IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and ASTRAZENECA UK LTD., Plaintiffs, vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES, Defendants.	Civil Action No. 1:25-cv-4212-MJM

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

Pursuant to Fed. R. Civ. P. 56, Plaintiffs, Astrazeneca Pharmaceuticals LP, Astrazeneca AB and Astrazeneca UK Ltd. ("Plaintiffs"), move for summary judgment declaring the Centers for Medicare and Medicaid Services' Guidance ("CMS") unlawful and to set the Guidance aside.

For the reasons set forth in Plaintiffs' Memorandum in Support of its Motion for Summary Judgment, the Court should grant Plaintiffs' Motion for Summary Judgment.

Dated: February 27, 2026

Respectfully submitted,

/s/ Michael A. Pichini

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CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 4.

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ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF ITS
MOTION FOR SUMMARY JUDGMENT

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Pharmaceutical development in the United States has long occurred under a market-based system that creates incentives to innovate. Under a well-established legal framework, developers of certain innovative drugs are statutorily eligible for a period of market exclusivity, meaning their products are protected from generic competition for a specified amount of time. Because developing new drugs is exceedingly expensive, risky, and time-consuming, market pricing and exclusivity provide crucial incentives for the development of novel products for patients.

In 2022, Congress enacted the Inflation Reduction Act (IRA), which imposes price controls on certain prescription drugs, while also seeking to preserve market-based pricing and exclusivity as incentives. The statute directs the Secretary of Health and Human Services (HHS) to establish a "Drug Price Negotiation Program" (Program), which allows the Centers for Medicare and Medicaid Services (CMS) to establish prices for a limited set of drugs with the highest Medicare expenditures. 42 U.S.C. § 1320f(a). At the same time, the IRA attempts to safeguard innovation, by limiting this novel price-fixing regime to a specified number of drugs that have already been on the market for a significant period. For what the IRA refers to as "initial price applicability year 2027," the statute limits CMS's price-setting authority to "15" qualifying "drugs" that were "approved" at least "7 years" earlier. *Id.* § 1320f–1(a)(2), (e)(1)(A)(i)-(ii).

The IRA defines these qualifying "drugs" by reference to the well-established legal framework for the approval of pharmaceutical products by FDA, the centerpiece of which is the "New Drug Application" or "NDA." To receive FDA approval, each "new drug" requires an NDA, meaning the manufacturer must submit "full reports of investigations" into the drug's safety and effectiveness. 21 U.S.C. § 355(a), (b)(1). Obtaining approval for a new drug thus involves a "long, comprehensive, and costly testing process" to determine whether the drug will be safe and effective in treating identified conditions in a specific patient population. *FTC v. Actavis, Inc.*, 570 U.S. 136,

142 (2013). A drug's statutory exclusivity period, in turn, begins "upon marketing approval"—that is, on the date of approval of the drug's NDA. U.S. Patent and Trademark Office, *Drug Patent and Exclusivity Study* 7 (June 2024) (*Drug Patent and Exclusivity*), https://perma.cc/2Z8D-HZAU.

Only a drug that has been "approved" via an NDA can qualify for IRA pricing. 42 U.S.C. § 1320f–1(e)(1)(A). But NDA approval alone is not enough; the drug also must be "marketed pursuant to such approval," and "at least 7 years [must] have elapsed since the date of such approval." *Id.* § 1320f–1(e)(1)(A)(i)-(ii). The drug also cannot be "the listed drug" (*i.e.*, the brand-named competitor) for an "approved and marketed" generic version that references the drug's NDA. *Id.* § 1320f–1(e)(1)(A)(iii).

In sum, to qualify as one of the fifteen drugs eligible for IRA pricing in 2027, a drug (1) must have received its NDA at least seven years earlier, (2) must currently be marketed pursuant to that NDA, and (3) cannot have a generic version that references its NDA. Once a drug meets those criteria, it can qualify for "selection" if it ranks as one of the top drugs based on its Medicare expenditures. *Id.* § 1320f–1(d). These constraints are designed to protect innovation, by limiting the number of drugs subject to price caps, and by tying each drug's eligibility for the Program to the length of time that the drug has been on the market—in other words, to its NDA.

CMS has refused to accept these statutory limits. Instead, CMS has issued "guidance" that circumvents the fifteen-drug limit, the seven-year timeline, and the expenditure threshold. *See* Ctrs. for Medicare & Medicaid Servs., *Medicare Drug Price Negotiation Program: Final Guidance* (Oct. 2, 2024) (*Guidance*). The agency achieves those results by rewriting the IRA's definition of a qualifying drug: Under the Guidance, if multiple drugs share an "active moiety"—a term that appears nowhere in the 270-page IRA—CMS will group them together as a *single* "drug" under the Program, even if they "are marketed pursuant to *different NDAs*." *Id.* at 167

(emphasis added). So, if a new drug approved under a new NDA shares an "active moiety" with an old drug approved under an earlier NDA, CMS will treat them both as *one* drug for purposes of the Program. Thus, under CMS's Guidance, a drug can be subject to price controls *less than* seven years after its approval—possibly even as soon as the drug is approved. And since multiple products can be grouped together into a single "drug," *more than* fifteen drugs can be eligible for price caps, even if none of their individual Medicare expenditures would meet the threshold.

CMS's redefinition of "drug," to encompass multiple products with "different NDAs," contravenes the IRA's plain language. Beyond defining each "drug" by reference to its individual NDA, the statute repeatedly relies on a one-drug, one-NDA framework. For example, the seven-year window before a drug becomes IRA-eligible begins with the drug's "approval," and runs from "*the* date of *such* approval." 42 U.S.C. § 1320f–1(e)(1)(A)(ii) (emphases added). The IRA's clear reference to a *single* approval ("*such* approval") on a *single* date ("*the* date") belies CMS's theory that a drug somehow can have "different NDAs"—and thus *multiple* "approvals" on *multiple* dates. Likewise, the IRA's requirement that a drug be "marketed pursuant to *such* approval," *id.* § 1320f–1(e)(1)(A)(i) (emphasis added), would be incoherent if a single drug could encompass multiple products "marketed pursuant to different NDAs," since "such approval" clearly references one specific approval, and no "drug" *can* be marketed pursuant to multiple NDAs. Finally, the IRA exempts a "drug" from eligibility when it has a generic competitor. *Id.* § 1320f–1(e)(1)(A)(iii). That provision, too, makes sense only if the original "drug" has a single NDA, since a generic version can be approved only *by reference to* a discrete NDA.

For these and other reasons explained below, CMS's Guidance contravenes the plain language of the IRA. In attempting to redefine "drug" to include *multiple* drugs, the Guidance is "not in accordance with law" and is "in excess of statutory jurisdiction, authority, or limitations."

5 U.S.C. § 706(2)(A), (C). The Court should declare the Guidance unlawful and set it aside.

BACKGROUND

A. Congress Has Created an Exclusivity Framework to Facilitate Innovation

The American pharmaceutical industry thrives on innovation. Manufacturers like AstraZeneca expend substantial time and resources to identify, test, and develop new medicines—with the average cost of successfully bringing a drug to market now reaching $2.23 billion.[1] Despite immense R&D costs, however, only one compound in 5,000 that enters preclinical testing achieves FDA approval, representing a failure rate of 99.98%.[2] And of the therapies approved for patient use, only one-third manage to recover their costs of development, much less provide an economic return significant enough to allow for continued investment and innovation in new medicines.[3]

Given the costs and risks involved in developing new drugs, the system depends on providing legal protections for the relatively few drug-development efforts that *do* succeed: "the prospect of patent protection and exclusivity can motivate innovators to invest in the development of novel products and new treatment options for patients." *Drug Patent and Exclusivity* at 7. The modern legal framework was ushered in by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. 98-417, commonly known as the Hatch-Waxman Act. By rewarding innovation, this framework benefits patients globally. But it helps Americans most. Manufacturers generally launch new drugs here first, so American patients are often the first to

[1] *See* Deloitte, *Be Brave, Be Bold: Measuring the Return from Pharmaceutical Innovation* 6 (Mar. 2025), https://perma.cc/7KFW-49ZG.

