UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TEVA PHARMACEUTICALS USA, INC., *et al.*, *Plaintiffs*, v. ROBERT F. KENNEDY JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*, *Defendants*.	No. 1:25-cv-00113-SLS

BRIEF OF *AMICUS CURIAE* ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Civil Rule 26.1, counsel for *Amicus Curiae* states as follows: The Association for Accessible Medicines is a 501(c) nonprofit organization. It has no parent corporation and issues no stock, and no publicly held corporation owns a 10% or greater interest in it.

INTEREST OF THE *AMICUS CURIAE*[1]

The Association for Accessible Medicines ("AAM") is a nonprofit, voluntary association representing manufacturers and distributors of generic and biosimilar medicines and bulk active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. AAM's members provide patients with access to safe and effective generic and biosimilar medicines at affordable prices. AAM's core mission is to improve the lives of patients by providing timely access to safe, effective, and affordable prescription medicines. Generic drugs constitute more than 90% of all prescriptions dispensed in the United States, yet generics account for only 13% of total drug spending.

AAM regularly participates in litigation as an *amicus curiae*. AAM and its members have a significant interest in the questions presented in this litigation, which directly impact the ability of generic and biosimilar manufacturers to continue to provide patients with a diverse supply of safe, effective, and lower-cost medicines. The Centers for Medicare & Medicaid Services ("CMS") has adopted interpretations of the Inflation Reduction Act ("IRA"), and its Drug Price Negotiation Program (the "Negotiation Program"), that, if upheld, would have market-distorting effects on the generic and biosimilar industries. Recognizing the historic role of generic and biosimilar competition in bringing down prices while expanding supply, Congress directed in the IRA that government price mandates would not apply to brand products once a corresponding generic or biosimilar is "marketed." But CMS has substantially narrowed this protection

[1] No counsel for a party authored this brief in whole or in part, and no party, party's counsel, or person or entity other than AAM or its counsel contributed money that was intended to fund the preparation or submission of this brief.

with atextual and indeterminate rewrites of the statute that expand CMS's authority to impose and mandate pricing controls despite generic and biosimilar entry. CMS's approach will cause price mandates to displace generic and biosimilar competition—competition that has promoted patient access to affordable medicines without undermining innovation. It will also erode the economic incentive for generic and biosimilar manufacturers to undertake the costly investments needed to enter the market, resulting in fewer supply sources for critical medicines and creating a risk of shortages.

Because AAM and its members have a strong interest in ensuring the continued strength of the generic and biosimilar marketplace—so as to ensure that patients have access to safe, affordable, and life-saving medicines—AAM respectfully submits this brief to urge the Court the grant Teva's motion for summary judgment.

INTRODUCTION

The public debate over the IRA and the Negotiation Program has centered on the law's impact on the manufacturers of branded medicines, as the Act provides a process for CMS to select brand medicines for the Program and then determine the maximum allowable prices for those selected products within Medicare. But the IRA's novel price mandates also threaten significant collateral impacts for generic and biosimilar medicines. If a branded product is subject to a government-mandated price maximum, that will inevitably affect the market-entry decision for generics and biosimilars. Yet the IRA gives generic and biosimilar manufacturers no guidance about which branded drugs will ultimately be selected, much less what the price controls will be, creating uncertainty that makes it difficult to invest the substantial sums needed to bring generic and biosimilar products to market.

As enacted by Congress, the IRA at least has certain provisions intended to mitigate the negative spillover effects of the Negotiation Program for generic and biosimilar manufacturers. In particular, CMS may not impose price controls, and it must lift those that are in place, if there is an approved and "marketed" generic or biosimilar competitor. *See* 42 U.S.C. §§ 1320f–1(c)(1), (d)(1), (e)(l). Whether a generic drug or biosimilar is "marketed" is a simple, objective inquiry: if there is a generic or biosimilar offered for sale in the market, then the statutory test is met and price controls may not be imposed. But CMS's application of the IRA undercuts this safety valve. Under its approach, price mandates may persist after a generic drug or biosimilar is approved and sold if CMS decides that such marketing is not "bona fide." CMS's application of this atextual qualifier is hopelessly vague, as CMS purports to use a "holistic inquiry" based on open-ended "factors."[2] Moreover, the data sources that CMS has identified as probative are typically time-lagged, meaning that even indisputably robust marketing may not become "bona fide" to CMS until several months after a product launch—at which point the price effects from government mandates may already be locked in.

CMS's policies not only conflict with the plain text of the IRA, but they threaten to undermine generic and biosimilar competition by eroding important limits that Congress placed on CMS authority. If left undisturbed, CMS's implementation will discourage generic and biosimilar manufacturers from undertaking the significant investments needed to bring much-needed medicines to the market. The result will be slower generic and biosimilar competition, from fewer generic and biosimilar manufacturers, leaving

[2] CMS, Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027, at 170-171 (Oct. 2, 2024), https://tinyurl.com/bdf5srv3 ("2027 Final Guidance").

prices higher for longer. This Court should reject CMS's attempts to rewrite the IRA in a way that compromises the strength of the generic and biosimilar markets that have proven so beneficial to the U.S. healthcare system.

ARGUMENT

I. The generic and biosimilar industries are vital to the U.S. healthcare system but the IRA threatens their continued survival.

The generic and biosimilar industries have been a boon to the U.S. healthcare system. Their development has saved the system trillions of dollars. But even with the abbreviated approval processes that have helped spur the industries' success, developing generic and biosimilar products requires significant investment and considerable risk. The industries thus remain fragile, meaning that market distortions threaten to upset the existing economic incentives that help ensure continued, robust generic and biosimilar competition.

A. Generics and biosimilars benefit the healthcare system by offering lower-cost alternatives.

The rise of the modern generic drug industry traces back to the 1984 passage of the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Act shortened the path to FDA approval, allowing generic manufacturers to "piggy-back on the pioneer's approval efforts" and file an application "specifying that the generic has the 'same active ingredient as,' and is 'biologically equivalent' to, the already-approved brand-name drug." *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (citation omitted). The idea was that the Hatch-Waxman Act would "'speed[] the introduction of low-cost generic drugs to market,'" increasing competition and decreasing prices. *See id.* (citation omitted).

