NOT YET SCHEDULED FOR ORAL ARGUMENT
No. 25-5425

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

TEVA PHARMACEUTICALS USA, INC., *et al.*,
Plaintiffs-Appellants,

v.

ROBERT F. KENNEDY, JR., in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *et al.*,
Defendants-Appellees.

On Appeal from the United States District Court for the District of Columbia, Case No. 1:25-00113 (Sooknanan, J.)

BRIEF OF *AMICUS CURIAE* ASSOCIATION FOR ACCESSIBLE MEDICINES IN SUPPORT OF PLAINTIFFS-APPELLANTS AND REVERSAL

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January 16, 2026

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Parties and Amici: All parties, intervenors, and *amici* appearing in this Court as of this filing are listed in Plaintiffs-Appellants' D.C. Circuit Rule 28(a)(1) certificate.

Rulings Under Review: References to the ruling at issue appear in Plaintiffs-Appellants' opening brief and in their D.C. Circuit Rule 28(a)(1) certificate.

Related Cases: To *amicus*'s knowledge, all related cases are listed in Plaintiffs-Appellants' D.C. Circuit Rule 28(a)(1) certificate.

DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a), and D.C. Circuit 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.

January 16, 2026

/s/ Brian T. Burgess
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INTEREST OF *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 12% 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 appeal, 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

[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. All parties have consented to the filing of this brief.

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 with atextual and indeterminate rewrites of the statute that expand CMS's authority to impose and maintain 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.

A separate brief by AAM is appropriate. AAM is uniquely positioned to address the impact that CMS's implementation of the IRA will have for the generic and biosimilar marketplace. AAM's *amicus* brief is addressed specifically to those issues where AAM believes its perspective as the leading trade association representing generic drug and biosimilar manufacturers will aid this Court.

INTRODUCTION AND SUMMARY OF ARGUMENT

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. And because the IRA gives no guidance about what the price controls will be, the Negotiation Program poses a significant uncertainty risk for generic and biosimilar manufacturers that makes it difficult to invest the substantial sums needed to bring generic and biosimilar products to market.

Congress took care, however, to mitigate this risk by reducing 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)(1). Under the statute, 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 satisfied 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]

[2] Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act*

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 market. The result will be slower generic and biosimilar competition, from fewer generic and biosimilar manufacturers, leaving prices higher for longer.

The district court declined to grapple with the legality of CMS's "bona fide" marketing test. It instead declared that Teva's challenge is not ripe for review based on the view that Teva has not yet launched a generic drug competing with government-mandated price controls and CMS might change how it applies its

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for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 § 30.1, at 170-71 (Oct. 2, 2024) ("2027 Final Guidance"), https://tinyurl.com/bdf5srv3; Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028*, § 70, at 314-16 (Sep. 30, 2025) ("2028 Final Guidance"), https://tinyurl.com/32sf8ajk.

atextual bona fide marketing test. Among other flaws, that reasoning overlooks the fact that manufacturers directly experience the negative effects from CMS's test well before they launch competing products—indeed, the test's existence may well cause generic and biosimilar manufacturers not to develop products they otherwise would if not for CMS's atextual bona fide qualifier.

This Court should address the merits of Teva's claim and 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' successes, developing generic and biosimilar products requires significant investment and considerable risk. The industries thus remain fragile, so 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 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 "piggyback 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 Act thus seeks to "speed[] the introduction of low-cost generic drugs to market," increasing competition and decreasing prices. *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 accumulate over the years, surpassing $3 trillion over the past decade.[4] Statistics for 2024, the most recent available, show that patients and payors saved $467 billion, with Medicare seeing $142 billion of those benefits. *Savings Report*, *supra* note 4, at 10. That same year, the "average out-of-pocket cost for a generic was $6.95," with "the average out-of-pocket cost for a brand drug [being] nearly five times higher—at $28.69." *Id.* at 13.

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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 1998), https://tinyurl.com/3n4jnjh5.

[4] Ass'n for Accessible Meds., *The U.S. Generic & Biosimilar Medicines Savings Report* 43 (Sep. 2025) ("*Savings Report*"), https://tinyurl.com/49d63sun.

