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. 25-cv-4212

PLAINTIFFS' COMBINED REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT AND OPPOSITION TO DEFENDANTS' MOTION TO DISMISS/MOTION FOR SUMMARY JUDGMENT

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CMS's reading of the IRA's "qualifying single source drug" definition is so untethered from the statutory language that the Government, in its effort to defend CMS's interpretation, fails to quote that definition even once. But the text is clear: The IRA defines a qualifying single source drug (Qualifying Drug) by reference to its New Drug Application (NDA). The drug must be "*approved* under" an NDA and "marketed pursuant to *such approval*," must be "at least 7 years" removed from "*the* date of *such approval*," and must not be "the listed drug for any drug that is approved and marketed under" generic approval. 42 U.S.C. § 1320f–1(e)(1)(A) (emphases added). The IRA thus defines Qualifying Drug as a drug approved under an NDA. One drug, one NDA.

CMS's Guidance says the opposite. According to CMS, a Qualifying Drug is actually any *combination* of drugs, approved under "different NDAs," so long as they share an "active moiety." CMS, *Medicare Drug Price Negotiation Program: Final Guidance* 167 (Oct. 2, 2024) (Guidance). In defending that reading, the Government makes no attempt to square CMS's "different NDAs" approach with the actual terms of the Qualifying Drug definition. Nor could it. The linchpin of CMS's approach—the term "active moiety"—appears in numerous *other* federal statutes, yet not in the IRA. The Government thus argues that Congress wanted eligibility under the IRA to turn on "active moiety," but then simply decided not to say so. To defend CMS's reading, the Government invokes other sections of the IRA, such as the "Use of Data" provision. But those provisions expressly apply only to later stages of the process: *After* CMS has identified a Qualifying Drug by its individual NDA, they instruct CMS to consider *supplemental* approvals under the same NDA.

Ultimately, the Government tries to justify CMS's Guidance as good policy. But an agency's policy preferences cannot override a statute's plain text. And anyway, CMS's Guidance is *not* good policy: CMS's approach creates a topsy-turvy regime, under which drugs may be subject to price caps immediately upon approval, and where developing an innovative new drug

can actually lead to price controls for a preexisting product—thus defeating the IRA's central purpose of balancing cost reductions with preserving key incentives for innovation.

Hoping to avoid the merits altogether, the Government insists that no court can stop CMS from interpreting (or rewriting) the statute however it wants. On the Government's view, the agency could interpret "7 years . . . since the date of [a drug's] approval," 42 U.S.C. § 1320f–1(e)(1)(A)(ii), to mean "2 years." It could interpret "total expenditures under part D," *id.* § 1320f–1(d)(1)(A), to include "part B" expenditures as well. Or, as here, it could redefine "drug" to mean *multiple* drugs. And according to the Government, no court could intervene.

A long line of precedent rejects that "preposterous position." *COMSAT Corp. v. FCC*, 114 F.3d 223, 227 (D.C. Cir. 1997). In certain cases raising threshold statutory issues, an APA challenge "rests not on a review of a 'determination under' the subparagraph covered by the [judicial-review] provision, but rather [asks] whether [the agency] has made the kind of determination required by the statute." *Sw. Airlines Co. v. TSA*, 554 F.3d 1065, 1071 (D.C. Cir. 2009) (cleaned up). In such a case—where "the challenge to the agency's action raises the question of the agency's statutory authority"—a court "merges consideration of the legality of agency action with consideration of the court's jurisdiction." *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1238 (D.C. Cir. 2020) (*AHA*) (cleaned up). Thus, "to determine whether the judicial-review bar applies in th[e] case," the Court first "must decide whether the challenged agency action counts as" the type of action to which the bar applies. *Id.* As a result, the Court "can simply skip to the merits." *Id.*

This case involves precisely that sort of merged jurisdictional/merits challenge. The IRA precludes review only of the "determination of qualifying single source drugs *under section 1320f–1(e)*." 42 U.S.C. § 1320f–7(2) (emphasis added). But here, AstraZeneca's claim is that CMS *never made* a determination "under section 1320f–1(e)," because the agency *replaced* the Qualifying

Drug definition in that provision with a different (atextual) definition. As a result, jurisdiction merges with the merits: Since "the [agency] has acted outside the scope of its statutory mandate," the Court "ha[s] jurisdiction to review the [agency] action." *COMSAT*, 114 F.3d at 227.

Regardless, the Government's jurisdictional argument contravenes the "well-established" rule "that a statutory provision barring review of an individual determination leaves regulated parties free to challenge the general rules or policies leading to those determinations," *Teva Pharms. USA, Inc. v. Kennedy*, 2025 WL 3240267, at *7 (D.D.C. Nov. 20, 2025) (quotation marks omitted). AstraZeneca does not challenge CMS's "determination" that any particular product is a "qualifying single source drug," 42 U.S.C. § 1320f–7(2); nor does it "seek a substantive declaration" that any of its products must be excluded from the Drug Price Negotiation Program, *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 495 (1991). Rather, AstraZeneca brings a facial challenge to CMS's Guidance, contending that CMS unlawfully *redefined* "qualifying single source drug." The Government seeks to reframe AstraZeneca's suit as a challenge to the selection of AstraZeneca's drugs, but the complaint—and the relief it seeks—tell a different story.

AstraZeneca's challenge is reviewable, and CMS's unlawful Guidance must be set aside. In light of the impending statutory deadline, AstraZeneca respectfully requests that the Court schedule oral argument on the parties' motions at the Court's earliest convenience.

ARGUMENT

I. ASTRAZENECA'S CHALLENGE IS REVIEWABLE

A. No Judicial-Review Bar Applies to AstraZeneca's Facial Challenge

The Government's jurisdictional argument fails for two independent reasons.

1. The IRA's Judicial-Review Bar Merges with the Merits of AstraZeneca's Challenge, Permitting the Court to Review Both

The judicial-review bar does not preclude review here because AstraZeneca is not challenging CMS's "determination of qualifying single source drugs under section 1320f–1(e)."