And it worked. By "making generic entry easier and less costly, the Hatch-Waxman

Act helped increase the number of generic manufacturers producing the same drug," causing the "average prescription price of a generic drug [to] fall[]."[3] The savings to patients and payors have continued to rack up over the years, touching $3 trillion over the past decade.[4] Statistics for 2023, the most recent available, show patients and payors saving over $445 billion, with Medicare seeing $137 billion of those benefits. *Id.* at 7. That same year, the "average out-of-pocket cost for a generic was $7.05, while the average out-of-pocket cost for a brand drug was nearly four times higher—at $27.10." *Id.* at 10. In short, increased generic competition has lightened the financial load for those who need medications, and those that are covering them.

While the Hatch-Waxman Act applies only to generic drugs, Congress later sought to build on its success by establishing a parallel abbreviated pathway for the approval of biosimilar versions of biological products. Whereas generic drugs are bioequivalent versions of "traditional [small-molecule] drugs … typically synthesized from chemicals," biosimilars are designed to mirror biological products—"a type of drug derived from natural, biological sources such as animals or microorganisms." *Sandoz Inc. v. Amgen Inc.*, 582 U.S. 1, 6 (2017). Biologics "often represent the cutting-edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available."[5] They are "the fastest-growing class of medications in the United States and account for a

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[3] Cong. Budget Off., *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii (July 1, 1998), https://tinyurl.com/3n4jnjh5.

[4] *See* Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 7 (Sept. 5, 2024), https://tinyurl.com/rh8mmtd5 ("*Savings Report*").

[5] FDA, *What Are "Biologics" Questions and Answers* (Feb. 6, 2018), https://tinyurl.com/pu7ubpxz ("*Biologics Questions and Answers*").

substantial and growing portion of health care costs."[6]

In 2010, Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA"), Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804 (2010). Mirroring the Hatch-Waxman Act, the BPCIA granted biosimilars an abbreviated pathway to FDA approval. 42 U.S.C. § 262. And it did so for the same reason: "encourage competition in the field of biologics."[7] Since then, the biosimilar market has experienced rapid growth and "robust price competition." *Savings Report*, *supra*, at 29. On average, biosimilars hit the market at 40% less than their reference biologics. *Id*. at 28, 32. And they drive down prices for the branded biologic, too, by an average of around 33%. *Id*. at 32. In all, patients and payors have saved almost $36 billion since 2015, when the first biosimilar hit the market—with savings increasing each year. *See id*. at 7-8.

Overall, history has shown that increased generic competition is good for those who need medications and for those who help pay for them. Patients have greater access to the medications they need at a lower cost to themselves and to those who provide coverage—including the federal government.

B. Developing generics and biosimilars is costly, time-consuming, and risky, so the industry model depends on predictable policies.

While abbreviated approval pathways have helped spur generic and biosimilar competition, profit margins in the industry are thin. Breaking into an already established drug market is not simple. Generic drug manufacturers have to engage in research and testing to develop bioequivalent formulations, while also securing the active

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[6] FDA, *Biological Product Innovation and Competition* (Apr. 10, 2024), https://tinyurl.com/37yr6x8b.

[7] Chittam Thakore Ph.D., *Basics of Biologics Price Competition and Innovation Act* (Nov. 21, 2016), https://tinyurl.com/mrxjcn3p.

pharmaceutical ingredient and satisfying FDA's demanding manufacturing standard.[8] For biologic manufacturers, time and cost only increase. "[M]ost biologics are … not easily identified or characterized," resulting in longer, more expensive research and development efforts.[9] Biosimilars are also subject to some clinical trials and the weighty costs coming with them.[10] As a result, "a typical biosimilar costs $100 million to $300 million to develop and takes six to nine years to go from analytical characterization to approval" with "the probability of success remain[ing] low."[11]

Manufacturers also face significant costs and delays from patent barriers erected by the brand. Both the Hatch-Waxman Act and the BPCIA provide avenues to challenge patents that the brand asserts cover its product. *See, e.g.*, *Sandoz*, 582 U.S. at 7-11 (describing BPCIA's framework for infringement litigation); *Teva Pharms. USA, Inc. v. Sebelius*, 595 F.3d 1303, 1305 (D.C. Cir. 2010) (same for the Hatch-Waxman Act). But seeking to market a generic or biosimilar product before all the brand patents expire comes "with the hazard of sparking costly litigation." *Teva*, 595 F.3d at 1305; *see also Mylan Inc & Subsidiaries v. Comm'r of Internal Revenue*, 76 F.4th 230, 241 (3d Cir. 2023) (noting that one generic manufacturer incurred nearly $130 million in legal fees for Hatch-Waxman Act litigation in a three-year period between 2012 and 2014).

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[8] FDA, *What Is the Approval Process for Generic Drugs?* (Aug. 31, 2017), https://tinyurl.com/44tdmvd8; Aylin Sertkaya, PH.D., *et al.*, *Cost of Generic Drug Development and Approval* 16-20 (Dec. 31, 2021), https://tinyurl.com/4mhb4b82.

[9] *Biologics Questions and Answers*, *supra*; *see* FDA, *Review and Approval* (Dec. 13, 2022), https://tinyurl.com/bdrjs6n2.

[10] Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 22 (Apr. 2021), https://tinyurl.com/5bafw7au.

[11] Miriam Fontanillo, *et al.*, McKinsey & Co., *Three Imperatives for R&D in Biosimilars* (Aug. 19, 2022), https://tinyurl.com/mu54xxcr.

These costs have only accelerated in recent years, as brand manufacturers have often erected large patent estates that impede timely generic and biosimilar entry.[12] Patent estates are an accumulation by a brand manufacturer of many, often dozens of, patents for the same drug, sometimes at the end of the drug's product lifecycle. *Id.* These types of patent estates can make the price of market entry prohibitive for a generic competitor. Even if all the brand's patents turn out to be invalid or not infringed, manufacturers of generics and biosimilars still face years of cripplingly expensive litigation.

Since bringing generics and biosimilars to market is time consuming and costly, manufacturers will invest in developing products only if they can reliably forecast the market that they are entering. In other words, generic and biosimilar manufacturers need to have some confidence that the drugs they invest in have a chance at success.[13] To do so, they need to be able to forecast what a particular market will look like years in advance: how many competitors will there be, and what will the prices of those competing products look like? If they cannot predict the answers to those questions with a reasonable degree of confidence, generic and biosimilar manufacturers might decide to forgo investing in developing a particular generic drug or biosimilar entirely. *Id.*

C. By removing predictability, the IRA threatens to undermine the successes of the generic and biosimilar industries.

As it stands, the IRA creates "significant uncertainty" for generic and biosimilar

[12] *See* Biosimilars Council, *Failure to Launch: Patent Abuse Blocks Access to Biosimilars for America's Patients* 5 (June 25, 2019), https://tinyurl.com/26vsdftw.