[2] *See* Sandra Kraljevic et al., *Accelerating Drug Discovery*, 5 Eur. Mol. Bio. Org. Reps. 837, 837 (2004).

[3] *See* John A. Vernon & Joseph H. Golec, *Pharmaceutical Price Regulation: Public Perceptions, Economic Realities, and Empirical Evidence* 7 (2008).

receive lifesaving and life-sustaining medicines. Nearly 80% of medicines approved by FDA in 2021 were available in the United States before any other country. *See* FDA, *Advancing Health Through Innovation: New Drug Therapy Approvals 2021* 21 (Jan. 2022), https://bit.ly/46Op0Dy.

To obtain the benefits of exclusivity for a new drug—and hence a market-based return on its investment—a manufacturer must subject its drug to a rigorous vetting process. "In the United States, new drugs generally cannot be legally marketed for human use without FDA approval." *Drug Patent and Exclusivity* at 8. The centerpiece of the approval process is the New Drug Application or "NDA." 21 U.S.C. § 355(a)-(b). "Applicants seeking to market a novel new drug must file a New Drug Application (NDA) with the FDA and provide enough information to permit the FDA to determine whether the drug is safe and effective for its intended use (i.e., that the benefits of the drug outweigh the risks for its intended use)." *Drug Patent and Exclusivity* at 8.

Approval of an NDA involves a "long, comprehensive, and costly testing process." *Actavis*, 570 U.S. at 142. The manufacturer must submit "full reports of investigations" into the drug's safety and efficacy, "a full list of the articles used as components," and a "full description" of how the drug is manufactured, processed, and packed. 21 U.S.C. § 355(b)(1)(A). If FDA is persuaded of the drug's safety and efficacy, the manufacturer receives "marketing approval," *id.* § 355(d), and the NDA is assigned its own number, *see* FDA, Ctr. for Drug Evaluation & Rsch., Manual of Policies & Procedures, *NDA Classification Codes*, https://bit.ly/3Zsq9vF. The date such approval "shall be made effective" is fixed by statute according to specified criteria. 21 U.S.C. § 355(c)(3).

After an NDA has been approved, the manufacturer generally may not make changes to the drug without notifying FDA. *Id.* § 356a; 21 C.F.R. § 314.70(a)(1)(i). For some changes, sponsors must obtain approval for a "supplement" to the original NDA. 21 C.F.R. § 314.70(b). Changes to a drug approved through a supplement are still considered part of the *existing* NDA.

Id. § 314.3(b) (NDA includes "all . . . supplements"). Thus, a supplement is approved under the existing NDA's number and is not assigned a new NDA number. *Id.* § 314.50(a)(1).

Changes so significant that they result in a *new drug*, by contrast, require the sponsor to submit a separate, original NDA. 21 U.S.C. § 355(a). FDA guidance addresses the circumstances in which alterations to a drug should be submitted under an original NDA, versus through a supplement to an existing NDA. *See* FDA, *Guidance for Industry Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees* (Dec. 2004) (*Separate Marketing Applications Guidance*), https://bit.ly/4khCQCV. The difference may depend on the drug's particular features. For instance, some relatively minor changes to a drug's dosage form[4] or strength can be approved through a supplement, whereas others are so significant that they result in an entirely new drug and should be submitted through a separate original NDA. *Id.* at 3-4.

Of particular relevance here are FDA's rules and guidance regarding a drug's "active moiety," which is the core "molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3. When a manufacturer introduces a new active moiety, FDA requires submission of a new NDA. Yet the converse is *not* true: Distinct drugs may *share* an active moiety yet still may be different enough that they require *separate* NDAs. For example, two drugs with the same active moiety but different active ingredients should be submitted under separate NDAs. *Separate Marketing Applications Guidance* at 3 & n.7. And a manufacturer cannot legally market a new drug *without* a separately approved NDA merely because FDA has approved a different drug that shares the same active moiety. *Id.* Otherwise, a manufacturer could market a new drug without providing FDA with the requisite safety and

[4] "Dosage form" refers to a drug's physical features, such as tablets, capsules, or injectables. *See Drugs@FDA Glossary of Terms* (2017), https://bit.ly/3N1KKnF.

efficacy data, simply because it shares an active moiety with a *different manufacturer's* drug.

"[U]pon marketing approval," a new drug can be "eligible for a period of exclusivity under the U.S. statutory framework . . . before lower cost generic competitors can be approved or licensed." *Drug Patent and Exclusivity* at 7. The relevant period of exclusivity varies depending on circumstances. *See, e.g.*, 21 U.S.C. § 360cc (seven-year period for so-called "orphan drugs"); *id.* § 355(c)(3) (three years for new clinical investigations); *id.* § 355(j)(5) (five years for new chemical entity, potentially extendable to seven-and-a-half years); *see also* 21 C.F.R. § 316.31 (orphan drugs); *id.* § 314.108(b)(4) (new clinical investigations); *id.* § 314.108(b)(2) (new chemical entity). Exclusivity generally runs from the date FDA "approves" the qualifying NDA; depending on that approval date, the exclusivity periods can overlap with each other or run consecutively. *See, e.g.*, 21 U.S.C. § 360cc(a)(2) ("seven years from the date of the approval"). Likewise, drugs can receive patent protection, serving a "critical role in incentivizing and protecting the investments essential for bringing life-saving and life-altering drugs to market." *Drug Patent and Exclusivity* at 2.

FDA is required to periodically publish a "list" of brand-name drugs approved under original NDAs, including their exclusivity and patent information. 21 U.S.C. § 355(j)(7). Once an NDA-approved drug's regulatory exclusivity and patent-protection periods have expired, generic competitors are eligible to enter the market. A generic manufacturer can obtain approval by filing an Abbreviated New Drug Application. In general, to obtain approval for a generic drug, an applicant first must identify the previously approved product it seeks to duplicate—often referred to as the "listed drug." *See* FDA, *Referencing Approved Drug Products in ANDA Submissions Guidance for Industry* (Oct. 2020). An applicant must attest "that the generic has the 'same active ingredients as,' and is 'biologically equivalent' to, the already-approved brand-name drug."

Actavis, 570 U.S. at 142 (cleaned up); *see* 21 U.S.C. § 355(j)(2)(A)(ii), (iv); 21 C.F.R. § 314.3.

This "statutory framework" for the approval of brand and generic drugs—which allows manufacturers of novel drugs to receive market-based returns *before* facing generic competition—is crucial to innovation. *Drug Patent and Exclusivity* at 7. "Innovator companies bear the expense and risk of developing life-saving drug products" based on the promise that the law will "protect[] those inventions for a limited period of time." *Id*. By the same token, "the generic industry relies on innovator companies taking substantial initial risks during [drug] development, which must occur before lower cost versions of innovator products can be brought to market." *Id.* at 7-8.

B. The IRA Exempts a Limited Set of Drugs from the Exclusivity Framework

Medicare is a federal program that provides health insurance coverage for individuals over 65 and patients with certain disabilities and medical conditions. "Medicare stands as the largest federal program after Social Security." *Azar v. Allina Health Servs.*, 587 U.S. 566, 569 (2019). Administered by CMS, a subagency of HHS, Medicare currently has almost seventy million enrollees. CMS, *Medicare Enrollment Dashboard* (Sept. 2025), https://perma.cc/YJC2-4739.