42 U.S.C. § 1320f–7(2). Rather, AstraZeneca alleges that CMS's Guidance *replaces* the IRA's definition of "qualifying single source drug" with CMS's own "active moiety" definition. As a result, CMS *never made* a determination authorized "under section 1320f–1(e)." Because AstraZeneca's "challenge to [CMS's] action raises the question of the [agency's statutory] authority," it "merges consideration of the legality of [CMS's] action with consideration of this court's jurisdiction," so the challenge is necessarily reviewable. *COMSAT*, 114 F.3d at 227.

a. "If a no-review provision shields particular types of administrative action, a court" first "must determine whether the challenged agency action is of the sort shielded from review." *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). When the provision insulates an agency's action "under" a particular subsection, "the jurisdiction-stripping provision does not apply if the agency's action fails to qualify as the kind of action" authorized "under" that subsection. *AHA*, 964 F.3d at 1237-38 (cleaned up). The challenge "rests not on a review of a 'determination under' the subparagraph covered by the [review] provision, but rather [asks] whether [the agency] has made the kind of determination required by the statute." *Sw. Airlines*, 554 F.3d at 1071 (cleaned up). It "merges consideration of the legality of the [agency's] action with consideration of th[e] court's jurisdiction," *COMSAT*, 114 F.3d at 227, so "the issue of jurisdiction to review the [action] is intertwined with the [merits]," *E.I. du Pont de Nemours & Co. v. Train*, 430 U.S. 112, 125 (1977).[1]

Southwest illustrates this merger principle. The statute there authorized TSA to charge

[1] To avoid confusing this type of challenge with an *ultra vires* theory, the D.C. Circuit recently clarified that it "does not implicate the [*ultra vires*] framework." *AHA*, 964 F.3d at 1238. It is *not* a claim that a "merits argument is so obviously correct that [the court] should consider it *despite* an applicable bar on [its] review," but rather that a "bar on judicial review *does not apply* if [the] merits argument is correct." *Id.* at 1239 (emphases added). The Government's lead case, *DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503 (D.C. Cir. 2019), "itself recognized the distinction between cases involving [the *ultra vires*] exception and cases such as this one in which the relevant statutory bar is effectively coextensive with the merits." *AHA*, 964 F.3d at 1238 (cleaned up).

"carrier fees" to airlines based on costs "for screening passengers." 554 F.3d at 1068-69. But the statute also barred judicial review of TSA's "[d]eterminations" of fees "under" the passenger-screening provision. *Id.* at 1071. When TSA calculated the fees, it included costs for screening *non*-passengers, arguing that "screening passengers" entails "anything done to protect passengers." *Id.* at 1070. Southwest brought an APA challenge to vacate TSA's fee assessment on the ground that the agency's interpretation "violated the plain meaning" of the statute. *Id.* The D.C. Circuit exercised jurisdiction—notwithstanding the review bar—explaining that Southwest did not seek "review of a 'determination under' the subparagraph covered by the [judicial-review] provision, but rather" sought review of "the question whether TSA ha[d] made the kind of determination required by the statute" in the first place. *Id.* at 1071 (cleaned up).

Courts apply the same reasoning to the Medicare statute. *AHA* involved a challenge by medical providers to an HHS regulation reducing Medicare reimbursements for outpatient services. 964 F.3d at 1233. HHS promulgated the regulation under its statutory authority to "adopt 'method[s] for controlling unnecessary increases in the volume' of covered outpatient services." *Id.* (quoting 42 U.S.C. § 1395l(t)(2)(F)). The Government invoked a provision barring "judicial review of . . . the establishment of methods described in paragraph (2)(F)," *id.* at 1237 (cleaned up), but the court exercised jurisdiction. The providers' "claim [was] that the payment reduction at issue [was] *not* a 'method described in paragraph (2)(F)' within the meaning of the statute," the court explained, so "to determine whether the judicial-review bar applie[d]," the court first needed to "decide whether the challenged agency action count[ed] as a 'method for controlling unnecessary increases,'" a question that merged with "the merits issue presented." *Id.* at 1238 (cleaned up). Thus, "the court [could] simply skip to the merits question in its analysis." *Id.*

The same principle applied in *Ardelyx, Inc. v. Becerra*, 757 F. Supp. 3d 37 (D.D.C. 2024),

where a statute limited Medicare payments "for renal dialysis services (as defined in subparagraph (B))," but also precluded review of CMS's "identification of renal dialysis services." *Id.* at 42-43 (citation omitted). The court nevertheless resolved a manufacturer's challenge to a CMS regulation classifying its drug as a "renal dialysis service." Since availability of review "turn[ed] on whether [the drug] qualif[ied] as [a] 'renal dialysis service[],' as defined by the statut[e]," the "jurisdictional question" there "merge[d] with . . . the merits" and thus was reviewable. *Id.* at 48. To hold otherwise, the court noted, would mean "any determination *purporting* to be an identification of a renal dialysis service would be precluded from review," leading to the "preposterous" result of allowing "CMS [to] identify anything, even 'all drugs,' as renal dialysis services." *Id.*

Likewise, in *COMSAT*, the court rejected the Government's attempt "to shield from judicial review" a challenge to FCC action "purportedly taken pursuant to" statutory authority. 114 F.3d at 227. The statute there barred review of fee changes "pursuant to this paragraph," *id.* at 224 (quoting 47 U.S.C. § 159(b)(3))—*i.e.*, to changes made "within the scope of [FCC's] authority under" the paragraph, *id.* at 227. Applying the "merge[r]" rule, the court held it could review *whether* FCC "ha[d] acted outside the scope of its statutory mandate." *Id.* Otherwise, it explained, FCC "could impose a tax on an unregulated railroad or a tax on an individual for eating ice cream, so long as the FCC claimed to be acting under [the paragraph]"—a "preposterous position." *Id.*

The Fourth Circuit has applied the same reasoning. In *Arlington Hospital v. Schweiker*, 547 F. Supp. 670 (E.D. Va. 1982), HHS denied a hospital's request to reimburse the cost of telephones provided to patients because telephones are "personal comfort items" for which "no payment may be made" under 42 U.S.C. § 1395y. The statute barred review of an HHS decision "that no payment may be made" for "items [that] are listed in section 1395y," including "personal comfort items." 42 U.S.C. § 1395oo(g). The district court held it could review the "merits" of the hospital's claim

that telephones *do not count as* "personal comfort items" because they are not "listed in Section 1395." 547 F. Supp. at 676. A contrary ruling would "allow[] potentially unbridled administrative action," thus "run[ning] contrary to the presumption in favor of judicial review." *Id.* "For the reasons expressed by the district court," the Fourth Circuit "reject[ed] the Secretary's contention that judicial review [wa]s barred." *Arlington Hosp. v. Heckler*, 731 F.2d 171, 173 (4th Cir. 1984).