[13] *See* Ass'n for Accessible Meds., *The IRA Hurts Generic and Biosimilar Medication Competition* (Feb. 10, 2025), https://tinyurl.com/bdhu7jsk ("*The IRA Hurts Competition*").

manufacturers.[14] Under the IRA, CMS selects top-spend drugs under Medicare to be subject to "price negotiations." 42 U.S.C § 1320f-1(a). CMS can select small molecule drugs for price negotiations if there is no approved and "marketed" generic version of the drug and seven or more years have elapsed since FDA's initial approval. *Id.* § 1320f-l(e)(l)(A). CMS can select a biologic drug if there is no licensed and "marketed" biosimilar and at least eleven years have elapsed since the date of its licensure. *Id.* § 1320f-l(e)(l)(B). During the putative "price negotiations" for selected drugs and biologics, CMS sets a "maximum fair price." *Id.* § 1320f-2(a)(l). The selected drug must be made available to Medicare beneficiaries at the government-mandated price beginning the first day of the first "price applicability year" for the selected drug, which falls roughly two years after the selection date. *Id.*

This regime imposes two key problems of clarity for generic and biosimilar manufacturers. The first is one of timing. "Generic and biosimilar companies undertake extensive market analysis, engage in extremely costly patent litigation, and participate in a complex FDA approval process, making key decisions years in advance of launch." *Hatch-Waxman Act turns 40*, *supra*, at 8. The typical generic or biosimilar manufacturer is deciding whether to enter a particular drug market about one to three years after a branded drug or biologic receives FDA approval. *Id.* Yet negotiation under the IRA takes place years after a generic or biosimilar manufacturer is making its investment decisions—seven years after launch for generics, and eleven years for biosimilars. *Id.* So, at the time generic and biosimilar manufacturers are deciding whether to undertake the "several hundred million dollars" of investments needed "to develop a generic or

[14] *See* Ass'n for Accessible Meds., *Hatch-Waxman Act turns 40*, at 7-8 (2024), https://tinyurl.com/4xfj8cn8 ("*Hatch-Waxman Act turns 40*").

biosimilar," they have no idea if CMS will meaningfully alter the market by the time they are able to enter it. *See id.* (noting generics typically enter the market 12.5-14.5 years after the brand, with biosimilars launching 20 years or more after biologics).

This problem is compounded by the lack of clarity surrounding what prices will emerge from the Negotiation Program. The IRA requires CMS to set the price of a selected biologic drug (or any small-molecule brand-name drug approved for 12-16 years without competition) at no higher than 65% of the average price paid by nongovernmental purchasers, and at no higher than 40% of the average price paid by non-governmental purchasers for selected drugs that have been approved for longer than 16 years by the time the mandated price takes effect. 42 U.S.C. § 1320f-3(c). These prices are maximums, however, and CMS could set them at lower levels. And the IRA does not provide any "clarity on what the negotiated price *should* be." *Hatch-Waxman Act turns 40*, *supra*, at 7 (emphasis added). Absent such guidance, there is no reliable way for generic and biosimilar manufacturers to predict how close to, or how far below, the IRA's price caps CMS might set a maximum fair price. The extent to which CMS will undercut market prices for drugs is an important part of the analysis for generic and biosimilar manufacturers thinking about entering a market. Yet the IRA makes it impossible for such manufacturers to forecast that pricing information at the time they need to make their decisions.

Together, these predictability problems threaten to chill generic and biosimilar competition. Generic and biosimilar manufacturers cannot reliably estimate the market for a particular drug, which "makes it more difficult for manufacturers to justify the investment needed to bring a generic or biosimilar to market." *The IRA Hurts Competition*, *supra*.

II. CMS's interpretation of the IRA exacerbates its threats to the viability of the generic and biosimilar markets.

The plain text of the IRA shows that Congress was aware of the risk price mandates pose for generic and biosimilar competition and tried to mitigate that risk. In particular, Congress directed that once generic or biosimilar marketing starts, government-price mandates end: CMS is not to select drugs for the Negotiation Program once a generic receives approval and enters the market, and the "maximum fair price" previously set for selected drugs ceases to apply. 42 U.S.C. §§ 1320f-l(c), (e)(l).

But CMS has rewritten the statute to expand its authority, replacing clear statutory text with an ambiguous and ill-defined "inquiry" for when products are subject to price negotiations that undermines statutory protections for generic and biosimilar markets. If left undisturbed, CMS's atextual expansions of its price-setting authority will further chill generic and biosimilar competition by creating uncertainty about whether and when generic entry will lift price mandates.

A. Properly applied, the IRA includes protections to limit the statute's disruptive effect on generic and biosimilar competition.

As relevant here, the IRA establishes the Negotiation Program, wherein CMS selects top-spend drugs under Medicare to be subject to "price negotiations" over a nine-month period. *See* 42 U.S.C § 1320f-1(a). CMS may select only "qualifying single source drug[s]" for negotiations. 42 U.S.C. § 1320f–1(d)(1). As noted, for small molecule drugs, that means drugs for which there are no approved and "marketed" generic versions and seven or more years have passed since FDA approval. *Id.* § 1320f-l(e)(l)(A). For biologics, there cannot be a licensed and "marketed" biosimilar and at least eleven years must have passed since licensure. *Id.* § 1320f-l(e)(l)(B). In other words, if a branded product is competing with a "marketed" generic (or biosimilar), that branded product cannot be a

qualifying single source drug and is not subject to "negotiation." *See id.* § 1320f–1(e)(1).

By directing that price controls cannot be imposed for a product when there is a "marketed" generic (or biosimilar), Congress created a bright-line rule to protect generic competition. The ordinary meaning of "marketed" is simply to have "expose[d] for sale in a market." *See Marke*t, Meriam-Webster, https://tinyurl.com/5x2j5w8b; *Marketed*, Cambridge Dictionary, https://tinyurl.com/mt43z3e6 ("to make goods available to buyers"). Thus, once a generic manufacturer has "expose[d]" a competing product "for sale in a market," the drug is no longer eligible for negotiation. *See* 42 U.S.C. § 1320f–1(c)(1). This clear, objective inquiry provides generic and biosimilar manufacturers with guidance for how to sell into a market free of price controls—just enter it.

