joint workshop to gain a better understanding the role rebate walls play in blocking lower cost branded medicines, biosimilars and generics from drug formularies. The FDA has historically sought information from various stakeholders to learn about the various obstacles that lower cost medicines including biosimilars and generics face.²⁴
- Fourth, the FDA should publicly report on the progress of the DCAP, generic approvals, and market access for generic drugs.

facts in the past. I'm going to be meeting with the FTC, the new FTC Commissioner really soon, and being with some of the individual commissioners as well, to talk about what more we can do here. So, I don't want to get too far ahead of myself, but I think that there are places where we can help identify information that can help them bring actions.”

²³ See Scott Gottlieb Remarks, “Capturing the Benefits of Competition for Patients,” March 7, 2018 (“Bringing more drug competition to the market, and addressing the high cost of medicines, is a top priority of the Administration and of the Secretary of Health and Human Services. And we’re working closely with Secretary Alex Azar on crafting policy options that can improve competition, access, and the chance for patients to benefit from safe, effective, and lower cost biosimilar alternatives.”); see also FDA BAP, “We also recognize that there are some significant factors affecting biosimilar competition and access outside of the FDA’s direct control. These include payor reimbursement practices, which may affect sponsors’ ability to successfully market new products even after FDA approval. When we see practices that we believe create an imbalance between innovation and competition that is contrary to statutory intent, we will use our leadership to highlight these issues, encourage market participants to seek solutions that ensure timely access to biosimilar products and work with our partners across the government to take corrective action where necessary and appropriate.”

²⁴ See FDA BAP, Recommendation 11, which recommends that “engaging in a public dialogue through a Part 15 hearing and opening a docket to request additional information from the public on what additional policy steps the FDA should consider as we seek to enhance our biosimilar program.”

We sincerely appreciate your thoughtful consideration of the issues discussed in this letter and look forward to working with you to ensure that rebate walls are eliminated.

If you have any questions regarding these comments, please contact David Balto at david.balto@dcantitrustlaw.com.

Respectfully submitted,

American Federation of State, County, and Municipal Employees

Alliance for Retired Americans

American Family Voices

Consumer Action

Coalition to Protect Patient Choice

Doctors for America

End AIDS Now

Services Employees International Union

Social Security Works

Treatment Action Group

UNITEHERE

U.S. PIRG Education Fund