b. Under the merger rule, the IRA's judicial-review bar allows review of AstraZeneca's statutory claim. AstraZeneca does not challenge a determination by CMS "*under* section 1320f–1(e)." 42 U.S.C. § 1320f–7(2) (emphasis added). Rather, AstraZeneca argues that CMS *never made* a determination "under" that provision; instead, the agency's Guidance *replaces* Section 1320f–1(e)'s definition of "qualifying single source drug" with a *new* definition based on "active moiety." AstraZeneca thus does not seek "review of a 'determination under' the subparagraph covered by the [judicial-review] provision, but rather [of] the question whether [CMS] has made the kind of determination required by the statute." *Sw. Airlines*, 554 F.3d at 1071 (cleaned up).[2]

Reading the IRA's judicial-review bar to preclude a statutory challenge to "any [agency] action purportedly taken pursuant to" section 1320f–1(e) would be "preposterous." *COMSAT*, 114 F.3d at 227. It would enable CMS to rewrite the IRA with impunity—such as by redefining "qualifying single source drug" to mean "all of AstraZeneca's drugs," or "all drugs that start with the letter A." That would violate separation of powers and should "not [be] countenance[d]." *Id.*

c. The Government fails to address the merger principle, instead arguing (at 15) that "[t]he

[2] The Government itself has acknowledged that when a preclusion provision references another subparagraph, "a court . . . would naturally refer to [that] subparagraph . . . to determine whether the Secretary's action was in fact [a barred action]." Gov't Reply Br. at 9, *Ardelyx, Inc. v. Becerra*, No. 24-cv-2095 (D.D.C. Oct. 16, 2024), Dkt. 19. Here, the IRA's preclusion provision references the Qualifying Drug definition and bars only determinations made "under" that provision, so it "naturally" requires the Court to assess whether CMS "in fact" applied that definition.

means by which CMS determines the list of qualifying single source drugs is by applying the statutory definition." But that is circular: If AstraZeneca is right about the IRA's meaning, then CMS never "appl[ied] the [IRA's] definition" or made the kind of "determination" the IRA shields from review; if the Government is right, then CMS made such a determination. AstraZeneca's challenge thus "merges consideration of the legality of agency action with consideration of the court's jurisdiction," and the Court can "skip to the merits." *AHA*, 964 F.3d at 1238 (cleaned up).

The Government cites cases (at 14) to argue that a judicial-review bar applies to any "issues that are 'inextricably intertwined' with the" barred action. But none turned on the threshold issue "whether [the agency] ha[d] made the kind of determination required by the statute." *Sw. Airlines*, 554 F.3d at 1071 (ellipsis omitted). Rather, each agency *had* made the type of decision permitted by statute, and the plaintiffs claimed the "decision [was] arbitrary, capricious, or procedurally defective." *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017) (cleaned up).

The Government's leading case, *DCH Regional Medical Center v. Azar*, 925 F.3d 503 (D.C. Cir. 2019), expressly recognizes the distinction. A provision there barred review of "[a]ny estimate of the Secretary" in calculating Medicare payments. 42 U.S.C. § 1395ww(r)(3). A hospital challenged HHS's refusal, in its estimates, to "consider[] data associated with both the surviving and non-surviving hospitals that underwent a merger." 925 F.3d at 505. Since the hospital did not dispute that HHS had made an "estimate" under the statute, but merely argued that the estimate was "arbitrary and capricious," the "statutory bar" was not "effectively coextensive with the merits." *Id.* at 510. The court thus distinguished *Southwest* and *COMSAT*, where "[t]the same agency error . . . simultaneously made the jurisdictional bar 'inapplicable' and compelled setting aside the challenged agency action." *Id.* The same review bar applied in *Florida Health Sciences Center, Inc. v. HHS*, where a hospital "challenge[d] [HHS's] refusal to use the most recent

available data" in its estimate, effectively seeking "case-by-case review of the [estimate's] reasonableness or procedural propriety." 830 F.3d 515, 518, 522 (D.C. Cir. 2016) (cleaned up).[3]

So too in *Texas Alliance for Home Care Servs. v. Sebelius*, 681 F.3d 402 (D.C. Cir. 2012), where the statute authorized HHS to award contracts to an entity that "meets applicable financial standards specified by the Secretary," but also barred review of "the awarding of contracts" and "the bidding structure" for such contracts. *Id.* at 405, 409 (citations omitted). Providers challenged CMS's *process* for "evaluation of bidders' financial eligibility without first specifying by regulation the applicable financial standards." *Id.* at 408 (cleaned up). Since the providers did not dispute that the Secretary had indeed "specified" financial standards under the statute, but merely contested her "formulation and application" of those standards, the review bar applied. *Id* at 410. The Court contrasted that type of challenge with a statutory merger case: "If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review." *Id.* at 409 (cleaned up).

The Government's other cases involve the same dynamic: The agency made the type of decision that the statute barred from review, and the plaintiff argued the "challenged agency decision [wa]s arbitrary, capricious, or procedurally defective" in some way. *Knapp*, 875 F.3d at 1128; *see Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062 (D.C. Cir. 2018) (provision barring review of "prospective payment rates" precluded challenge to "arbitrary and capricious adjustments" to those rates); *U.S. Anesthesia Partners of Tex., P.A. v. HHS*, 126 F.4th 1057 (5th Cir. 2025) (provision

[3] *Florida Health* declined to "permit [the hospital] to couch this type of reasonableness challenge in terms of the agency's exceeding its statutorily-defined authority." *Id.* at 522-23 (cleaned up). Here, by contrast, the Government concedes that AstraZeneca does not challenge reasonableness, but instead raises a "statutory-authority argument." Opp. 20 (citation omitted); *accord* Opp. 13.

barring review of "identification of measures and activities" used to calculate costs precluded challenge to the "*manner* by which" CMS calculated costs); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9, 15-26 (2d Cir. 2022) (precluding challenge to agency's notice-and-comment failure); *Fischer v. Berwick*, 503 Fed. App'x 210, 212 (4th Cir. 2013) (unpublished) (precluding challenge to agency's "overreliance" on particular data in making barred determinations). Given the nature of those challenges, there was no real "question whether [the agency] ha[d] made the kind of determination required by the statute," *Sw. Airlines*, 554 F.3d at 1071, so "the relevant statutory bar" *was not* "coextensive with the merits," *DCH*, 925 F.3d at 510.[4]