B. CMS's "bona fide" marketing test has no basis in the statute.

CMS has interpreted the constraints on its selection authority to provide the agency with maximum flexibility and power—leaving generic and biosimilars manufacturers with minimal certainty and eroding the protections Congress provided. In particular, CMS has replaced the straightforward question whether a generic or biosimilar is "marketed" with an open-ended, subjective inquiry of whether, in the agency's view, the level of competition is "meaningful" enough to be "bona fide." 2027 Final Guidance, *supra*, at 292. CMS's test is not supported by the text, injects uncertainty into the statute, and creates significant administrability concerns.

CMS rewrites the statute's "marketed" inquiry to ask not whether there is an approved generic on the market, but whether that approved generic is engaging in "bona fide marketing." 2027 Final Guidance, *supra*, at 170-171. What "bona fide marketing" means is opaque: CMS reports that divining the answer requires a "holistic inquiry" based on "the totality of the circumstances." *Id.* That "holistic inquiry" is informed by certain

"sources of data," like Part D Prescription Drug Event ("PDE") data, and whether a "generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain." *Id.* at 171. Ultimately, CMS states that it will determine if "meaningful competition" exists before deciding to forgo price controls. *See id.* at 292. And CMS applies this "bona fide marketing" test on an ongoing basis, meaning the agency can reimpose price mandates if it decides that generic competition slips below some ill-defined threshold. *Id.* at 278.

Initially, this "bona fide marketing" test has no footing in the IRA's text and therefore violates the APA as contrary to law. As explained, p. 12, *supra*, by using the term "marketed," the IRA creates a clear, objective inquiry asking whether there is any approved or licensed generic or biosimilar that is "expose[d] for sale in a market." But CMS has eschewed this bright-line test in favor of a vague, all-things-considered inquiry asking whether a generic that is being marketed has reached some undefined threshold of market penetration. That interpretation cannot stand, particularly in the wake of the Supreme Court's holding that courts are not to defer to agency interpretations of a statute. *See Loper Bright Enterp. v. Raimondo*, 603 U.S. 369 (2024). Under *Loper Bright*, there is no longer any basis for CMS to justify policymaking under the guise of statutory construction, with creation of a "bona fide marketing" standard intended to fill in purported gaps left by the statute. Rather, "courts must exercise independent judgment in determining the meaning of statutory provisions," recognizing that "agencies have no special competence in resolving" any "statutory ambiguities." *Id.* at 394, 400-401. The Court's task is necessarily "based on the traditional tools of statutory construction"—not insertions of qualifiers found nowhere in the text intended to further the agency's views of desirable policy. *Id.* at 403.

In any event, CMS's policy-driven approach fails even on its own terms, as it frustrates Congress's objective in minimizing the IRA's disruptive impact on generic and biosimilar manufacturers. Among other issues, the "bona fide marketing" test discourages long-term investments by generic and biosimilar manufacturers by making it impossible for those manufacturers to reliability predict when market entry will prevent (or lift) price mandates. What level of sales do generics and biosimilars have to meet for their marketing efforts to be considered "bona fide"? CMS does not say. And because CMS refuses to limit its discretion by employing an everything-is-always-potentially-relevant "totality of the circumstances" test, 2027 Final Guidance, *supra*, at 170-171, manufacturers are left to guess about which sources might be driving CMS's decision-making for any particular drug. The uncertainty can also never truly abate, since CMS has said it will revisit the "bona fide marketing" decision on an ongoing basis. *Id.* at 278.

CMS's atextual test will also make it substantially more difficult for generics and biosimilars to enter markets for products that have not already been shaped by price mandates. According to CMS, the first year a selected drug can be de-selected from the Negotiation Program is the year that begins at least nine months after CMS determines that a biosimilar or generic version of the drug is approved and "marketed." 2027 Final Guidance, *supra*, at 131. The only exception that CMS recognizes is if it "makes the determination before or during the negotiation period that a generic drug or biosimilar product for the selected drug" is being "marketed" under the agency's test. *Id.* CMS's test stacks the deck in favor of price mandates and against generic or biosimilar competition. The negotiation period is short—only nine months, 42 U.S.C. § 1320f(b)(4)—and it may take many months (or longer) after generic or biosimilar launch for CMS to conclude that uptake is sufficiently robust to deem the marketing that has been taking place "bona fide."

CMS's test thus allows the agency to impose price controls for drugs with existing generic and biosimilar competitors and to keep those mandates around well after generic or biosimilar entry. And because the statute guarantees continued Medicare coverage of selected products depending on the timing of generic or biosimilar marketing, generics and biosimilars may face slower adoption rates for products subject to the Negotiation Program. 42 U.S.C. § 1395w-104(b)(3)(I) (requiring Part D formularies to cover higher-cost branded medicines despite availability of lower-cost generics and biosimilars in certain cases). Indeed generics and biosimilars, particularly those targeting chronic diseases, "commonly face a slower adoption curve" for Medicare plans.[15] Part D formularies often delay coverage of first-to-market generics, "primarily due to skewed incentives in the current Medicare Part D Program." *Id.*[16] For example, only about "24 percent of Medicare plans" are covering "first generics launched in 2024."[17] And historically, it has taken about three years before first generics are covered on more than half of Medicare Part D formularies. *See id.* Conversely, commercial plans adopt generics more often and faster than their Part D counterparts. *See id.* In fact, whereas only 24% of Part D plans covered first generics launched in 2024, 84% of commercial plans were covering those very same drugs. *Id.*

Given these realities, CMS's reliance on Part D PDE data guarantees a distorted

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[15] Letter from Ass'n for Accessible Meds. to CMS Regarding Solicitation of Comments 2 (Apr. 14, 2023), attached hereto as Exhibit 1.

[16] *See* Ass'n for Accessible Meds., *New Generics Are Less Available in Medicare Than Commercial Plans* 4 (July 2021), https://tinyurl.com/4cej86zv (explaining features that "incentivize Part D plans to use higher-priced brand drugs" over generics).