Medicare includes two major prescription drug programs. Part B covers medically necessary and preventive healthcare services, including drugs administered by a physician. 42 U.S.C. §§ 1395k(a)(1), 1395x(s)(2)(A). Part D covers self-administered prescription drugs. *Id.* § 1395w–102. For decades, prices in Parts B and D have been dictated by the market. *See, e.g.*, *id.* § 1395w–111(i)(1) (Part D); *id.* § 1395w–3a (Part B).

The IRA removes a specified number of drugs from the standard market-based pricing model. It directs HHS to establish a "Drug Price Negotiation Program," under which CMS will set new prices for drugs that meet strict eligibility requirements and have been on the market for at least seven years. 42 U.S.C. § 1320f(a). The Program is limited to Medicare Part D drugs for the first two annual cycles, after which CMS "selects" Part B drugs as well. *Id.* § 1320f(b). Although

the IRA is designed to reduce drug prices, it also seeks to preserve incentives for innovation, by limiting which drugs qualify for price-caps based on the amount of time since their approval.

Here is how the Program works. Each applicable year, CMS must "publish a list of selected drugs" that will be subject to what the statute calls "maximum fair prices." *Id.* § 1320f(a). The IRA then directs the agency to "negotiate" with manufacturers and "enter into agreements" setting the price. *Id.* § 1320f–2(a)(1)-(3). While the IRA calls this process a "negotiation," it functionally allows CMS to dictate the price for each "selected" drug and compel the manufacturer to "agree" to that price. *Id.* § 1320f–3(c). With one minor exception, the statute does not limit how *low* a price HHS can demand. *See id.* § 1320f–3(b)(2)(F). But it does place a "ceiling" on how *high* the ultimate price can be, requiring a minimum discount of 25% to 60%. *Id.* § 1320f–3(b)(2)(F), (c)(1)(C). Below that "ceiling," HHS must "consider" various "factors," but it ultimately must "achieve the lowest maximum fair price for each selected drug." *Id.* § 1320f–3(b)(1). The statute then requires CMS to "compute and apply the maximum fair price across different strengths and dosage forms of a selected drug." *Id.* § 1320f–5(a)(2).

Once CMS has imposed a new price for a selected drug, the manufacturer must provide "access to such price to" nearly 70 million Medicare "eligible individuals," millions of private providers, and thousands of private pharmacies. *Id.* § 1320f–2(a)(1)-(3). Manufacturers that fail to provide the required access to that price are subject to a civil monetary penalty of *ten times* the difference between the actual sales price and the CMS-selected price, multiplied by the total number of units sold. *Id.* § 1320f–6(a). And manufacturers that do not "agree" to "negotiate," or that fail to accede to CMS's ultimate price "offer," are subject to a steep and escalating daily penalty. 26 U.S.C. § 5000D(b). The penalty starts at approximately 186%, and it quickly escalates to 1,900% of each sale of the selected drug. *See id.* § 5000D(b)-(d).

For a manufacturer, the only "alternative" to these penalties is to exit Medicare and Medicaid with respect to *all* of its products—not just the selected drug. *Id.* § 5000D(c). But doing so would be devastating for the manufacturer, and it would jeopardize patients' access to crucial medicines. *See* Cong. Budget Off., *Prescription Drugs: Spending, Use, and Prices* 8 (Jan. 2022), https://www.cbo.gov/publication/57050. The only real option is to accede to CMS's price.

C. The IRA Expressly Limits the Set of Drugs Eligible for Price Caps

Because the Program overrides the standard pricing framework that provides crucial incentives for innovation, the IRA strictly limits how many drugs—and which ones—can qualify for price caps each year. The statute effectuates these limits through a three-step process.

Step One*: *Qualifying Drug. Whether a drug can qualify for price caps under the Program depends on the timing of its FDA approval. The IRA directs CMS to begin the price-setting process by identifying each "qualifying single source drug"—also known as a "QSSD" or "Qualifying Drug"—which must be "a covered part D drug," as defined in the Medicare statute. 42 U.S.C. § 1320f–1(e).[5] The Medicare statute, in turn, defines a "covered part D drug" as a drug "described in" the Medicaid Drug Rebate Program statute, *id.* § 1395w–102(e), meaning a drug "which is approved" by FDA, *id.* § 1396r–8(k)(2)(A)(i). For a drug to be a Qualifying Drug, its manufacturer must have completed the "long, comprehensive, and costly testing process" necessary to gain FDA approval of its NDA. *Actavis*, 570 U.S. at 142.

The IRA then uses that same FDA-approval framework to specify *when* a drug becomes—or ceases to be—a Qualifying Drug. The statute limits the definition to a "covered Part D drug":

[5] The definition also includes certain "drug[s] or biological product[s]" payable under Part B, but Part B is not included in the Program for 2027. 42 U.S.C. § 1320f–1(a)(2).

> (i) that is approved under section 355(c) of title 21 [(*i.e.*, the FDA-approval provision)] and is marketed pursuant to such approval;
>
> (ii) for which . . . at least 7 years will have elapsed since the date of such approval; and
>
> (iii) that is not the listed drug for any drug that is approved and marketed under section 355(j) of [title 21].

42 U.S.C. § 1320f–1(e)(1)(A).[6]

Note the ways in which the Qualifying Drug definition relies on the NDA framework:

- Clause (i) says a Qualifying Drug must have been "approved under section 355(c)," which governs the FDA-approval process for new drugs. *See* 21 U.S.C. § 355(c). The drug must also currently be "marketed pursuant to such approval." 42 U.S.C. § 1320f–1(e)(1)(A)(i).

- Clause (ii) says that at least 7 years must have elapsed "since the date *of such approval*." So to be a Qualifying Drug under the IRA, the product must be FDA approved and must have received "such approval" at least seven years earlier. *Id.* § 1320f–1(e)(1)(A)(ii).

- Clause (iii) refers to a drug that "is not the listed drug" for a drug "approved and marketed under section 355(j)." The cross-referenced provision describes standards for approval and marketing of *generic* drugs, *see* 21 U.S.C. § 355(j), which gain approval using "abbreviated procedures" to show equivalency to an "already-approved brand-name drug," *Actavis*, 570 U.S. at 142, all of which appear on a "list" published periodically by the Secretary—hence the term "listed drug," 21 U.S.C. § 355(j)(7). Thus, in specifying that a Qualifying Drug is "is *not* the listed drug for" any generic version, the IRA ensures that NDA-approved drugs already facing generic competition are not subject to price caps.

Step Two: Negotiation Eligibility. After identifying Qualifying Drugs based on the timing and status of their FDA approval and the existence of any generic competitor, CMS must determine which Qualifying Drugs are "negotiation-eligible drug[s]." 42 U.S.C. § 1320f–1(d). To do so, CMS must rank Qualifying Drugs based on each drug's total expenditures under Medicare Part D or Part B over the previous year. *Id.* § 1320f–1(d)(1). Because only Part D drugs can be selected during the first two cycles, the ranking for those initial cycles includes only Part D expenditures. *Id.* § 1320f–1(a)(1), (2). "Negotiation-eligible drugs" are the Qualifying Drugs that are among the

[6] The IRA excludes certain drugs from the Qualifying Drug definition, including "[c]ertain orphan drugs," "[l]ow spend medicare drugs," and "[p]lasma-derived products." *Id.* § 1320f–1(e)(3).

top 50 highest-expenditure Part D or top 50 highest-expenditure Part B drugs. *Id.* § 1320f–1(d).

In determining whether a Qualifying Drug ranks as a negotiation-eligible drug, the IRA instructs CMS to "use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation." *Id.* § 1320f–1(d)(3)(B). Thus, after the agency has identified each Qualifying Drug (by reference to its FDA approval), the agency must aggregate expenditures across dosage forms and strengths of each Qualifying Drug to determine whether its total expenditures make it "negotiation-eligible."