Here, by contrast, AstraZeneca is not challenging the "reasonableness or procedural propriety" of a determination of Qualifying Drugs under Section 1320f–1(e). *Fla. Health*, 830 F.3d at 522 (citation omitted). Nor does it challenge CMS's "overreliance" on certain data in making shielded determinations. *Fischer*, 503 Fed. App'x at 212. Rather, AstraZeneca alleges that CMS *did not* "determin[e] qualifying single source drugs under section 1320f–1(e)" at all; instead, the agency *rewrote* the definition wholesale. 42 U.S.C. § 1320f-7(2). If AstraZeneca is correct on the merits, then CMS's action "fails to qualify as the kind of" determination subject to the review bar. *AHA*, 964 F.3d at 1238. Thus, because "the determination of whether the court has jurisdiction is intertwined with the question of whether [CMS] has authority for the challenged action," the Court

[4] The Government notes (at 13) that "'policy concerns cannot trump the best interpretation of the statutory text' of a preclusion provision," *Shaiban v. Jaddou*, 97 F.4th 263, 268 (4th Cir. 2024), and that "'the first issue [the Court] must address' is the text of the preclusion provision," *Lee v. USCIS*, 592 F.3d 612, 619-20 (4th Cir. 2010). Quite true. But the "the text of the [IRA's] preclusion provision" allows review here. Notably, neither *Shaiban* nor *Lee* involved the merger rule. Both involved challenges to individual denials of immigration status that were insulated from review under a provision covering "any . . . decision" committed to agency discretion. *Id.* (citation omitted); *see Shaiban*, 97 F.4th at 266. As *Lee* noted, moreover, an applicant for adjustment of status can "obtain further review . . . by renewing the application *during removal proceedings*." 592 F.3d at 618. AstraZeneca, by contrast, has no avenue for review other than this case.

"must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review." *Amgen*, 357 F.3d at 113.

2. AstraZeneca Is Not Challenging CMS's "Determinations"

Even apart from the merger principle, the Government's judicial-review argument contravenes another "well-established" rule: "that a statutory provision barring review of an individual determination 'leaves regulated parties free to challenge the general rules' or policies 'leading to' those determinations." *Teva*, 2025 WL 3240267, at *7 (citation omitted).

a. As the Supreme Court held in *McNary*, a statute barring "judicial review of individual determinations" does not also bar a "general challenge" to an agency's rules. 498 U.S. at 491. The statute there precluded "review of a determination respecting an application for adjustment of status." *Id.* Unsuccessful applicants challenged INS's "practices and policies" for determining "Special Agricultural Worker" status, and the Court allowed the challenges to proceed. *Id.* at 492, 494. The Court held that "review 'of *a determination* respecting *an application*' for SAW status . . . describes a single act"—namely, the "denial of a particular application"—"rather than a group of decisions or a practice or procedure employed in making decisions." *Id.* "[H]ad Congress intended the [judicial-review bar] to encompass challenges to INS procedures and practices," the Court explained, "it could easily have used broader statutory language." *Id.* at 494. Because "the individual [applicants did] not seek a substantive declaration that they [were] entitled to [an adjustment of] status," their challenge could proceed. *Id.* at 495.

The Court reiterated the point in *Reno v. Catholic Social Services, Inc.*, 509 U.S. 43 (1993). There, the statute required immigration applicants to satisfy continuous-residency and physical-presence requirements. *Id.* at 46-47. The plaintiffs challenged INS regulations that implemented those requirements, *id*. at 47-50, and in response the Government invoked a bar on review of "determinations respecting applications for adjustment of status," *id.* at 53 (cleaned up). Relying

on *McNary*, the Court held that it could review "an action challenging the legality of a regulation without referring to or relying on the denial of any individual application." *Id.* at 56.

McNary and *Reno* were settled law when Congress enacted the IRA. "When judicial interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute is presumed to incorporate that interpretation." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 330 (2015) (cleaned up). Now, "the term 'determination' in a jurisdiction stripping statute is understood to only shield review of individual decisions but not policies or guidance." *Teva*, 2025 WL 3240267, at *9; *accord CASA de Md., Inc. v. Trump*, 355 F. Supp. 3d 307, 320 (D. Md. 2018) (statute barring "judicial review of any determination" is not "an absolute bar," but merely bars reviewing "the merits of an individual determination").

AstraZeneca does not challenge any of the specific "determinations" the IRA shields from review. Just as the applicants in *McNary* and *Reno* did not challenge the "determination" whether they qualified for a particular status, AstraZeneca does not challenge CMS's "determination" that any particular product is a "qualifying single source drug," its "determination" that any drug is "negotiation-eligible," or its "selection" of any drug. 42 U.S.C. § 1320f–7(2). Nor does AstraZeneca "seek a substantive declaration" that any products must be excluded. *McNary*, 498 U.S. at 495. Rather, AstraZeneca challenges CMS's Guidance on its face, arguing that CMS *redefined* "qualifying single source drug." AstraZeneca asks the Court to declare the Guidance unlawful, set it aside, and require CMS to comply with the IRA. *See* Compl. at p. 44. Whether CMS's Guidance correctly reads the IRA is *not* a "determination" the IRA shields from review.

Congress had good reason to insulate from review only discrete "selection[s]" and "determination[s]" by CMS, 42 U.S.C. § 1320f–7, while permitting "general challenge[s]" to its statutory interpretations, *McNary*, 498 U.S. at 491. CMS's expertise encompasses "the complex

and technical niceties" of administering Medicare programs, *Univ. of Md. v. Cleland*, 621 F.2d 98, 100 (4th Cir. 1980) (citation omitted), whereas "legal interpretation" of a statute is "emphatically the province and duty of the judicial department," *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 412 (2024) (cleaned up). Congress understandably shielded CMS's individual determinations and calculations, such as CMS's ability to track the time since "the date of [a drug's] approval," to assess whether an "exclusion" applies, to calculate and compare each drug's total Medicare expenditures, and to decide a "maximum fair price." 42 U.S.C. § 1320f–1(d)-(f). But Congress understandably *did not* insulate efforts by CMS to replace statutory terms with the agency's preferred language. "Such an inquiry into the legality of agency action, as opposed to its appropriateness within legal bounds, is uniquely appropriate for judicial determination." *Garcia v. Neagle*, 660 F.2d 983, 988 (4th Cir. 1981) (cleaned up).

b. The Government attempts to evade *McNary* and its progeny by arguing that (1) "[t]he selection of drugs . . . is not some sort of individualized adjudication," (2) AstraZeneca's challenge is not "collateral to the merits," and (3) AstraZeneca is actually seeking to reverse an individual "determination." Opp. 17-18. The Government is wrong on all three points.