[17] Ass'n for Accessible Meds., *Redesigned Medicare Drug Program Still Allows PBMs to Deny Patients Access to Lower-Cost Generics & Biosimilars*, https://tinyurl.com/3urahaxk (last visited Mar. 10, 2025).

picture. These data are "summary record[s]" submitted by "a prescription drug plan" reflecting "[e]very time a beneficiary fills a prescription under Medicare Part D."[18] As multiple commenters explained to CMS, PDE data "may not include the full scope of evidence for bona fide marketing because of delayed timing of initial uptake for biosimilars and generics, in addition to when determinations for insurance coverage are made." 2027 Final Guidance, *supra*, at 21-22. CMS is aware of this problem, but it has largely shrugged it off. In CMS's view, the "time lag between a generic drug or biosimilar's availability and the ability to detect it in PDE data" is "relatively short," because "Part D plans are instructed to submit original PDEs to CMS within 30 days." *Id.* This point is nonresponsive to the issue of slower generic and biosimilar uptake for Medicare patients. Moreover, even the month-long lag that CMS acknowledges is significant because it can be the difference between meeting the bona fide marketing test during the nine-month negotiation period, or not.

Applying the plain text of the statute—*i.e.*, recognizing that "marketed" *means marketed*, without some added-on, vaguely defined threshold—would avoid these significant implementation problems.

C. As interpreted by CMS, the IRA contains no meaningful protections for generics or biosimilars.

The problems for the generic and biosimilar industries created by CMS's statutory interpretation are not offset by other statutory provisions centered on biosimilar competition, such as the "[s]pecial [r]ule" allowing CMS to delay selection and negotiation of biologics for biosimilar market entry. 42 U.S.C. § 1320f-1(f). Under that rule, a

[18] CMS, *Questions and Answers on Obtaining Prescription Drug Event (PDE) Data* 1, https://tinyurl.com/7j3bxhjt (last visited Feb. 22, 2025).

biosimilar manufacturer can request that CMS delay the selection of a brand-name biologic for price controls if the biologic will have been licensed for fewer than 16 years by the time the government-mandated price would take effect, based on a "high likelihood" that the biosimilar will be licensed and marketed by the time the price mandate would go into effect if the branded biologic were selected. *See id.* This requires compiling and submitting substantial documentation to show CMS that (1) the reference drug's patents are unlikely to prevent the biosimilar from being marketed, and (2) the biosimilar will be operationally ready to market within two years of when the reference product would otherwise be selected. 42 U.S.C. § 1320f-1(f)(1)(B)(ii).

To start, the purported relief afforded by the biosimilar-delay provision is limited. Its timing requirements provide that biosimilar manufactures must submit any delay request *before* a reference biologic is selected for negotiations. 2027 Final Guidance, *supra*, at 182-183. And because biosimilar manufacturers do not know what drugs CMS might choose for a program year by the rule's request deadline, manufacturers must hedge their bets and file costly delay requests as to every biologic even potentially in their pipelines. *Id.* at 182.

Moreover, CMS has applied the provision narrowly. Indeed, CMS did not grant a single initial delay request for the 2026 price applicability year. 2027 Final Guidance, *supra*, at 180. That is unsurprising given that CMS has also grafted its "bona fide marketing" test onto the biosimilar-delay provision, requiring a manufacturer to show "a high likelihood that the [b]iosimilar [m]anufacturer will engage in bona fide marketing of that biosimilar" in the time period. *Id.* at 181. And if CMS decides that a biosimilar has not cleared that threshold, manufacturers are left without recourse. Delay requests are private, and CMS conducts its review behind closed doors, notifying the requestor if a

delay has been granted or denied only after it announces what drugs it has selected for price controls. 2027 Final Guidance, s*upra*, at 180. When CMS eventually does inform the requestor that its delay application has been denied, it is not required to explain why or to provide any justification for its "bona fide marketing" determination. *Id.* at 181-182. Nor are manufacturers likely to ever find out, as there is no judicial review available for CMS delay determinations. *Id.* at 186.

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In all, by grafting a vague "bona fide" marketing test onto the statute, CMS has undermined one of the only limited protections afforded by the IRA for generic and biosimilar competition. Under CMS's reading of the IRA, generic and biosimilar manufacturers deciding whether to start or continue investing millions of dollars into bringing a lower-cost alternative to market undertake substantial risk that they will be locked out of Medicare, even when they offer a lower-cost option. Rather than accept the risk of not recouping their investments, generics and biosimilars might delay entry or simply not enter the market at all. The IRA's text, existing industry dynamics, and Congress's long history of promoting generic and biosimilar competition all counsel against that result.

CONCLUSION

The Court should grant Teva's motion for summary judgment.

Dated: March 14, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the District of Columbia by using the court's CM/ECF system on March 14, 2025.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the court's CM/ECF system.

Dated: March 14, 2025

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EXHIBIT 1

April 14, 2023

Dr. Meena Seshamani, M.D., Ph.D
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Submitted via IRARebateandNegotation@cms.hhs.gov

RE: Solicitation of Comments; Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments

Dear Deputy Administrator Seshamani,

The Association for Accessible Medicines (AAM) and its Biosimilars Council appreciates the opportunity to provide comments in response to the *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments*.

AAM is the nation's leading trade association for manufacturers of generic and biosimilar prescription medicines. AAM's core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic and biosimilar medicines. The Biosimilars Council works to increase patient access to lifesaving, high-value biosimilar medicines. Over the last ten years, generic and biosimilar medicines have provided more than $2.6 trillion in savings to U.S. patients and the healthcare system. In 2021 alone, these medicines provided more than $373 billion in savings, including more than $119 billion in savings for the Medicare program.[1] Because of their low cost and high value, generic and biosimilar medicines today account for more than 91% of all prescriptions dispensed in the US but only 18% of drug spending.

We are concerned by several key aspects of the approach outlined in the Initial Memorandum. These concerns, and suggested alternative approaches, are described below:

CMS Should Determine Marketing Status of Generic Drugs or Biosimilar Biological Products Based on Marketing, Not Sales [Section 30 – Identification of Selected Drugs for Initial Price Applicability Year 2026]

[1] Association for Accessible Medicines. (September 2022). "2022 Generic and Biosimilar Medicines Savings Report." Accessible at: https://accessiblemeds.org/resources/reports/2022-savings-report

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Under the Inflation Reduction Act ("IRA"), a product is not considered a "qualifying single-source drug" if a generic or biosimilar product is approved and *marketed*.

The IRA does not include any statutory definitions for the term "marketing." For the initial selection year, CMS is proposing to use Part D Prescription Drug Event ("PDE") data for the 12-month period beginning August 16, 2022, and ending August 15, 2023, to assess whether a generic drug or biosimilar product meets the "marketing" requirement. CMS further states it will seek to determine that the manufacturer of the biosimilar or generic has "engaged in bona fide marketing."[2] We are concerned that this approach ignores practical challenges associated with relying solely on PDE data and is inconsistent with the statutory language within the IRA.