In short, increased generic competition has lightened the financial load for those who need medications, and those 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 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). Similar to the Hatch-Waxman Act, the BPCIA provided biosimilars an abbreviated

[5] U.S. Food & Drug Admin., *What Are "Biologics" Questions and Answers* (Feb. 6, 2018), https://tinyurl.com/pu7ubpxz.

[6] U.S. Food & Drug Admin., *Biological Product Innovation and Competition* (Apr. 10, 2024), https://tinyurl.com/37yr6x8b.

pathway to FDA approval. 42 U.S.C. § 262. And it did so for the same reason: to "encourage competition in the field of biologics."[7] Since then, the biosimilar market has experienced rapid growth and "robust price competition." *Savings Report*, *supra* note 4, at 34. On average, biosimilars cost about 40% less than their reference biologics. *Id.* at 32. And they drive down prices for the branded biologic, too, by an average of around 23% after three years of competition. *Id.* at 38. In all, patients and payors have saved over $56 billion since 2015, when the first biosimilar hit the market—with savings increasing each year. *Id.* at 34.

Overall, history has shown that increased generic and biosimilar 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 engage in research and testing to develop bioequivalent formulations, while also securing the active pharmaceutical ingredient and satisfying FDA's demanding manufacturing

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

standard.[8] For biosimilar manufacturers, time and cost only increase. Historically, "a typical biosimilar costs $100 million to $300 million to develop and takes six to nine years to go from analytical characterization to approval."[9] While recent draft guidance from the FDA proposes shifting away from the comparative efficacy studies contributing to those approval costs,[10] the complexity of biologics continues to demand significant time and resources for biosimilar development.

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 Mylan Inc v. Comm'r*, 76 F.4th 230, 241 (3d Cir. 2023)

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[8] U.S. Food & Drug Admin., *What Is the Approval Process for Generic Drugs?* (Sep. 16, 2025), https://tinyurl.com/44tdmvd8; Aylin Sertkaya *et al.*, *Cost of Generic Drug Development and Approval* 16-20 (Dec. 31, 2021), https://tinyurl.com/4mhb4b82.

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

[10] *See generally* U.S. Food & Drug Admin., *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies* (Oct. 2025), https://tinyurl.com/ydvcjmrt.

(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).

These costs have only accelerated in recent years, as brand manufacturers often erect large patent estates that impede timely generic and biosimilar entry.[11] 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. *Failure to Launch*, *supra* note 11, at 5. They 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 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.[12] And to have that confidence, they must be able to forecast what a particular market will look like years in advance: how many competitors will there

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

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

be, and what will the prices of competing products look like? If they cannot predict the answers to those questions with reasonable confidence, generic and biosimilar manufacturers might forgo investing in developing a particular generic drug or biosimilar entirely. *The IRA Hurts Competition, supra* note 12.

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

As it stands, the IRA's Negotiation Program creates "significant uncertainty" for generic and biosimilar manufacturers.[13] 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 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-1(e)(1)(A). Similarly, 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-1(e)(1)(B). During the putative "price negotiations," CMS sets a "maximum fair price." *Id.* § 1320f-2(a)(1). 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 just under two years after the selection date. *Id.*

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

This regime creates two significant potential 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* note 13, at 8. The typical 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 approval for generics, and eleven years for biosimilars. *Id.* So, at the time manufacturers are deciding whether to undertake the "several hundred million dollars" of investments needed "to develop a generic or biosimilar," they have no idea if CMS will meaningfully alter the market by the time they are able to enter it. *Id.* at 7-8 (noting generics typically enter the market 12.5-14.5 years after the brand, with biosimilars launching 20 years or more after originator 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—which it did in initial price applicability years 2026 and 2027.[14] And the IRA does not provide any "clarity on what the negotiated price *should* be." *Hatch-Waxman Act turns 40*, *supra* note 13, 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 problems threaten to chill generic and biosimilar competition by "remov[ing] [the] predictability needed to support investment in developing new generic and biosimilar products." *Savings Report*, *supra*, note 4, at 43. Under the IRA, generic and biosimilar manufacturers cannot reliably estimate the market for a particular drug, which "makes it more difficult for manufacturers to justify [the]

[14] Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2027*, at 2-3 (Nov. 2025), https://tinyurl.com/mvsftcc8; Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, at 2 (Aug. 2024), https://tinyurl.com/yf92e4bm.

investment needed to bring a generic or biosimilar to market." *The IRA Hurts Competition*, *supra* note 12.