First, CMS's "determination of qualifying single source drugs," 42 U.S.C. § 1320f–7(2), *is* an "individualized adjudication," Opp. 17. In *McNary*, the challenge to INS's rule was reviewable because the preclusion provision covered only "adjudicatory determinations" about *particular* applications, rather than "broad estimates made by rule." *DCH*, 925 F.3d at 508. Likewise, the IRA bars review only of "adjudicatory decisions" that particular drugs meet the statutory criteria. *Teva*, 2025 WL 3240267, at *8 (cleaned up). CMS makes that "adjudicatory determination" entirely apart from issuing its Guidance. *See* CMS, *Fact Sheet: Medicare Drug Price Negotiation Program Final Guidance for 2027* (Oct. 2024), https://perma.cc/S4ZB-RWDD.

Second, AstraZeneca's challenge *is* "collateral" to the selection of particular drugs. The Government describes *McNary* as a collateral attack because "victory [for the applicants there] would not have reversed the denial of their applications" but "would [have] allow[ed] only for their applications to be reconsidered with new procedures in place." Opp. 17 (citation omitted). Exactly right, and also true here. AstraZeneca does not "seek a substantive declaration" that any drugs *must* be excluded from the Program. *McNary*, 498 U.S. at 495. Its challenge would not automatically "reverse[]" the selection of any drugs, but would merely require CMS to "reconsider" each drug's eligibility under a correct reading of the IRA. Opp. 17. Whichever drugs are ultimately selected will be "a mere by-product of th[e] court's primary function of reviewing [CMS's] interpretation of federal law." *Bowen v. Massachusetts*, 487 U.S. 879, 910 (1988).

Third, the Government makes a semantic argument that AstraZeneca's challenge to the *redefinition* of Qualifying Drug in CMS's Guidance is really a challenge to "CMS's *determination* of what constitutes a 'qualifying single source drug.'" Opp. 13 (emphasis added). But that is the very argument *McNary* rejected when it held that a statute barring "judicial review of individual determinations" *does not* bar a "general challenge" to the broader rules. 498 U.S. at 491. So while courts cannot second-guess CMS's administrative determination that "7 years . . . have elapsed since the date of [a drug's] approval," 42 U.S.C. § 1320f–1(e)(1)(A)(ii), courts *can* prevent CMS from redefining "7 years" to mean "2 years." While courts cannot review CMS's calculation of "total expenditures under part D," *id.* § 1320f–1(d)(1)(A), courts *can* prevent CMS from redefining "part D" to also include "part B." And while courts cannot review CMS's determination whether "[a] drug" is "the listed drug" for a generic competitor, *id.* § 1320f-1(e)(1)(A)(iii), they *can* prevent CMS from redefining "drug" to encompass multiple drugs with multiple generic competitors.

The Government argues (at 15) that AstraZeneca *must be* challenging an individual

"determination" because, it reckons, the selection of AstraZeneca's drugs supplies its "Article III standing." But the "substance" of a claim "and the standing for [that] claim" are distinct. *Heckler v. Ringer*, 466 U.S. 602, 620 (1984). While the selection of AstraZeneca's drugs inflicts an Article III *injury*, that does not make its complaint any less of "a facial challenge to the Guidance." Opp. 15. After all, the plaintiffs in *McNary* had standing because INS had denied their applications, but the Court nevertheless reviewed their facial challenge to INS's rules. *See* 498 U.S. at 487-88. The Government is wrong that the IRA bars review by any claimant with standing to seek it.

c. The Government relies (at 14-17) on cases that precluded review of issues "inextricably intertwined" with unreviewable actions. Yet those cases reiterate the rule that "even if judicial review of a [specific] decision is barred," parties are still "free to challenge the general rules leading to that decision." *Fla. Health*, 830 F.3d at 521 (cleaned up). The Government's cases instead turned on whether the plaintiffs there were *genuinely* challenging "general rules," or instead merely "attempt[ing] to undo a shielded determination." *Id.* at 522 (cleaned up).

The statute in *Florida Health* and *DCH*, for instance, barred review of "[a]ny estimate of the Secretary" used in calculating hospitals' Medicare payments, 42 U.S.C. § 1395ww(r)(3), and the plaintiffs in both cases challenged HHS's refusal to consider certain data in making the required estimates. *See Fla. Health*, 830 F.3d at 518, 522; *DCH*, 925 F.3d at 505, 510. While the claimants nominally challenged the "inputs" and "methodology" HHS had used to generate the data for its estimates, the bar applied because "the data [were] the entire basis for the estimate[s]," *Fla. Health*, 830 F.3d at 519, so the hospitals were really just "attack[ing] the very estimates that the preclusion provision insulates from review," *DCH*, 925 F.3d at 506, 508 ("a challenge to the methodology for estimating uncompensated care is unavoidably a challenge to the estimates themselves"). The plaintiffs there—and in the Government's other cases—thus "sought to 'reverse' an agency

'determination' by challenging the data or calculations used to reach it." *Teva*, 2025 WL 3240267, at *8; *see Knapp*, 875 F.3d at 1131 (declining to distinguish between data "inputs" and "outputs"); *Fischer*, 503 Fed. App'x at 212 (precluding challenge to agency's "overreliance" on particular data); *Mercy Hosp.*, 891 F.3d at 1065, 1071 (barring challenge to calculations); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 401-05 (D.C. Cir. 2005) (barring action where "the specific relief requested" was "solely" to "reverse" an individual reimbursement decision); *Yale*, 56 F.4th at 15-26 (precluding notice-and-comment challenge to choice of data, since the data were "not just underlying data for the relevant estimate" but *were* "the estimate") (cleaned up). The cases reflect a narrow "exception" for "challenges to 'estimates used to make a decision,'" rather "than to 'adjudicatory decisions,' like in *McNary*" and here. *Teva*, 2025 WL 3240267, at *8 (cleaned up).