PDE Data would be Insufficient to Identify Generic or Biosimilar Marketing, in part, due to Part D Policies that Limit Adoption of New Generics and Biosimilars

There are numerous barriers in place throughout the Part D program design, the competitive landscape, and product safety and handling requirements that initially limit volume for generics and biosimilars as they enter a market. The proposal to use PDE data ignores these market and policy realities that can delay generic and biosimilar adoption.

For instance, some generics and biosimilars commonly face a slower adoption curve, especially in markets covering chronic diseases. In fact, many observers have pointed out that while a biosimilar adalimumab is in on the market today, and more are slated to launch this summer, there are a series of naturally occurring factors that point to why biosimilar adoption in that market may not ramp up until next year.[3]

Moreover, previous AAM research demonstrates how Part D formularies often delay coverage of "first generics"[4], calling into question the proposal to exclusively rely on PDE data in order to determine whether a generic or biosimilar is "marketed. Furthermore, Part D policies do not currently permit plan sponsors to substitute reference biological products with newly launched biosimilars on their formularies at the mid-year point as a maintenance change. This represents an additional barrier for biosimilars as they seek to gain market share and bring lower costs to the healthcare system, especially within the art D program.

In June 2022, the Federal Trade Commission ("FTC") released an enforcement policy statement outlining the legal authorities that may apply when dominant drug companies pay rebates and fees to middlemen

[2] Centers for Medicare and Medicaid Services (March 2023) Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments (cms.gov) Accessible at: https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf

[3] Matrix Global Advisors (February 2023) Near-Term Expectations for Adalimumab Biosimilars in the United States. Accessible at: https://getmga.com/wp-content/uploads/2023/02/Adalimumab_Biosimilars.pdf

[4]Association for Accessible Medicines (July 2021) New Evidence Shows Medicare Part D Plans Continue to Fail to Get New Generics to Seniors. Accessible at: https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf

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that foreclose competition from less expensive generic and biosimilar alternatives.[5] This very principle identified by the FTC is at the heart of why PDE data will not be reliable in this case. Until CMS or the FTC act to eliminate anti-competitive rebate contracts that give maximum market power to high-cost, brand drugs, PDE data cannot be exclusively used to determine if a biosimilar or generic launch meets the statutory criteria that the product is "marketed."

Determining Marketing Status Based on Volume of Sales is Inconsistent with the IRA

To assess whether a generic or biosimilar is marketed, CMS plans to use PDE data to determine whether the generic or biosimilar has engaged in "bona fide marketing". This implies that CMS will make the determination based on specific levels of generic or biosimilar market adoption. However, the IRA only requires a generic or biosimilar to be "marketed" and does not require that the generic or biosimilar have achieved a certain level of market penetration, either in the Medicare program or in the broader U.S. pharmaceutical environment. A requirement for "bona fide marketing" is therefore new and not found in the IRA. As such, this new requirement should not be implemented. The formal notice and comment process could have provided the agency with meaningful stakeholder input noting the inconsistency of a "bona fide marketing" requirement with the statute and helped the agency to craft a workable approach to measure "marketing" in line with the statutory requirements.

The new requirement for "bona fide marketing" appears to be an attempt to give CMS discretion to continue negotiating a brand drug's price even after a generic or biosimilar is on the market, even though this authority was not provided by Congress. While we understand that CMS may be concerned about attempts to game the system, the statutory language is clear and such concerns are not supported by historical trends or currently available evidence. Generic and biosimilar manufacturers work aggressively to launch products quickly and successfully. During the early years of the generic market, there were similar concerns that the Hatch-Waxman Act, which established the legal framework for generic submissions, would incentivize generic manufacturers to limit the volume of products launched. But this has not been the case. Whereas pre-Hatch-Waxman only 35% of the top selling drugs had a generic available, generics now represent 91% of all prescriptions dispensed.[6, 7]

CMS Should Use Multiple Data Sources to Determine Marketing Status

Multiple existing federal and non-federal resources already exist to answer the question of whether a generic or biosimilar is available in the marketplace. For instance, the National Institutes of Health (NIH) DailyMed publishes product marketing dates, information that is then used by CMS for Average Sales Price ("ASP") submission verification. Furthermore, first generic applicants must notify the FDA of the date on which they commence commercial marketing.[8]

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[5] Federal Trade Commission (June 2022) FTC to Ramp Up Enforcement Against Any Illegal Rebate Schemes, Bribes to Prescription Drug Middleman That Block Cheaper Drugs. Accessible at: https://www.ftc.gov/news-events/news/press-releases/2022/06/ftc-ramp-up-enforcement-against-illegal-rebate-schemes

[6] Silver R. A Wall Street Perspective on Generics (2007) GPhA Meeting, March 1-3, 2007. Accessible at: www.gphaonline.org/AM/CM/ContentDisplay.cfm?ContentFileID=593

[7] Association for Accessible Medicines (September 2022) The U.S. Generic & Biosimilar Medicines Savings Report. Accessible at: https://accessiblemeds.org/sites/default/files/2022-09/AAM-2022-Generic-Biosimilar-Medicines-Savings-Report.pdf

[8] The FDA has the primary jurisdiction over regulating product launches and has issued regulations that include a clear and workable definition of marketing consistent with the IRA. **21 CFR § 314.3(b)** *defines "commercial*

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In fact, it may be that there will be no single perfect source. Therefore, we encourage CMS to take a multi-faceted approach including (1) use of existing resources (market compendia such as Micromedex's RED BOOK, First Databank, Medispan, or Gold Standard; or federal sources such as DailyMed, FDA NDC directory) for marketing status, (2) allowing generic or biosimilar manufacturers to certify marketing status to the Agency on a rolling basis (including the opportunity to appeal a CMS marketing determination), and (3) as necessary, consultation of broader datasets reflecting the full U.S. pharmaceutical market, such as IQVIA, to identify sales.

As noted, this should include the opportunity for generic or biosimilar manufacturers to certify to the Agency that a generic or biosimilar has been "marketed" and to appeal a marketing determination through provision of information demonstrating that the product is available for purchase. Such an approach is consistent with the language in Appendix C of the memorandum, where the Agency specifies "marketing" is defined as the introduction or delivery for introduction into interstate commerce of a drug product.