Step Three: Selection. The IRA then directs CMS to "select" a specified number of the highest-ranked negotiation-eligible drugs for the Program each year. *Id.* § 1320f–1(a)-(b). CMS was required to select ten Part D drugs during the first annual cycle, with price caps taking effect in 2026. *Id.* § 1320f–1(a)(1). For the second cycle—at issue here—the IRA directs CMS to select fifteen additional drugs, with price caps scheduled to take effect in 2027. *Id.* § 1320f–1(a)(2).[7]

Once chosen, a drug remains selected until a defined period after the agency determines that a generic version of the drug has been "approved by" FDA and marketed "pursuant to such approval." *Id.* § 1320f–1(c)(1)(B), (c)(2). Thus, the IRA also uses the FDA-approval framework—including approval of a generic version of a "listed drug"—to determine when a drug *no longer* qualifies as a "selected drug." *Id.* § 1320f–1(c)(1)(A)(i).

D. CMS's Program Guidance

On October 2, 2024, CMS promulgated the Guidance at issue in this case. The Guidance sets forth the agency's plan for implementing the Program during "initial price applicability year 2027," *Guidance* at 1, for which the IRA directs CMS to select fifteen Part D drugs for price caps.

[7] For the third cycle, the statute directs CMS to select fifteen Part B or D drugs for price caps taking effect in 2028. *Id.* § 1320f–1(a)(3). The statute instructs CMS to select twenty more Part B or D drugs for the fourth cycle and for each cycle thereafter. *Id.* § 1320f–1(a)(4).

Section 30 of the Guidance articulates CMS's approach to the IRA's numerical limit on drug selection, including its implementation of "the requirements governing the identification of qualifying single source drugs" (*i.e.*, Qualifying Drugs). *Id.* at 165. Key here:

> CMS will identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same *active moiety* and the same holder of a New Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs*.

Id. at 167 (emphases added) (footnotes omitted).

The term "active moiety" does not appear in the IRA. As discussed above, drugs that share an "active moiety" often require distinct NDAs—for instance, when they contain different "active ingredients." *Separate Marketing Applications Guidance* at 3 & n.7. Thus, under CMS's Guidance, two or more *distinct* drugs with *different* active ingredients—drugs whose distinct NDAs have been separately approved by FDA at different times based on different safety and efficacy data—could nevertheless be treated collectively as a *single* Qualifying Drug under CMS's Guidance.

As noted, the IRA's definition of Qualifying Drug requires "at least 7 years [to] have elapsed since the date of such approval." 42 U.S.C. § 1320f–1(e)(1)(A). To implement this requirement where two or more products with the same active moiety were approved under different NDAs at different times, CMS has elected to start the seven-year eligibility countdown from the "earliest date of approval or licensure of the initial FDA application." *Guidance* at 170. As a result, a new product could be subject to a price cap under the Program *immediately* after its FDA approval, so long as it shares an active moiety with a different product with an older approval date. And so long as the two drugs have the same NDA-holder, CMS will aggregate their Medicare sales for purposes of the Program. *Id.* at 14, 167.

ARGUMENT

Summary judgment is appropriate where "the movant is entitled to judgment as a matter

of law." Fed. R. Civ. P. 56(a). The Administrative Procedure Act (APA) requires courts to "hold unlawful and set aside" agency action that is "not in accordance with law" or is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(A), (C). "[T]he duty of an administrative agency is to follow [a statute] as written, not to supplant [the statute's] commands with others it may prefer." *SAS Inst., Inc. v. Iancu*, 584 U.S. 357, 363 (2018). The only "permissible" reading of a statute is the "best" one, which is the interpretation the court would adopt "if no agency were involved." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 400 (2024). Here, Plaintiffs are entitled to judgment as a matter of law because the Guidance does not reflect the "best" interpretation—or even a plausible interpretation—of the IRA.

I. CMS'S GUIDANCE CONTRAVENES THE IRA

The IRA requires CMS to "publish a list of . . . 15 negotiation-eligible drugs" for price caps in 2027. 42 U.S.C. § 1320f–1(a)(2). Each "drug" must be a "qualifying single source drug" (*i.e.*, Qualifying Drug), defined as "a covered part D drug" that was approved by FDA at least seven years earlier. *Id.* § 1320f–1(e)(1)(A)(i)-(ii). A "covered part D drug" is a drug "approved" via a New Drug Application (NDA). *Id.* § 1320f–1(e)(1)(A)(i). When the IRA says fifteen drugs, that means fifteen NDAs; it does not mean *more than* fifteen drugs approved under *more than* fifteen NDAs. The Guidance attempts to redefine Qualifying Drug based on "active moiety," a term that appears nowhere in the IRA. That approach makes a hash of the statute's language and creates numerous practical and structural problems. The Guidance then attempts to solve those problems by introducing even *more* new terms—which *also* have no grounding in the statute. The Guidance must be set aside.

A. A Qualifying Drug Cannot Have Multiple New Drug Applications

The IRA defines "drug" by incorporating the FDA-approval framework. Under that framework, every "new drug" must be approved pursuant to its own, distinct NDA. Numerous

textual provisions rely on that fundamental fact. Indeed, the statute would be incoherent if a single "drug" could somehow encompass *multiple* products with different NDAs and approval dates.

1. Start with the first subsection of the Qualifying Drug definition, which specifies that only "*a* covered part D drug" can be a Qualifying Drug. 42 U.S.C. § 1320f–1(e)(1) (emphasis added).[8] Given the pairing of the single, indefinite article ("a") with a singular noun ("drug"), a Qualifying Drug must be *one* "covered part D drug," not multiple drugs. *See, e.g.*, *Garland v. Aleman Gonzalez*, 596 U.S. 543, 550 (2022). Each "covered part D drug," in turn, has a single NDA. The IRA defines "covered part D drug" as "a drug" "that *is approved* under Section 355(c)." 42 U.S.C. § 1320f–1(e)(1)(A) (emphasis added).[9] And for "a covered part D drug" to be a Qualifying Drug, it must be "marketed pursuant to *such approval*." *Id.* § 1320f–1(e)(1)(A) (emphasis added). That means a Qualifying Drug has *one* approval.

The reference to approval under Section 355(c) is important: It governs FDA's drug-approval process. "[B]efore any 'new drug' may be introduced into interstate commerce," it must be approved pursuant to that process, via its own unique NDA. *United States v. Generix Drug Corp.*, 460 U.S. 453, 458 (1983); *see* 21 U.S.C. § 355(b)-(c). So "*a* covered Part D drug . . . that *is approved* under" Section 355(c) must have *an* NDA—that is, a *single* NDA. 42 U.S.C. § 1320f–1(e)(1)(A)(i) (emphases added).

The other components of the Qualifying Drug definition reinforce that each "covered Part

[8] Indeed, the IRA repeatedly references "*the* drug," "*a* drug," and "*a* qualifying single source drug." *Id.* § 1320f-1 (emphases added).

[9] As explained above, *see* pp. 10-11, *supra*, the IRA defines "covered part D drug" by reference to the Medicare statute. *See* 42 U.S.C. § 1320f–1(e)(1) (referencing 42 U.S.C. § 1395w–102(e)). The Medicare statute defines "covered part D drug" as a "covered outpatient drug" under the Medicaid Drug Rebate Program statute. *Id.* § 1395w–102(e) (referencing 42 U.S.C. § 1396r–8(k)(2)). That statute, in turn, defines "covered outpatient drug" as "a drug" that "is approved" by FDA under 21 U.S.C. § 355. 42 U.S.C. § 1396r–8(k)(2)(A)(i) (referencing "section 505 or 507 of the Federal Food, Drug, and Cosmetic Act," which is 21 U.S.C. § 355).