Texas Alliance also does not help the Government. The Secretary's failure in that case to specify the "financial standards" necessary to obtain healthcare contracts was "integral to the bidding structure" and to "the awarding of contracts," both of which the statute insulated from review. 681 F.3d at 408, 409-11. "Importantly, there, the plaintiff did not challenge 'the general rules leading to denial' of contracts but instead the denial of contracts without general rules." *Teva*, 2025 WL 3240267, at *7. "Without such a policy, the action amounted to nothing more than a challenge to the awarding of the contracts themselves." *Id.* (cleaned up). The Government responds (at 18-19) that, like "the awarding of contracts" insulated from review in *Texas Alliance*, "§ 1320f–7(2)'s reference to 'drugs' is plural." From that, the Government infers that both review-bar provisions apply more broadly than just to individual agency decisions. But the IRA shields from review only a *singular* agency action: "the determination" of Qualifying Drugs each annual cycle. That singular "determination" involves multiple "drugs," because the statute requires "CMS [to] release 'a list' of 'drugs' by specified deadlines." *Teva*, 2025 WL 3240267, at *9. But it still refers

to individual selections. So "the provision at issue here is no different than that in *McNary*," because "it applies to a singular 'determination,' *i.e.*, what 'drugs' are included in the list." *Id.*

The Government cites (at 18) *Bakran v. DHS* for the proposition that "[t]he word 'determine' means 'to fix conclusively or authoritatively' as well as 'to come to a decision concerning as the result of investigation or reasoning.'" 894 F.3d 557, 563 (3d Cir. 2018) (cleaned up). But as the Government admits (at 18), *Bakran* involved "a different review bar" with different language in a different context. And anyway, "*Bakran*'s rationale [is] inconsistent with . . . *McNary*." *Teva*, 2025 WL 3240267, at *9 n.6 (cleaned up).

Finally, the Government misplaces its reliance (at 13-14) on *Novo Nordisk Inc. v. HHS*, 154 F.4th 105 (3d Cir. 2025), *petition for cert. filed*, No. 25-761 (U.S. Dec. 29, 2025). The manufacturer there asked the court to declare that its selected products were "not properly subject to price controls under the statute." Compl. at 59, *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814 (D.N.J. Sept. 29, 2023), Dkt. 1. The Third Circuit deemed that a challenge to CMS's "determin[ation]" that it would "treat[] six of Novo Nordisk's products as one negotiation-eligible single-source drug." 154 F.4th at 111. But it was not a facial challenge to CMS's Guidance.

d. Even if the issue were close, the "strong presumption favoring judicial review" would be decisive. *Mach Mining, LLC v. EEOC*, 575 U.S. 480, 489 (2015). When a review bar "is reasonably susceptible to divergent interpretation," a court must "adopt the reading that accords with . . . review." *Guerrero-Lasprilla v. Barr*, 589 U.S. 221, 229 (2020). Consider the parties' "divergent interpretation[s]" here: Did Congress truly intend, as the Government asserts, to prevent review of a facial challenge to CMS's Guidance alleging that CMS rewrote Congress's own language? Or, as AstraZeneca submits, did Congress simply want to prevent courts from second-guessing CMS's individual determinations that *particular* drugs meet the statutory criteria to

qualify for the Program? The IRA is at least "reasonably susceptible to" the latter interpretation.

Moreover, "had Congress intended the [judicial-review bar] to encompass challenges to" CMS's Guidance, "it could easily have used broader statutory language." *McNary*, 498 U.S. at 494. For instance, the judicial-review provision in *Knapp* was "unqualified": It "preclud[ed] review of 'the process' in its broadest sense." 875 F.3d at 1130-31. And elsewhere, Congress has broadly precluded review of a "regulation or instruction that relates to a method for determining the amount of payment under" Medicare Part B, 42 U.S.C. § 1395ff(e)(1), or "all questions of law and fact" arising from a decision "allowing or denying a payment," 5 U.S.C. § 8128(b). Not so here. At minimum, the IRA "is reasonably susceptible to divergent interpretation," so the Court must "adopt the reading that accords with . . . review." *Guerrero-Lasprilla*, 589 U.S. at 229.

B. CMS's Guidance Is *Ultra Vires*

"[E]ven when the statutory language bars judicial review," review is permitted for "claims that the agency . . . violated a clear statutory mandate." *Hanauer v. Reich*, 82 F.3d 1304, 1307 (4th Cir. 1996). Here, CMS's violation of a "specific and mandatory statutory provision" could hardly be clearer. *Scottsdale Cap. Advisors Corp. v. Fin. Indus. Regul. Auth., Inc.*, 844 F.3d 414, 421 (4th Cir. 2016) (cleaned up). The IRA requires CMS to choose 15 Qualifying Drugs, defined as a single drug with a single NDA. 42 U.S.C. § 1320f–1(a), (e)(1)(A). To overcome the 15-drug limit, CMS redefined Qualifying Drug as *multiple* drugs with *different* NDAs. As discussed below, CMS's interpretation is not just wrong but implausible. And "the absence of federal court jurisdiction [here] would wholly deprive [AstraZeneca] of a meaningful and adequate means of vindicating its statutory rights." *Scottsdale*, 844 F.3d at 421 (cleaned up). The Government responds (at 20) with *dicta* from *Nuclear Regulatory Commission v. Texas*, 605 U.S. 665, 681 (2025), for the notion that *ultra vires* review is unavailable when "the statute expressly forecloses all other forms of judicial review." But the Fourth Circuit has instructed that review *is* available where, as here, "the statutory

language bars judicial review." *Hanauer*, 82 F.3d at 1307. This Court "should follow the case which directly controls." *Agostini v. Felton*, 521 U.S. 203, 237 (1997) (cleaned up).

II. CMS'S GUIDANCE UNLAWFULLY REDEFINES "QUALIFYING SINGLE SOURCE DRUG"

CMS's Guidance is indefensible on the merits. The IRA defines Qualifying Drug by reference to the drug's NDA. The drug must be "a covered part D drug . . . that is approved under Section 355(c) of Title 21," which is the provision of the Food, Drug, and Cosmetic Act governing NDA-approval. 42 U.S.C. § 1320f–1(e)(1). The drug must be "marketed pursuant to such approval," meaning pursuant to *that* NDA. *Id.* § 1320f–1(e)(1)(A). "[A]t least 7 years [must] have elapsed since the date of such approval," meaning approval of *that* NDA. *Id.* § 1320f–1(e)(1)(A)(ii). And the drug is exempt from eligibility if it is "the listed drug" for a generic version, meaning a generic competitor that references *that* NDA. *Id.* § 1320f–1(e)(1)(A)(iii). The IRA thus defines Qualifying Drug as a drug approved under an NDA. One drug, one NDA.

A. The Government fails to reconcile CMS's Guidance with any of these statutory provisions—much less all of them. It cannot explain how a Qualifying Drug could somehow consist of *multiple* drugs approved under "different NDAs," *Guidance* at 167, yet still be "*a* covered part D drug . . . that *is* approved under Section 355(c) of Title 21 and *is* marketed pursuant to *such* approval." 42 U.S.C. § 1320f–1(e)(1) (emphases added). Nor can the Government explain why Congress would have started eligibility "7 years [after] *the* date of *such* approval," *id.* § 1320f–1(e)(1)(A)(ii), if a single Qualifying Drug could somehow span multiple NDA approvals on multiple dates. In fact, the Government fails even to *acknowledge* AstraZeneca's point (MSJ 15-16) that these terms ("*the* date" and "*such* approval") necessarily tie each Qualifying Drug to one specific "approval." Insofar as the Government references those provisions at all, it omits their key limitations, instead rewriting them to say: "seven years have elapsed since approval." Opp. 23. The Government's attempt to save CMS's Guidance by rewriting the statute is telling.