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. 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-1(c), (e)(1), (f)(2).

But CMS has rewritten the statute to expand its authority, replacing clear 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 and biosimilar 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. *Id.* § 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-1(e)(1)(A). For biologics, there cannot be a licensed and "marketed" biosimilar and at least eleven years must have passed since licensure. *Id.* § 1320f-1(e)(1)(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." Likewise, if after a branded product is selected for the Negotiation Program, FDA later approves or licenses a corresponding generic or biosimilar product that is "marketed," then such marketing will ultimately trigger removal of the branded product from the Program. *Id.* § 1320f-1(c)(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." *Market*, Meriam-Webster, https://tinyurl.com/5x2j5w8b; *see also Marketed*, Cambridge Dictionary, https://tinyurl.com/mt43z3e6 ("to make goods available to buyers"); *cf.* 21 C.F.R. § 314.3 (defining "[c]ommercial marketing" as "the introduction or delivery for introduction into interstate commerce of a drug product described in an ANDA").

Thus, once a generic or biosimilar 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.

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

In the face of the plain text, CMS has re-interpreted the constraints on its selection authority in a manner that improperly erodes the protections Congress provided for generic and biosimilar competition. In particular, CMS has replaced the straightforward question whether a generic or biosimilar is "marketed" with an open-ended, subjective inquiry into whether, in the agency's view, the level of competition is "meaningful" enough to be "bona fide." 2027 Final Guidance, *supra* note 2 § 90.4, at 292; *see also* 2028 Final Guidance, *supra* note 2 § 90.4.2, at 336. CMS's test is not supported by the text, injects uncertainty into the statute, and creates significant administrability concerns.

CMS's "bona fide marketing" requirement is hopelessly opaque. CMS reports that divining the answer requires a "holistic inquiry" based on "the totality of the circumstances." 2027 Final Guidance, *supra* note 2 § 30.1, at 170; *see also* 2028 Final Guidance, *supra* note 2 § 70, at 315 (same). That "holistic inquiry" is informed by certain "sources of data," like Part D Prescription Drug Event ("PDE") data, but CMS's determination "will not necessarily turn on any one source of" it.

2027 Final Guidance, *supra* note 2 § 70, at 278-79; *see also* 2028 Final Guidance, *supra* note 2 § 70, at 315 (same). CMS also considers whether a "generic drug or biosimilar is regularly and consistently available for purchase through the pharmaceutical supply chain." 2027 Final Guidance, *supra* note 2 § 70, at 279; *see also* 2028 Final Guidance, *supra* note 2 § 70, at 315 (same). Ultimately, CMS states that it will determine if "meaningful competition" exists before deciding to forgo price controls. 2027 Final Guidance, *supra* note 2 § 90.4, at 292; *see also* 2028 Final Guidance, *supra* note 2 § 90.4.2, at 336 (same). And CMS applies this "bona fide marketing" test on an ongoing basis, meaning the agency can reimpose price mandates if it decides that generic or biosimilar competition slips below some ill-defined threshold. 2027 Final Guidance, *supra* note 2 § 90.4, at 292; *see also* 2028 Final Guidance, *supra* note 2 § 90.4.2, at 336 (same).

This "bona fide marketing" test has no footing in the IRA's text and therefore violates the APA as contrary to law. As explained, pp. 15-16, *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." *Market*, Meriam-Webster, https://tinyurl.com/5x2j5w8b. 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 must interpret statutes independently. *See Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400-01 (2024). Under *Loper Bright*, there is no 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 policy views. *Id.* at 403. And as Teva explains in more detail, the traditional tools of construction all point away from CMS's all-things-considered test, which diverges from how Congress and the agency have interpreted "marketed" in similar contexts. *See* Teva Br. 45-46.

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 reliably 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, 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. 2027 Final Guidance, *supra* note 2 § 90.4, at 292; *see also* 2028 Final Guidance, *supra* note 2 § 90.4.2, at 336 (same).