D drug" can have only one NDA. Clause (ii) requires not only that a Qualifying Drug be "approved" under an NDA, but also that "at least 7 years will have elapsed since *the* date of *such* approval." 42 U.S.C. § 1320f–1(e)(1)(A)(ii) (emphases added). When Congress "us[es] a definite article with a singular noun," it refers to "a discrete thing." *Niz-Chavez v. Garland*, 593 U.S. 155, 166 (2021). Here, the IRA pairs the definite article ("*the* date") with a singular noun. And the statute does not merely refer to "approval," but to "*such* approval." As the Supreme Court has explained, "the word 'such' usually refers to something that has already been 'described,'" especially where there is a "clear referent." *Slack Technologies, LLC v. Pirani*, 598 U.S. 759, 766 (2023) (citation omitted). And here, the referent is crystal clear: The date of "*such* approval" obviously refers to the date on which the drug was "approved under section 355(c)," 42 U.S.C. § 1320f–1(e)(1)(A)(i)—that is, the date that FDA approved the drug's unique NDA.

Congress clearly meant for each Qualifying Drug to be connected to the approval of a specific NDA on a particular date. That makes good sense: The date that the "covered part D drug" was "approved" is *the* date that triggers the seven-year clock. By contrast, if a single Qualifying Drug could encompass multiple drugs with *different* NDAs approved at different times, then it could not be possible to start eligibility for price-setting under the IRA "7 years [after] *the* date of *such* approval." *Id.* § 1320f–1(e)(1)(A)(ii) (emphases added).

It similarly makes sense that a Qualifying Drug must be "marketed pursuant to *such* approval." *Id.* § 1320f–1(e)(1)(A)(i) (emphasis added). Under FDA's approval framework, each individual "drug" is "marketed pursuant to" an individual NDA, meaning a distinct "such approval." *See Generix Drug*, 460 U.S. at 458; 21 U.S.C. § 355(b). In saying that a Qualifying Drug is "marketed pursuant to such approval," the statute necessarily means that each Qualifying Drug was approved under its own distinct NDA, "pursuant to" which it is now marketed.

The same is true for clause (iii), which specifies that a Qualifying Drug cannot be "the listed drug" for a generic version "that is approved and marketed." 42 U.S.C. § 1320f–1(e)(1)(A)(iii). A "listed drug" means "the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its [generic version]." 21 C.F.R. § 314.3. Every listed drug is approved under a single NDA. *See* 21 U.S.C. § 355(j)(2)(A)(i), (j)(7) (requiring each generic drug application to reference a "listed drug"). When the IRA discusses the possibility of "a covered part D drug" being "the listed drug" for a generic, it necessarily assumes that each such "covered part D drug" will have its *own* NDA.

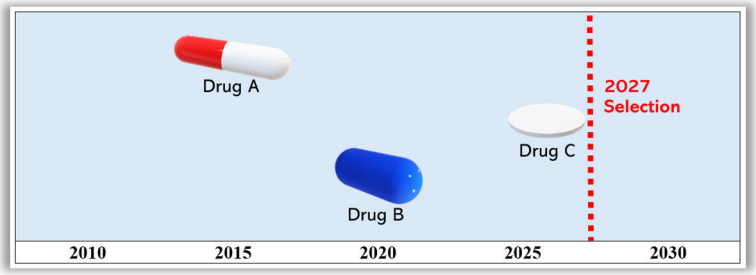
Finally, once selected as negotiation-eligible, a drug remains a selected drug until a defined period after the agency determines that a generic version of the "listed drug" "is approved" by FDA and "is marketed pursuant to such approval." 42 U.S.C. § 1320f–1(c)(1)-(2). Again, the reference to "*such* approval" obviously refers to the approval of a particular generic drug for which the Qualifying Drug is its corresponding "listed drug." The statute clearly contemplates that entry into the market of a single generic drug will knock out the eligibility of a single "listed" (*i.e.*, non-generic) competitor. S*ee* 42 U.S.C. § 1320f–1(c)(1); 21 U.S.C. § 355(j)(2)(A)(i), (j)(7). Thus, at every turn, the IRA confirms that each "drug" has *one* NDA.

2. Congress had good reasons for tying each drug's potential IRA eligibility to its NDA, as opposed to using a definition that would encompass *multiple* products with *distinct* NDAs. As discussed, the availability of market pricing and the prospect of market exclusivity are key incentives for innovation. *See* pp. 4-8, *supra*. Because the vast majority of drugs never reach the market, the rare drugs that do receive FDA approval after the lengthy and costly testing and approval processes must be able to generate enough revenue to support the manufacturer's entire pipeline. Once "the statutory requirements [have been] met," a drug's "[e]xclusivity attaches upon

approval." FDA, *Frequently Asked Questions on Patents and Exclusivity* (2020), https://bit.ly/4rjaWJ0. At that point, the private market generally determines the drug's price—including for sales under Medicare Parts D and B, *see, e.g.*, 42 U.S.C. § 1395w–111(i)(1) (Part D); *id.* § 1395w–3a (Part B)—until generic competition is allowed to begin.

Congress was well aware of the importance of market pricing and exclusivity when it enacted the IRA. That is why a drug does not become eligible for a price cap under the IRA until "at least 7 years will have elapsed since the date of [its FDA] approval." 42 U.S.C. § 1320f–1(e)(1)(A)(ii). As one Congressmember put it in endorsing the IRA, "We don't negotiate during [a drug's] initial exclusivity period." HOUSE RULES, *Rules Committee Meeting on H.R. 5376*, at 34:20 (YouTube, Nov. 3, 2021), https://perma.cc/GFJ9-L3KZ.

If, however, a single Qualifying Drug could span *multiple* products that are marketed pursuant to *different* NDAs, then the statute would create an unanswered question: Which date starts the seven-year clock? For instance, imagine that Drug A was approved in 2015, Drug B was approved in 2020, and Drug C was approved in 2026:

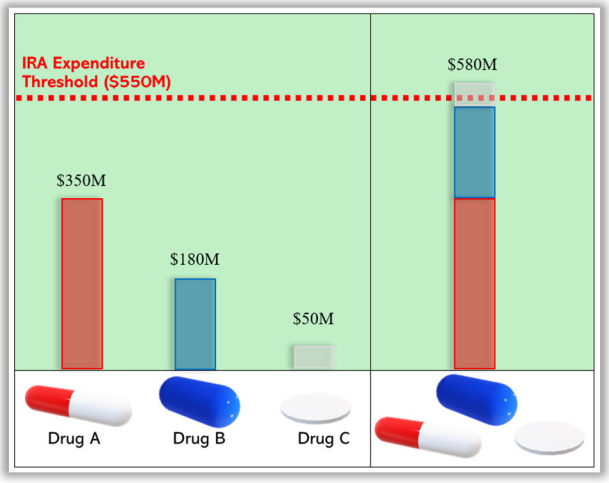


Combining the three together into a single Qualifying Drug, despite their separately approved NDAs, would require choosing between their approval dates. Yet the statute provides no guidance about how to decide in this situation whether "7 years will have elapsed since the date of *such* approval." 42 U.S.C. § 1320f–1(e)(1)(A)(ii) (emphasis added). That is a clear sign that Congress did not contemplate this scenario at all. *See Stern v. Marshall*, 564 U.S. 462, 476 (2011) (rejecting

interpretation under which statute "provides no guidance on" necessary implementation decision).

Defining Qualifying Drug to encompass multiple NDAs would create even more problems: Many newly approved drugs could be subject to IRA pricing *during* their initial exclusivity period. Consider the example above, where Drug C was approved in 2026. If Drug C were lumped in with Drug A based on the date of Drug A's NDA approval, then Drug C would have only a single year of exclusivity between reaching the market in 2026 and receiving a price cap under the IRA in 2027. Indeed, in some cases a drug could be subject to price caps *immediately* upon approval.