The Government argues (at 22) that the Qualifying Drug definition does not turn on NDA-approval because "the IRA and the Food, Drug, and Cosmetic Act are different statutes with fundamentally different objectives." That ignores the IRA's plain language, which expressly incorporates the approval framework: "the term 'qualifying single source drug' means . . . a covered part D drug . . . that is *approved under Section 355(c) of Title 21* and is marketed pursuant to *such approval*." 42 U.S.C. § 1320f–1(e)(1) (emphases added). "Section 355(c) of Title 21" is the FDCA's approval provision. Indeed, CMS itself admits that "at least 7 years must have elapsed since the drug product was approved *by the FDA*." *Guidance* at 15 (emphasis added). The IRA thus indisputably defines Qualifying Drug by reference to FDA approval under the FDCA.[5]

As for the seven-year window from "the date of such approval," the Government repeats (at 23) CMS's circular position that the Guidance "reasonably determined that the relevant date is the earliest approval date." But that is no answer. The Government concedes (as it must) that the IRA does not say "7 years since the *earliest* date of approval," even though Congress easily could have written the statute that way. MSJ 21-22. Nor does the Government even try to explain why Congress would have started the seven-year countdown from "*the* date of *such* approval" if a single drug might have multiple "different" approvals across numerous dates. *Guidance* at 167. Plainly, "*the* date of *such* approval" means the date of the drug's singular NDA "approv[al] under Section 355(c)." 42 U.S.C. § 1320f–1(e)(1)(A). And even if CMS's interpretation were "reasonable," Opp. 23—which it is not—courts no longer "defer[] to the agency's interpretation" simply because it is "a 'reasonable' construction" of the statute. *Loper Bright*, 603 U.S. at 383.

[5] The Government criticizes (at 23) AstraZeneca for relying on "a series of attenuated cross-references that ends with a reference to FDA approval." Yet the IRA defines Qualifying Drug to include "a covered part D drug . . . *that is approved under Section 355(c) of Title 21*." 42 U.S.C. § 1320f–1(e)(1) (emphasis added). It is telling that the Government—which relies wholly on text *outside* the Qualifying Drug definition—criticizes AstraZeneca for relying on text *within* it.

Finally, the Government makes no attempt whatsoever to reconcile CMS's NDA-grouping approach with the IRA's exemption for "the listed drug" for a generic competitor. 42 U.S.C. § 1320f–1(e)(1)(A)(iii). The Government does not dispute that "*the* listed drug" means a drug approved under the specific NDA on which the generic competitor relied for its own approval. *See* MSJ 17; *see also* 21 U.S.C. § 355(j)(2)(A)(i), (j)(7). By exempting "the listed drug" for a generic version, therefore, the IRA clearly contemplates that each Qualifying Drug has its own NDA. The Government also fails to account for the numerous logistical problems its NDA-grouping approach creates, *see* MSJ 20 (providing examples), instead citing CMS's invented (and atextual) workaround, Opp. 24. But the need for such a workaround is telling; had Congress intended to enact CMS's NDA-grouping approach, it obviously would have addressed those problems itself.

B. The Government's position is equally indefensible regarding what the IRA *does not* say. The Government concedes that the linchpin of CMS's Guidance on Qualifying Drugs is the identification of a drug's "active moiety." MSJ 22. The Government also concedes that Congress is well aware of that term; understands its "long history and prominent role in FDA's practice," Opp. 26; and regularly uses it in *other* statutes, MSJ 22-23. And yet the term does not appear in the IRA—not even once. So the Government's position is that Congress wanted everything to turn on whether drugs share an "active moiety," but then simply decided *not to say so*. Blackletter interpretive principles require the opposite inference: "Courts are required to give effect to Congress' express inclusions and exclusions, not disregard them." *Nat'l Ass'n of Mfrs.* (*NAM*) *v. Dep't of Def.*, 583 U.S. 109, 126 (2018). The Government theorizes (at 26) that Congress's reliance on "active moiety" was just so obvious that it did not "need [to] specify." That is preposterous. The Government offers no reason to "believe that Congress omitted the term . . . simply because it wanted to save ink or assumed that regulators and interested parties would understand that the

omission of the term was inconsequential." *San Francisco v. EPA*, 604 U.S. 334, 344 (2025).

The Government also has no coherent defense of CMS's addition of a "same-NDA-holder" requirement. Congress obviously did not want CMS to group together multiple drugs with "different NDAs," *Guidance* at 167, because that would mean drugs marketed by different manufacturers would be lumped into one "negotiation," MSJ 23-24. Indeed, the Government *admits* that would make no sense, since—in the Government's own words (at 26)—the IRA "repeatedly presumes that CMS will engage in negotiations with a drug's manufacturer, not a consortium of competitive manufacturers." Yet the Government somehow fails to see that fact for what it is: yet more evidence that the IRA prohibits grouping multiple drugs by "active moiety" in the first place. CMS's "same-NDA-holder" requirement is a necessary (but atextual) workaround, used only because its interpretation of Qualifying Drug strays so far from the statutory definition.

C. In defending CMS's approach, the Government rests almost entirely on provisions that *are not* part of the Qualifying Drug definition and expressly apply only *after* a Qualifying Drug has been identified: the "Use of Data" provision, the "Compute and Apply" provision, and the "Applications and Approvals" provision. The Government asserts (at 20-21) that these provisions require CMS "to consider all dosage forms, strengths, and formulations of a drug together," an instruction that "applies at each stage of the process." Even if the Government were right that aggregation is required "at each stage of the process," of course, that *still* would not produce an "active moiety" test: Active moiety is a different and far broader concept than dosage form, strength, or formulation. MSJ 22.

Regardless, by their own terms, the Government's cited provisions plainly *do not* "appl[y] at each stage of the process." The Use of Data provision says:

> ***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.

42 U.S.C. § 1320f–1(d)(3)(B) (emphasis added). The Government self-servingly omits the emphasized text, which makes clear that the Use of Data provision applies only at Step Two, when deciding whether a Qualifying Drug is negotiation-eligible. And the Compute and Apply Provision kicks in even later: It 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) (emphasis added). So it applies only after CMS has already "selected" a drug at Step Three. *See id.* § 1320f–1(a)-(b).