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, stacking the deck in favor of such mandates over competition. Under CMS's test, a drug or biologic could be selected for the Negotiation Program even if there is already generic or biosimilar competition—so long as CMS does not consider the marketing to be "bona fide." And, according to CMS, a selected drug may only escape a price mandate for its initial price applicability year if CMS makes a determination of bona fide marketing before or during the negotiation period. *See* 2027 Final Guidance, *supra* note 2 § 70, at 279; *see also* 2028 Final Guidance, *supra* note 2 § 70, at 316 (same). But the negotiation period is short—only nine months, 42 U.S.C. § 1320f(b)(4)—and it may take many months (or even 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). Generics and biosimilars (particularly those targeting chronic diseases) commonly face a slower adoption curve for Medicare plans. *Savings Report*, *supra* note 4, at 24. Part D formularies often delay coverage of first-to-market generics, "primarily due to skewed incentives in the current Medicare Part D Program."[15] Indeed, only about "24 percent of Medicare plans" are covering "first generics launched in 2024."[16] And historically, it has taken about three years before first generics are covered on more than half of Medicare Part D formularies. *See Access to Lower-Cost Generics*

[15] 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).

[16] Ass'n for Accessible Meds., *Redesigned Medicare Drug Program Still Allows PBMs to Deny Patients Access to Lower-Cost Generics & Biosimilars* (Jan. 27, 2025) ("*Access to Lower-Cost Generics & Biosimilars*"), https://tinyurl.com/3urahaxk.

& Biosimilars, supra note 16. Conversely, commercial plans adopt generics more often and faster than their Part D counterparts. *See id.*

Given these realities, CMS's reliance on Part D PDE data risks a distorted 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."[17] As multiple commenters have 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." 2027 Final Guidance, *supra* note 2, at 21; *see also* 2028 Final Guidance, *supra* note 2, at 24. While CMS has acknowledged this concern and noted that it might rely on additional data sources, 2027 Final Guidance, *supra* note 2 § 30.1, at 171; 2028 Final Guidance, *supra* note 2 § 30.1, at 169-170, that does not solve the problem. CMS has empowered itself to pick and choose among those sources to make the bona fide marketing determination, leaving it with discretion to rely on misleading PDE data to conclude that the marketing of a generic or biosimilar product is not "bona fide."

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.

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[17] Ctrs. for Medicare & Medicaid Servs, *Questions and Answers on Obtaining Prescription Drug Event (PDE) Data* 1, https://tinyurl.com/7j3bxhjt (last visited Jan. 10, 2026).

C. The negative impact of CMS's interpretation is not offset by other statutory protections for generic drugs and 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 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 within two years of the date the branded biologic would otherwise have been selected for the Negotiation Program. *See id.* According to CMS, this requires compiling and submitting substantial documentation to show 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. 2027 Final Guidance, *supra* note 2 § 30.3.1.2, at 184-85; 2028 Final Guidance, *supra* note 2 § 30.3.1.3, at 190-91.

To start, the purported relief afforded by the biosimilar-delay provision is limited. Among other problems, its timing requirements provide that biosimilar manufactures must submit any delay request *before* a reference biologic is selected for negotiations. 2027 Final Guidance, *supra* note 2 § 30.3.1.1, at 182-83; 2028

Final Guidance, *supra* note 2 § 30.3.1, 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. 2027 Final Guidance, *supra* note 2 § 30.3.1.1, at 182; 2028 Final Guidance, *supra* note 2 § 30.3.1, at 182.

Moreover, CMS has further limited the already cribbed relief the delay provision provides by applying it narrowly. For example, CMS requires biosimilar applicants to affirmatively show that patents are unlikely to impose a barrier to marketing. 2027 Final Guidance, *supra* note 2 § 30.3.1.2, at 185; 2028 Final Guidance, *supra* note 2 § 30.3.1.3, at 191. 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. 2027 Final Guidance, *supra* note 2 § 30.3.1, at 181; 2028 Final Guidance, *supra* note 2 § 30.3.1.1, at 184. Unsurprisingly, CMS did not grant a single initial delay request for either the 2026 or 2027 price applicability years. 2027 Final Guidance, *supra* note 2 § 30.3.1, at 180; 2028 Final Guidance, *supra* note 2 § 30.3.1, at 182-83.