That's not all. If a new drug could be lumped together with an old drug for purposes of IRA-eligibility, the new drug's Medicare expenditures would be added to the old drug's expenditures, increasing the likelihood that *both* drugs would qualify for the Program. *See* 42 U.S.C. § 1320f–1(d)(1). So even if expenditures for Drugs A, B, and C would not independently cross the top-50 threshold to qualify as negotiation-eligible, their *combined* expenditures might. Drug C could reach the market in 2026 and push *all three* drugs over the IRA threshold for 2027. Imagine, for example, the expenditure threshold for 2027 is $550M. Introduction of Drug C, with expenditures of $50M, could push Drug A ($350M) and Drug B ($180M) over the line:



In other words, developing a new drug (Drug C) would risk not only a price cap for *that* drug, but

might also expose *earlier-approved* drugs (Drugs A and B) to price caps that they would otherwise be ineligible to receive. That anti-innovation approach is hardly what Congress intended.

Finally, defining Qualifying Drug to encompass multiple NDAs would make a mess of the interplay between IRA-eligibility and generic competition. Recall that generic competition leads to the removal of a "listed drug" from negotiation-eligibility. *Id.* § 1320f–1(c)(1)(B), (c)(2). But what about where there is a generic competitor for only *one* of several drugs that have been grouped together? What happens when FDA approves a generic version of Drug B, but *not* of Drugs A or C? Would competition from Generic Drug B disqualify *all three* brand-name drugs from being negotiation-eligible? Or only Drug B? Again, the statute's utter silence on this question is a strong sign that Congress never intended for multiple drugs to be lumped together in the first place. *See Stern*, 564 U.S. at 476 (rejecting statutory interpretation that would mean "Congress failed to provide any framework for identifying or adjudicating [an important] category").

B. CMS's Guidance Contravenes the IRA's Key Limits by Redefining "Qualifying Single Source Drug"

On its face, CMS's Guidance contravenes the IRA. Although the statute deliberately incorporates FDA's one-drug, one-NDA framework into the definition of Qualifying Drug, the Guidance treats multiple drugs approved under separate original NDAs as a *single* Qualifying Drug. Under the Guidance, CMS will "identify a potential qualifying single source drug using . . . all dosage forms and strengths of the drug with the same *active moiety* and the same *holder* of a New Drug Application (NDA), *inclusive of products that are marketed pursuant to different NDAs*." *Guidance* at 167 (emphases added) (footnote omitted). The Guidance thus treats multiple drugs—approved at different times under different NDAs—as a single Qualifying Drug, so long as they share an "active moiety" and have the same NDA-"holder." That *ad hoc* interpretation cannot be squared with the statutory text, and CMS's reasons for adopting it are unpersuasive.

1. The Guidance Conflicts with the Statute

In an attempt to maximize the number of drugs subject to the IRA's price caps, CMS has adopted a definition of Qualifying Drug that strays far from the statutory text. That interpretation contravenes the statute—and certainly is not its "best" reading. *Loper Bright*, 603 U.S. at 400.

First, as discussed, the Qualifying Drug definition refers to the relevant product in the singular: "*A* drug that *is* approved" under an NDA and is "marketed pursuant to *such* approval." 42 U.S.C. § 1320f–1(e)(1)(A)(i) (emphases added) (cleaned up). That language is an obvious mismatch with the Guidance's interpretation, under which a single Qualifying Drug can "includ[e]" multiple "products that are marketed pursuant to different NDAs." *Guidance* at 167.

The Qualifying Drug definition also requires "at least 7 years [to] have elapsed since *the* date of *such* approval." 42 U.S.C. § 1320f–1(e)(1)(A)(ii) (emphases added). Again, the reference is to a singular point in time ("*the* date") at which a particular NDA was approved ("*such* approval"). The phrase does not contemplate that a single drug might somehow have multiple "different" approval dates. *Guidance* at 167. Nor does the statute provide any clues about *which* approval date should be used if there are more than one.

In fact, CMS itself recognizes that starting eligibility "7 years [after] the date of such approval" would make no sense if a Qualifying Drug could have multiple "approvals." So in its Guidance, CMS adds a requirement that appears nowhere in the IRA: "CMS will use the *earliest* date of approval" to start the seven-year clock. *Id.* at 170 (emphasis added). Why the earliest date, as opposed to the latest date (or some other date)? Because CMS wants to maximize the number of drugs subject to the IRA's price caps. In the example above, Drugs B and C would be eligible for selection in 2027—not because seven years have elapsed since *they* were approved, but because seven years have elapsed since *Drug A* was approved.

But the IRA does not say "7 years since the *earliest* date of approval," even though

Congress easily could have written the statute that way had it intended that meaning. *Cf.* 5 U.S.C. § 9003(d) (requiring the Office of Personnel Management to contract with long-term-care insurers "for a term of 7 years," with "the 7-year period beginning on the earliest date as of which any long-term care insurance coverage under this chapter becomes effective"). Nor can CMS explain why Congress started the seven-year countdown from "the" date of "such" approval, if it actually meant for the clock to start from the date of the "earliest" of multiple potential "approvals."

Second, the Guidance lumps together different products into a single Qualifying Drug based on whether they share an "active moiety." Indeed, the term "active moiety" is essentially the linchpin of CMS's interpretation. Yet that term cannot be found anywhere in the IRA's 270 pages.

That is no accident. An "active moiety" is not itself a "drug," but is merely the "molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." 21 C.F.R. § 314.3(b). And when the FDA-approval provision—which the IRA incorporates—uses the "term 'drug,'" it does *not* refer to an active moiety, active ingredient, or to any other *feature* of a drug, but rather "to the entire product." *Generix Drug*, 460 U.S. at 454. This "product-specific interpretation of 'new drug'" has long been a central feature of the legal framework for drug regulation; it "underpins FDA's drug regulatory system" and "has significant implications for public health." 86 Fed. Reg. 28605, 28606 (2021). By expressly incorporating the well-established FDA approval framework into the IRA's Qualifying Drug definition, Congress deliberately chose a "product-specific" definition, *id.*, not a definition that turns on a drug's "active moiety."

Congress *could have* done things differently. Congress is familiar with the term "active moiety," which appears in other sections of the U.S. Code. *See* 21 U.S.C. §§ 355, 360b, 360n, 360ff, 360bbb-4a. When Congress intends to distinguish between products based on active moieties, it does so expressly. Congress's decision in the IRA to link each Qualifying Drug to its

NDA, rather than to its "active moiety," reflects a legislative choice CMS is not free to override.

Third, CMS's attempt to replace the NDA framework with an "active moiety" test is at war with the IRA's broader structure, because *separate manufacturers* can (and do) develop and market different drugs that share an active moiety. Recall again the example in which separately approved Drugs A, B, and C share an active moiety. Those drugs might have been developed and marketed by three separate manufacturers to treat three distinct conditions, based on health and safety data for three distinct patient populations. Yet under an "active moiety" test, all three of those manufacturers' distinct drugs would be treated as *one* Qualifying Drug.

This is not merely an abstract concern. Consider Prograf and Protopic, two distinct drugs that share an active moiety. Prograf was developed by Astellas Pharma U.S., Inc., and approved in 1994 to prevent organ rejection in patients receiving liver transplants. Protopic, by contrast, was developed by LEO Pharma A/S and approved in 2000 as an ointment to treat eczema. Under the IRA's plain text, Prograf and Protopic are each distinct "drugs." Yet applying an "active moiety" test would mean treating them both as *the same drug*, theoretically eligible for a *single* "maximum fair price," despite having *separate* developers.