If CMS seeks to determine information available regarding sales activity, reliance on PDE data would inappropriately narrow the opportunities for confirmation. Accordingly, any such confirmatory analysis of sales should use a broader data set, such as data from IQVIA®, IDB or other data sources, that capture near real-time transactions involving generic and biosimilars in the market as a whole.

CMS Should Allow for a "Rolling" Determination of Generic or Biosimilar Marketing

We note that the memorandum does not address <u>when</u> the Agency will determine whether a generic or biosimilar is marketed once the negotiation process has already started. The memorandum is clear that a selected drug will be removed from the negotiation process once the Agency determines there is generic or biosimilar availability on or after the selected drug publication date and during the negotiation period for an initial price applicability year. However, the memorandum does not outline when or how this determination will be made. For example, if a generic or biosimilar is marketed during the negotiation process (e.g., one day or three months after CMS announces the selected drugs), how and when will CMS make this determination? Creation of a pathway for generic or biosimilar manufacturers to certify marketing status is one way to immediately make a marketing determination and, if applicable, remove the reference product from the negotiation process.

CMS Should Use Alternative Data Sources to Confirm Marketing and Sales

As noted, we believe the statutory language is clear that the marketing determination does not allow for consideration of <u>levels</u> of adoption as a requirement. However, when verifying details of marketing through reporting generated by generic and biosimilar manufacturers, there may be no individual source that is sufficiently comprehensive. AAM urges CMS to clarify that the Agency will closely adhere to the statutory requirements outlined in the IRA with respect to making a determination of whether a

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marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA, outside the control of the ANDA applicant, except that the term does not include transfer of the drug product for investigational use under part 312 of this chapter or transfer of the drug product to parties identified in the ANDA for reasons other than sale. Commercial marketing includes the introduction or delivery for introduction into interstate commerce of the reference listed drug by the ANDA applicant."

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product is a single-source drug and will not impose additional requirements related to market share minimums. Specifically, CMS should clarify that listing in pharmaceutical compendia or in Federal resources (NIH DailyMed), a certification of marketing from the generic or biosimilar manufacturer, or the presence of *any* sales of a biosimilar and generic drug in PDE files and/or a real-time transaction data source will satisfy the IRA's statutory requirement to demonstrate that a generic or biosimilar has been marketed. We urge CMS not to impose a different, more demanding standard than what is required by statute.

CMS Should Maintain An Updated Part D Dashboard To Allow For Appropriate Evaluation Of Drug Expenditures [30.3.1.1 Requirements for Granting an Initial Delay Request for Initial Price Applicability Year 2026]

The memorandum encourages stakeholders to rely on publicly available information including the Medicare Part D Drug Dashboard to determine which products may be selected for negotiation. We would note that the most recent data available from the CMS Part D Drug Dashboard was published March 2023 using 2021 data. This represents a significant lag that undermines biosimilar developers' ability to forecast likely products for selection and submit appropriate requests for delay. Accordingly, AAM requests that the Agency update the dashboard on a more frequent timeframe or provide more recent information related to the top 50 Part D products. Alternatively, if CMS believes that other reliable data sources exist, we encourage them to identify those publicly. This will enable stakeholders, including generic and biosimilar manufacturers, to prepare for potential delay applications and ensure the Agency is aware of products that have been approved and marketed.

CMS Should Expand the Criteria for the Two-Year Delay [Section 30.3.1.2 High Likelihood]

The IRA guidance provides biosimilar applicants with only two options to demonstrate "high likelihood" of marketing, both of which require resolution of any patent disputes, either by a court decision or an agreement with the reference product sponsor, no later than May 22, 2023. This approach is unduly narrow for several reasons.

First, this approach would disqualify any 351(k) BLAs submitted after May 22, 2023 from eligibility, as patent litigation cannot commence—much less be resolved—until after application submission (*See id. § 271(e)(2)(C)).*

Applications submitted by May 22, 2023 do not fare much better, as CMS's requirements do not appropriately address the practicalities of patent litigation and the statutory requirements governing these disputes. To the extent that it is used, the "patent dance" takes approximately 250 days—and that is just before the first wave of litigation. Accordingly, for litigation to even have commenced by May 22, 2023, the biosimilar applicant must have *already* submitted its 351(k) BLA by September 14, 2022.

Second, ongoing patent litigation may be irrelevant to biosimilar launch. If, for example, a biosimilar applicant carves out the relevant patented indication from its labeling—a common practice in the biosimilar space—it may never be sued by the reference product sponsor consistent with applicable law. CMS's limited criteria provide no basis for the biosimilar applicant to demonstrate a "high likelihood" in that circumstance—despite the fact that there are no barriers precluding the biosimilar manufacturer from entering the market.

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Separately, CMS's view that "active litigation" disqualifies a biosimilar manufacturer from satisfying the "clear and convincing evidence"[9] standard is inconsistent with the statutory intent of the IRA biosimilar delay provision, and it will ultimately lead to less aggressive patent challenges. Patent litigation is inherently uncertain, fast-moving and should not be indicative of approval or marketing of a biosimilar. Under CMS' current standard, a biosimilar manufacturer that overwhelmingly establishes at trial that the relevant patents are invalid and/or not infringed upon would be ineligible for the delay—even if the decision from the district court was a mere few days away. Moreover, multiple biosimilars on the market today have launched 'at risk' during ongoing litigation, and this type of aggressive commercialization is a goal that CMS should seek to support.[10]

Furthermore, establishing a de facto standard that ongoing litigation disqualifies a biosimilar from receiving a two-year delay grants brand manufacturers too much control over this process, as they would have the ability to keep litigation active regardless of the willingness of a biosimilar manufacturer to launch at risk.

The IRA Includes Safeguards for Taxpayers if the Biosimilar Fails to Launch within Two Years

It is important to keep in mind that the IRA is intended to encourage generic and biosimilar competition, and that, furthermore, it provides a safeguard for situations in which a biosimilar delay is granted, but the biosimilar is not marketed. Under the IRA, if a delay is granted and a biosimilar is not subsequently marketed, a brand manufacturer will be required to pay a rebate for the years during which they would have provided access to a Maximum Fair Price (MFP). Accordingly, since there is already a defined safeguard in place to protect the negotiation program and taxpayers if a biosimilar is not launched, it is appropriate to expand the criteria for biosimilars to be eligible to receive the two-year delay. This approach will reduce uncertainty for biosimilar manufacturers as they invest in development, increase competition, and reduce prices for patients and the Medicare Program.