Importantly, Congress *did not* direct CMS "to consider all dosage forms, strengths, and formulations" at Step One, in determining whether a product is a Qualifying Drug in the first place. At that stage, the IRA says to identify Qualifying Drugs using FDA's approval framework—*i.e.*, using the NDA. *See id.* § 1320f–1(e). Indeed, Congress's specification that the Use of Data provision applies "[i]n determining whether a qualifying single source drug satisfies any of the criteria [for a negotiation-eligible drug] described in paragraph (1) or (2)," *id.* § 1320f–1(d)(3)(B), strongly indicates that the provision *does not* apply more broadly. *See NAM*, 583 U.S. at 126.

The Government nevertheless insists that aggregating data at the Program's later stages is "irreconcilable" with the requirement that each Qualifying Drug is limited to its discrete NDA. Opp. 22, 23, 24, 27. Nonsense. As AstraZeneca explained, "changes to dosage forms, strengths, and formulations may be encompassed within a single NDA." Compl. ¶ 40; *see id.* ¶¶ 36-43. As a result, a single "drug product" with a single NDA can have multiple *supplemental* approvals reflecting "changes in the qualitative or quantitative formulation of the drug product." *Id.* ¶ 36 (citations omitted). Likewise, a single NDA may include more than one drug strength. *Id.* ¶ 42. Same with new dosage forms. *Id.* ¶ 41. The Government does not dispute any of this. Thus, in determining whether a Qualifying Drug is negotiation-eligible, CMS must aggregate data across

all of the dosage forms, strengths, and formulations *of that previously identified Qualifying Drug*.

The Government's approach to the Applications and Approvals provision, 42 U.S.C. § 1320f–3(e)(1)(D), reflects the same error. While this provision indeed "contemplates that one 'drug' may [have] different applications or approvals," Opp. 21, it simply tells CMS that it must consider the drug's original NDA *and* any supplemental applications and approvals under the same NDA number. MSJ 26-27. The Government similarly does not dispute that the provision applies only "in setting a price *after* a drug has been identified as a Qualifying Drug." *Id.*

D. Ultimately, the Government tries (at 22-23) to justify CMS's rewrite of the IRA as good policy. But an agency's "policy preferences" cannot override statutory language. *Loper Bright*, 603 U.S. at 403. Regardless, CMS's approach *contradicts* the policies that underlie the IRA.

The IRA seeks to balance competing considerations: reducing the "financial impact on Medicare," Opp. 23, while preserving market incentives to undergo the "long, comprehensive, and costly testing process" necessary for NDA-approval, *FTC v. Actavis, Inc.*, 570 U.S. 136, 142 (2013). The IRA does so by protecting a new drug from selection until "7 years . . . have elapsed since the date of [the drug's NDA] approval." 42 U.S.C. § 1320f–1(e)(1)(A)(i)-(ii). CMS cannot "negotiate during [a drug's] initial exclusivity period." HOUSE RULES, *Rules Committee Meeting on H.R. 5376*, at 34:20 (YouTube, Nov. 3, 2021). Yet CMS's drug-grouping approach would mean that "[m]any newly approved drugs could be subject to IRA pricing *during* their initial exclusivity period," MSJ 19, undermining the incentive "to invest in the development of novel products and new treatment options for patients," USPTO, *Drug Patent and Exclusivity Study* 7 (June 2024), https://perma.cc/2Z8D-HZAU. And under CMS's approach, a "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." MSJ 19. Developing a new drug thus risks exposing "*earlier-approved*

drugs" to price caps, *id.* at 19-20, a result that Congress could not possibly have intended.

The Government speculates (at 24-25) that, if CMS follows the plain language of the IRA, manufacturers could "introduce slight variations to a drug that would otherwise qualify for negotiation in order to circumvent the negotiation." But the Government cites nothing in the IRA to suggest that Congress shared that concern. Not a word. Courts cannot "construe the law" based on "policy preferences that ha[ve] not made it into the statute." *Loper Bright*, 603 U.S. at 403-04. That is particularly true here, since Congress has repeatedly introduced—but never enacted—legislation to address so-called "product-hopping." *See, e.g.*, S. 1040, 119th Cong., 1st Sess.

Regardless, the Government's policy concern ignores FDA's guidance, which "addresses the circumstances in which alterations to a drug should be submitted under an original NDA, versus through a supplement to an existing NDA." MSJ 6; *see* Compl. ¶¶ 35-45. One of AstraZeneca's drugs, acalabrutinib maleate salt, illustrates the point. The Government seizes on the fact that it shares a tradename ("Calquence") with acalabrutinib free base, Opp. 25, but fails to acknowledge that, despite sharing an active *moiety*, acalabrutinib maleate salt has a different active *ingredient* and is indicated for a broader patient population, Compl. ¶¶ 75, 84-85. After AstraZeneca spent "years of research" and "millions in R&D costs" developing acalabrutinib maleate salt, FDA determined "that AstraZeneca should submit [it] to FDA via a separate original NDA." *Id.* ¶¶ 83-84. The IRA—like FDA—accordingly recognizes that acalabrutinib maleate salt is a distinct drug.

Indeed, many drugs share an active moiety despite even starker differences: *e.g.*, a liver-transplant medication and an eczema ointment, MSJ 23; and a psoriasis medication and an injection for Crohn's disease, *Amicus* Br., Dkt. 22-1, at 13-14. The Government ignores these examples. If Congress had wanted such distinct drugs to be treated as one, it would have said so.

CONCLUSION

This Court should grant summary judgment to Plaintiffs.

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Respectfully submitted,

/s/Michael A. Pichini

Michael A. Pichini
GOODELL, DEVRIES, LEECH & DANN, LLP
One South Street, 20th Floor
Baltimore, MD 21202
(410) 783-4000
map@gdldlaw.com

William T. Sharon*
ARNOLD & PORTER
KAYE SCHOLER LLP
250 West 55th St.,
New York, NY 10019-3743
(212) 836-8000

Allon Kedem*
Jeffrey L. Handwerker
Catherine A. Brandon*
ARNOLD & PORTER
KAYE SCHOLER LLP
601 Massachusetts Ave., NW
Washington, DC 20001-3743
(202) 942-5000
allon.kedem@arnoldporter.com

** Pro hac vice*

Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document will be served on Defendants in accordance with Fed. R. Civ. P. 5(a).

/s/Michael A. Pichini
Michael A. Pichini