The IRA forecloses this possibility. Once a Qualifying Drug has been "selected" for the Program, CMS must sign an agreement to "negotiate" with "*the* manufacturer" of that selected drug. 42 U.S.C. § 1320f–2(a), (d) (emphasis added). CMS must obtain information from "*the* manufacturer," "negotiate" a price with "*the* manufacturer," and ensure that "*the* manufacturer" provides access to the price. *Id.* § 1320f–2(a)-(b) (emphases added). If one Qualifying Drug could encompass multiple drugs "with the same active moiety," notwithstanding their "different NDAs," *Guidance* at 167, then one Qualifying Drug could encompass multiple products marketed by multiple manufacturers. That would render the IRA's negotiation provisions incoherent.

CMS understands that Congress intended nothing of the sort. But instead of abandoning its implausible position, CMS attempts a workaround by adding yet *another* requirement that is not in the statute: According to the Guidance, CMS will combine drugs "with the same active moiety *and the same holder of a New Drug Application*." *Id.* (emphasis added). That is, CMS will count two drugs with the same active moiety as a single Qualifying Drug if they share an NDA-"holder," but those same drugs *do not* count as one Qualifying Drug if different companies hold their NDAs.

Much as that distinction might solve CMS's *practical* problems, it bears no relationship to the text Congress enacted. Nothing in the Qualifying Drug definition indicates that separately approved drugs might be grouped together depending on whether their NDAs are held by the same manufacturer. Indeed, the very need to solve such practical problems by adding terms to the statute is yet another sign of how far the agency's approach deviates from the IRA's plain language.

2. CMS's Attempts to Justify Its Definition Are Unpersuasive

To defend its outcome-driven interpretation, CMS's Guidance invokes language from several *different* provisions of the IRA: the "Use of Data" provision, 42 U.S.C. § 1320f–1(d)(3)(B); the "Compute and Apply" provision, *id.* § 1320f–5(a)(2); and the "Applications and Approvals" provision, *id.* § 1320f–3(e)(1)(D). Those provisions are not part of the Qualifying Drug definition and do not support the agency's view.

Use of Data. This provision is part of the IRA's second step—that is, the process for determining whether a particular Qualifying Drug counts as a "negotiation-eligible drug":

> In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2) [(*i.e.*, the criteria for a negotiation-eligible drug)], the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

Id. § 1320f–1(d)(3)(B). According to CMS's Guidance, this provision "necessarily establish[es] that the statutory negotiation procedures apply more broadly than to a distinct NDA," and supports

"identify[ing] a potential qualifying single source drug" using "all dosage forms and strengths of the drug." *Guidance* at 12-14. In fact, it does nothing of the sort.

In step one, the IRA instructs CMS *first* to identify Qualifying Drugs using FDA's approval framework—*i.e.*, the NDA. *See* 42 U.S.C. § 1320f–1(e). The statute does *not* instruct CMS to "aggregate[]" during *that* process at all, let alone to aggregate across multiple drugs with distinct NDAs. Then, once a Qualifying Drug has been identified, a *separate* subsection instructs CMS to determine whether that Qualifying Drug is eligible for "negotiation," a step that involves aggregating data "across [its] dosage forms and strengths." *Id.* § 1320f–1(d)(3)(B). But the aggregation provision applies at step two, only *after* a Qualifying Drug has been identified (by its specific NDA). *See* pp. 11-12, *supra*. The Guidance thus improperly seeks to import the data-aggregation requirement into an earlier step that is conducted under a different subsection.

The Guidance's attempted reliance on the "Use of Data" provision also fails on its own terms: The provision itself *does not* assume that a single Qualifying Drug can have multiple NDAs. As discussed, a single Qualifying Drug approved via a single NDA can have multiple "dosage forms" and "strengths" approved via *supplemental* applications. *Separate Marketing Applications Guidance* at 3; *see Drug Patent and Exclusivity* at 8 (noting that "[a] single NDA may include more than one strength"). So once a Qualifying Drug has been identified by its NDA, the statute instructs CMS to determine the drug's negotiation-eligibility using data about *all* of its dosage forms and strengths, including those approved through supplements. But the Use of Data provision does not assume that multiple drugs with multiple NDAs can be *one* Qualifying Drug.[10]

[10] Another court recently opined that this interpretation would render the Use of Data provision "surplusage" because even without that provision, "sales of a drug under a supplemental formulation are included in the sales of the drug in the original NDA." *Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *11 (D.D.C. Nov. 20, 2025). Not so. Because the IRA expressly defines each Qualifying Drug by reference to the "approval" *of its NDA*, the Use of Data provision was necessary to make clear that CMS must determine negotiation-eligibility based not simply on

Compute and Apply. The Guidance's reliance on this provision is unpersuasive for the same reason. It requires CMS to "compute and apply the [maximum price] across different strengths and dosage forms of a selected drug." 42 U.S.C. § 1320f–5(a)(2). Like the "Use of Data" provision, the "Compute and Apply" provision applies only *after* a Qualifying Drug has been identified. Indeed, it applies *after step three*—that is, after CMS has identified all Qualifying Drugs, determined which of them are negotiation-eligible, and selected some of them for "negotiation." Only after CMS has set maximum prices for all selected drugs does the statute instruct CMS to "compute and apply" each drug's maximum price across the different dosage forms and strengths of the Qualifying Drug. The Compute and Apply provision—which is not even codified in the same statutory *section* as the Qualifying Drug definition—thus has no bearing on whether a product is a Qualifying Drug in the first place. And like the Use of Data provision, it does not assume that a single Qualifying Drug can have multiple NDAs, because different dosage forms and strengths can be approved through supplements.

Applications and Approvals. This provision also applies in setting a price *after* a drug has been identified as a Qualifying Drug, has been determined to be negotiation-eligible, and has been selected for negotiation. It requires "the Secretary [to] consider . . . [d]ata on . . . applications and approvals under section 355(c) . . . for the drug." 42 U.S.C. § 1320f–3(e)(1)(D). According to

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sales data for that original NDA "approval," but also using data for supplemental "approvals" tied to the same NDA. At minimum, Congress had ample reason to "remove doubt" about how the agency should aggregate data in cases involving multiple approvals (*i.e.*, in cases involving an original NDA plus any supplemental approvals). *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 385 (2013). And regardless, "the canon against surplusage assists only where a competing interpretation gives effect to every clause and word of a statute." *Id.* (quotation marks omitted). In addition to being untenable as a matter of interpretation, *see* pp. 21-24, *supra*, CMS's argument—that each Qualifying Drug can encompass multiple NDAs—would make the IRA's *other* provisions far *more* superfluous. For instance, if CMS were right, Congress would not have needed to separately instruct CMS to consider multiple "applications and approvals," 42 U.S.C. § 1320f-3(e)(1)(D), which obviously would already be subsumed by a definition of Qualifying Drug that includes multiple drugs with "different NDAs," *Guidance* at 167 (footnote omitted).

CMS, the reference to applications and approvals "in the plural, for the 'drug,' in the singular," means an individual Qualifying Drug can have multiple NDAs. *Guidance* at 13.

Not at all. The cross-referenced provision, Section 355(c), describes *both* the process for obtaining approval of an NDA *and* the process for supplemental applications for an existing NDA. *See* 21 U.S.C. § 355(c)(1) (approval of an original application); *id.* § 355(c)(5) (approval of "a supplemental application"). A single drug with a single NDA thus can have multiple "applications and approvals" under Section 355(c)—one approval for the original NDA, and any number of additional approvals for supplemental applications related to the original NDA. So the IRA simply tells CMS to consider *all* data for each Qualifying Drug: data submitted in connection with its original NDA, as well as data submitted in connection with any supplemental approvals.[11]

II. THE COURT SHOULD SET THE GUIDANCE ASIDE

A. No Judicial Review Bar Applies to Plaintiffs' Facial Challenge

In defending against other challenges to its guidance documents implementing the IRA, CMS has asserted that the statute bars judicial review. But as the U.S. District Court for the District of Columbia recently held, the IRA allows "a facial challenge to set aside CMS's guidance." *Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *7 (D.D.C. Nov. 20, 2025).