And if CMS rejects a delay application, manufacturers are left without recourse. The 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* note 2 § 30.3.1, at 180; 2028 Final Guidance, *supra* note 2 § 30.3.1.1, at 185. When CMS eventually does inform the requestor that its delay application has been denied, it is not required to explain why. 2027 Final Guidance, *supra* note 2 § 30.3.1, at 181-182; 2028 Final Guidance, *supra* note 2 § 30.3.1.1, at 184-85. Nor are manufacturers likely to ever find out, as CMS takes the view that there is no judicial review available for CMS delay determinations. 2027 Final Guidance, *supra* note 2 § 30.3.1.2, at 186; 2028 Final Guidance, *supra* note 2 § 30.3.1.5, at 196.

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In all, by grafting a vague "bona fide" marketing test onto the statute, CMS has undermined the key protection 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.

III. CMS's IRA interpretation is ripe for review in this litigation.

The Federal Defendants never questioned that Teva's challenge to the CMS's bona fide marketing test is ripe for review given the ongoing impact the agency's interpretation has on its selection authority. The district court nevertheless declined to reach the issue based solely on a conclusion that Teva's challenge is unripe. JA194-97. That reasoning is unsound. In addition to the defects that Teva identifies (at 37-43), adopting the district court's approach would negatively impact the generics and biosimilars industry as a whole by making it more difficult to secure prompt relief against CMS's application of an amorphous standard that discourages investment and interferes with marketing plans.

The district court reasoned that Teva's challenge is unripe because, notwithstanding the existence of carefully negotiated licensed entry dates for its generic products, it might not secure FDA approval to launch its generic drugs "early enough for the [operative] Guidance to ... have an impact." JA194. In addition to mistaken factual and legal premises that Teva addresses (at 38-39), that view fails to appreciate the full scope of the harm associated with CMS's imposition of its bona fide marketing test, which impacts manufacturers even before generic or biosimilar launch. As discussed above, that atextual test affects the decision to even begin the research and development needed to secure FDA approval. Pp. 18-21, s*upra*. And for products that proceed beyond that initial stage, the uncertainty CMS's test creates

impacts the investments and planning for bringing a generic drug or biosimilar product to market. Pp. 8-11, *supra*. The harm for generic manufacturers like Teva is thus not limited to the period of time *after* they begin marketing a generic version of a product that remains subject to the Negotiation Program, in contravention of the statute. Rather, CMS's test impacts how and when generic manufacturers will enter the market in the first place.

This unduly narrow conception of the harm associated with CMS's vague test also underlies the district court's mistaken conclusion that Teva would "suffer[] no hardship from postponing review." JA196 (quotation marks omitted). The district court suggested that Teva could return to court once it launches an approved generic product, if the corresponding brand drug remains subject to price mandate despite the launch. *See id.* But among other defects, that possibility is nonresponsive to the harm created by the opacity of CMS's test, which interferes with the ability of generic drug manufacturers to plan and execute a successful product launch. Generic drug and biosimilars manufacturers like Teva must make decisions regarding the commitment of scare resources and engage in contract negotiations well before they make their first sales. Requiring manufacturers to wait to bring purely legal challenges to CMS's interpretation until after the agency has applied its fuzzy bona fide marketing test serves only to reinforce the harm caused by CMS's discretion-maximizing rewrite of the statute. *See Nat'l Ass'n of Home Builders v.*

U.S. Army Corps of Eng'rs, 440 F.3d 459, 464 (D.C. Cir. 2006) (noting a "purely legal claim in the context of a facial challenge [to agency action] is presumptively reviewable") (quotation marks omitted); *see also Cement Kiln Recycling Coal. v. EPA*, 493 F.3d 207, 215 (D.C. Cir. 2007) (recognizing that a challenge to the facial validity of a regulation as being contrary to the statute was fit for immediate review); Teva Br. 37-38 (collecting additional decisions).

CONCLUSION

The Court should reverse the district court's grant of summary judgment and direct that it be entered for Teva instead.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) because this brief contains 6,418 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 32(e)(1).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using the Microsoft Office Word software in 14-point Times New Roman type style.

Dated: January 16, 2026

/s/ Brian T. Burgess
Brian T. Burgess

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 January 20, 2026.

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: January 20, 2026

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