AAM urges CMS to alter this standard to allow biosimilars with ongoing litigation <u>but no adverse court decision</u> to be eligible to receive the two-year delay. Moreover, CMS could permit biosimilar manufacturers to submit explanations detailing why market entry is likely that could then be evaluated by the agency, rather than resorting to an overly restrictive test that undermines biosimilar competition.

<u>CMS Should Ensure the Information Provided During the Biosimilar Initial Delay Request Process Remains Confidential</u> [Section 40.2.1 Confidentiality of Proprietary Information]

CMS proposes to maintain proprietary information submitted to inform the negotiation process confidential in accordance with statutory requirements. AAM agrees that this nonpublic information should remain undisclosed. Thus, we urge CMS to clarify that information submitted as part of the Biosimilar Initial Delay Request will be exempt from Freedom of Information Act (FOIA) requests or other disclosures.

[10] The following products were launched at-risk and are currently available on the market: Kanjinti (trastuzumab-anns) [July 2019], Inflectra (infliximab-dyyb) [November 2016], Fulphila (pegfilgrastim-jmdb) [June 2018], Mvasi (bevacizumab-awwb) [July 2019]

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CMS Should Clarify Appropriate Maximum Fair Price and Administrative Fees [Section 40.4 Providing Access to the MFP]

The memorandum notes that, in addition to MFP-eligible individuals, manufacturers are also required to ensure that pharmacies, mail order services, and other dispensers are also able to access the selected drug at the MFP. Specifically, CMS intends to require a Primary Manufacturer to reimburse a pharmacy, mail order service, or other dispenser within 14 days if the entity does not have access to the MFP. The memorandum specifies that manufacturers or contracted entities may not charge any transaction fee for this process. We encourage CMS to also prohibit pharmacy benefit managers (PBMs) or Part D plan sponsors from charging any additional transaction or administrative fees from manufacturers or pharmacies in connection with the MFP or the selected drug dispensing process. PBMs or Part D plan sponsors should not be able to generate revenue from pharmacies or manufacturers complying with the requirements of the IRA or subsequent program rules. We have urged the agency in the past to ensure patients receive the benefit of all rebates, discounts, and direct and indirect remuneration at the pharmacy counter, and we continue to encourage CMS to ensure this occurs for products subject to the MFP as well as for all other Part D products.

CMS Should Provide Greater Clarity on the Determination of the Maximum Fair Price [Section 50 - Evidence Regarding Therapeutic Alternatives]

Although the IRA seeks to protect generic and biosimilar competition by removing a reference product from negotiation if a generic or biosimilar is approved/licensed and marketed, the framework nonetheless creates significant uncertainty that, without greater clarity from CMS, will harm future generic and biosimilar development. Generic and biosimilar manufacturers make decisions on how to direct capital investments, in relation to a reference product's market activity, years before loss of exclusivity is imminent and years before CMS will begin the negotiation process. Currently, generic and biosimilar manufacturers rely on current, publicly accessible trends in commerce and free market economics to govern how they direct their operations in bringing affordable medicines to the US healthcare system. However, the market uncertainty created by this guidance could undermine their decision to invest the $100-$250 million and 8-12 years necessary to bringing the lower-cost options to market in key areas such as complex generics and biosimilars. We are concerned that not providing concrete information on pricing that allows stakeholders to operate with predictability would harm long-term opportunities for greater savings through the market-based competition that biosimilars and generics offer. Accordingly, it is important for CMS to establish a predictable and transparent method for determining the MFP that allows generic and biosimilar developers to reasonably forecast the market in their investment decisions.

For instance, section 50.2 of the memorandum discusses the requirement under section 1194(e)(2) of the Act that the Secretary consider evidence regarding alternative treatments. AAM encourages CMS to provide clarity on how it will determine what constitutes a "therapeutic alternative." For instance, does CMS intend to consider the selected drug's overall place in therapy? Does CMS intend to consider drugs in other categories or classes such as those included in treatment guidelines? In considering indications for the selected drugs, does CMS intend to use a process similar to the evaluation for Medically Accepted Indication within Part D?

Likewise, the memorandum appears to envision a high degree of privacy in the actual price setting process. This is not in the public interest and will undermine the ability of generic and biosimilar

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developers to reasonably support costly future development. We encourage CMS to continue to refine its approach to provide greater predictability and transparency.

Patients deserve access to more high-quality products, rather than fewer, and payers will be able to save in an environment with more competition rather than less. The uncertainty and subjectivity inherent in the approach CMS outlined in this guidance will make the process of investment in biosimilars and generics more uncertain, and risks leaving many Medicare beneficiaries and the health care system overall worse off with fewer options for care and higher costs.

CMS Should Clarify Intent of "Robust and Meaningful" Competition [Section 90.4 - Monitoring for Bona Fide Marketing of Generic or Biosimilar Product]

CMS also proposes "to monitor whether robust and meaningful competition exists in the market once it makes such a determination… [including whether it is] consistently available for purchase through the pharmaceutical supply chain."[2] As noted previously, structures within the Medicare program have inhibited the increased adoption of generics and biosimilars. The intent of this provision is unclear, especially since the IRA clearly demonstrates the negotiation process is intended to encourage competition and the use of generics and biosimilars. Further, the metrics outlined for consideration within the guidance do not reflect the most appropriate method of evaluation. For instance, specialty products may not, and likely will not, be readily available in community pharmacies. And because PDE data implies formulary access and a product's market share, this measure could be heavily weighted on factors such as long-standing branded rebate agreements with PBMs that have little to do with the effort, resources, or ability of a generic or biosimilar company to launch successfully. We encourage CMS to align coverage and payment policies with the statutory intent of the IRA by promoting approaches that increase overall adoption.

It is important to bear in mind that, as noted previously, the IRA only refers to "marketing," not "robust and meaningful competition." Moreover, the IRA does not include a provision for the re-introduction of a product for negotiation after a determination has been made that a biosimilar or generic has been launched and marketed nor does it include a market share threshold related to "robust and meaningful competition". It is essential to robust and competitive biosimilar and generic markets that manufacturers have clarity on the anticipated requirements and that additional regulatory difficulties are not introduced that increase uncertainty in the launch, marketing, and introduction of new products.

Overall, we encourage CMS to exercise flexibility and collaboration during the ongoing development and implementation of the program. We look forward to continuing to engage with HHS and CMS on improving competition, care, and access for America's patients.

Sincerely,

Craig Burton

Craig Burton
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Executive Director, Biosimilars Council

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