The Supreme Court has "long applied a strong presumption favoring judicial review of administrative action." *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015). "This default rule

[11] The *Teva* court recently rejected what it perceived to be Teva's argument that "applications and approvals" under Section 355(c) "should be narrowly construed to apply *only* to supplemental applications." 2025 WL 3240267, at *11 (emphasis added). That appears to have been a misunderstanding of Teva's position, *see* Appellants' Br., *Teva Pharms. USA, Inc., v. Kennedy*, No. 25-5425, at 31 (D.C. Cir., Jan. 9, 2026), and it certainly does not reflect AstraZeneca's. "Applications and approvals" under Section 355(c) encompasses *both* supplemental applications *and* the original NDA. CMS thus must "consider . . . [d]ata" submitted in connection with *all* of a drug's "applications and approvals"—not only the original NDA, but any supplements as well.

is well-settled, and Congress is presumed to legislate with it in mind." *Salinas v. United States R.R. Ret. Bd.*, 592 U.S. 188, 197 (2021) (citation and quotation marks omitted). To overcome the strong presumption of reviewability, the government must produce "clear and convincing evidence of congressional intent to preclude" review of the specific agency action that is challenged. *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020) (citation and quotation marks omitted). And judicial review bars must be construed narrowly, such that any "ambiguity in the meaning" of their terms "must be resolved in . . . favor" of permitting review. *Salinas*, 592 U.S. at 196. If the bar "is reasonably susceptible to divergent interpretation" regarding review of a particular challenge, the court must "adopt the reading that accords with . . . review." *Guerrero-Lasprilla*, 589 U.S. at 229.

When a statute bars "judicial review of individual determinations" by an agency, it is only *those* "determinations" that are precluded; the statute does not *also* bar a "general challenge" to the agency's rules and practices. *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 491 (1991). To the contrary, a statute that precludes "judicial review of [an agency's] substantive decision[s] . . . does not insulate from judicial review a challenge to the very legality of the [agency's] guidelines or their application, i.e., to whether the [agency] acted completely outside the scope of the discretion given it by Congress." *Garcia v. Neagle*, 660 F.2d 983, 988-89 (4th Cir. 1981); *accord ParkView Med. Assocs., L.P. v. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998) (holding that a statute barring review of HHS's decisions declining to reclassify hospitals as "urban" for Medicare purposes "leaves hospitals free to challenge the general rules leading to denial").

The IRA bars review of certain specific "determinations," but it does not bar review of a facial challenge to CMS's Guidance. It provides that there "shall be no administrative or judicial review" of eight discrete agency decisions: (i) "[t]he determination of" what constitutes "a unit . . . pursuant to section 1320f(c)(6)" (which defines "unit" as "the lowest identifiable amount . . . of

the drug or biological product that is dispensed or furnished"); (ii) "[t]he selection of drugs" for "negotiation"; (iii) "the determination of negotiation-eligible drugs"; (iv) "the determination of qualifying single source drugs"; (v) "the application of section 1320f–1(f)" (which concerns delaying the selection and negotiation of biologics); (vi) "[t]he determination of a maximum fair price"; (vii) "[t]he determination of renegotiation-eligible drugs"; and (viii) "the selection of renegotiation-eligible drugs." 42 U.S.C. § 1320f–7 (footnotes omitted).

Each of these narrow categories involves CMS's decisions about *which* particular drugs are subject to price-setting under the Program. The statutory bar is clearly designed to prevent courts from "second guess[ing]" CMS "on the merits of particular" determinations and to avoid "involv[ing] the courts in the complex and technical niceties" of, for example, calculating a given drug's Medicare expenditures. *Univ. of Md. v. Cleland*, 621 F.2d 98, 100 (4th Cir. 1980) (citation omitted). But it is *not* intended to "insulate from judicial review the limits of [CMS's] authority" under the IRA. *Id.* (citation omitted). Nor would it make sense to permit the agency to redefine key statutory terms—such as Qualifying Drug—without any judicial oversight whatsoever. Certainly "had Congress intended" the "expansive" result of barring facial challenges to CMS's interpretation of statutory provisions, "it could easily have used broader statutory language" instead of barring discrete substantive determinations. *McNary*, 498 U.S. at 494.

Thus, as the court in *Teva* recently held, the judicial-review "provision does not bar [an] APA challenge" to CMS's *redefinition* of Qualifying Drug, since such a challenge "is not an as-applied action to vacate any selections but rather a facial challenge to set aside CMS's guidance." 2025 WL 3240267, at *7. Like the *Teva* plaintiff, AstraZeneca does not challenge CMS's "determination" of any Qualifying Drug or "negotiation-eligible" drug, nor its "selection" of any drug for "negotiation." Indeed, AstraZeneca is not challenging the Guidance as applied to any

particular product. It brings a facial challenge, arguing that the Guidance unlawfully *redefines* Qualifying Drug. The IRA does not preclude AstraZeneca's challenge.

B. CMS's Guidance Is *Ultra Vires*

Regardless of the IRA's judicial review bar, the Court may review AstraZeneca's challenge under the exception for *ultra vires* agency action. "[E]ven when the statutory language bars judicial review, courts have recognized that an implicit and narrow exception to the bar on judicial review exists for claims that the agency exceeded the scope of its delegated authority or violated a clear statutory mandate." *Hanauer v. Reich*, 82 F.3d 1304, 1307 (4th Cir. 1996) (citing *Leedom v. Kyne*, 358 U.S. 184 (1958)). To "satisfy this court's two-pronged test to invoke the *Leedom* exception," a plaintiff "must make (1) a strong and clear demonstration that a clear, specific and mandatory statutory provision has been violated, and (2) the absence of federal court jurisdiction over an agency action would wholly deprive the aggrieved party of a meaningful and adequate means of vindicating its statutory rights." *Scottsdale Cap. Advisors Corp. v. Fin. Indus. Regul. Auth., Inc.*, 844 F.3d 414, 421 (4th Cir. 2016) (cleaned up).

This is a paradigm case for *ultra vires* review. For the reasons discussed, CMS's Guidance violates multiple "clear, specific and mandatory statutory provision[s]," including: (1) the requirement that each Qualifying Drug be "approved" and "marketed" pursuant to its own NDA, and that seven years shall have elapsed since "such approval," and (2) the IRA's limit of fifteen drugs. And this lawsuit is the only "means of vindicating" AstraZeneca's rights. So even if the IRA's judicial review bar could be read to apply, the Court may review AstraZeneca's challenge.

CONCLUSION

For the foregoing reasons, this Court should grant summary judgment to Plaintiffs, declare CMS's Guidance unlawful, and set the Guidance aside.

Dated: February 27, 2026

Respectfully submitted,

/s/ Michael A. Pichini

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and ASTRAZENECA UK LTD.,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the U.S. Department of Health and Human Services; the U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; MEHMET OZ, in his official capacity as Administrator of the Centers for Medicare and Medicaid Services; and the CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants.

Civil Action No. 1:25-cv-4212-MJM

ORDER

Upon consideration of Plaintiffs' Motion for Summary Judgment, and any responses thereto, it is this ___ day of _____, 2026, by the United States District Court for the District of Maryland, hereby

ORDERED, that Plaintiffs' Motion for Summary Judgment be and is **GRANTED.**

Honorable Matthew J. Maddox
United States District Judge