UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

DAYTON AREA CHAMBER OF COMMERCE *et al.*, Plaintiffs, v. XAVIER BECERRA *et al.*, Defendants.	Civil Action No. 3:23-cv-00156-MJN-PBS Judge Michael J. Newman Magistrate Judge Peter B. Silvain, Jr.

DEFENDANTS' NOTICE OF SUPPLEMENTAL AUTHORITY

Defendants respectfully submit this notice of supplemental authority to inform the Court of a July 31, 2024 Opinion by the United States District Court for the District of New Jersey in *Novo Nordisk Inc. v. Becerra*, No. 23-cv-20814 (D.N.J.) (Quraishi, J.). A copy of that decision is attached to this Notice as Exhibit A.

Like Plaintiffs here, the plaintiffs in *Novo Nordisk* raised Due Process Clause and separation of powers challenges to the Drug Price Negotiation Program created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169. Indeed, several of the arguments advanced by plaintiffs in *Novo Nordisk* were substantively identical to the arguments presented in this case.

As for the Due Process Clause, the district court agreed with every court to consider the question, including this Court, "that because Plaintiffs' participation in the Program is voluntary, Plaintiffs do not have a protected property interest to sell drugs to Medicare at their professed 'fair market value' nor do they have a property interest in their expectation that they will continue selling their drugs to Medicare at a fair market value." Ex. A at 13. "Accordingly, Plaintiffs cannot demonstrate that the Program deprives them of a protected interest and therefore their Due Process Clause claim fails as a matter of law." *Id.*

As for the separation of powers, the *Novo Nordisk* plaintiffs' claim (like Plaintiffs' claim here) was "largely premised on the nondelegation doctrine." *Id.* at 13. And the *Novo Nordisk* plaintiffs (like Plaintiffs here) also "argue[d] that nondelegation concerns are heightened by 'Congress's decision to withdraw judicial review of CMS's price-setting decisions.'" *Id.* (citation omitted). The district court rejected those arguments, holding "that the IRA does not violate the nondelegation doctrine and it does not violate separation of powers." *Id.* at 17.

First, the district court explained that, although "[t]he statute sets forth a broad delegation to CMS to negotiate maximum fair prices for selected drugs," it "also narrowly defines relevant terms, sets forth the timelines for the various applicability periods, and provides CMS with guidance during the price negotiation phase." *Id.* at 16; *see also id.* ("Finding that the IRA fails to delegate an intelligible principle to CMS would disturb nearly century-long precedent.").

Second, the district court held that "Plaintiffs' argument that the nondelegation doctrine is violated because CMS's decisions are not subject to judicial review is misplaced." *Id.* at 17. The court agreed with the government that "the nondelegation doctrine focuses on 'the power Congress has delegated to the Executive Branch, *on the front end*—not whether the exercise of that power is subject to otherwise-unrelated constraints, *on the back end*.'" *Id.* (citation omitted). And it recognized that "courts have consistently considered statutes that preclude judicial review and have not indicated that such preclusion violates the nondelegation doctrine." *Id.*

The district court in *Novo Nordisk* thus rejected these (and other) challenges and entered judgment in favor of the government on all claims.

Dated: August 2, 2024

Respectfully submitted,

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NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVO NORDISK INC., *et al.*, Plaintiffs, v. **XAVIER BECERRA, *et al.***, Defendants.	Civil Action No. 23-20814 (ZNQ) (JBD) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (collectively, "Plaintiffs") filed a Motion for Summary Judgment. ("Plaintiffs' Motion", ECF No. 28.) Plaintiffs filed a brief in support of their Motion. ("Plfs.' Moving Br.", ECF No. 28-1.) Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services ("HHS"), and Centers for Medicare & Medicaid Services ("CMS") (collectively, "Defendants") filed a Cross-Motion for Summary Judgment. ("Defendants' Cross-Motion", ECF No. 37.) Defendants filed a combined brief in support of their Cross-Motion and in opposition to Plaintiffs' Motion. ("Defs.' Cross-Br.", ECF No. 37.1.) Plaintiffs then filed a combined brief in opposition to Defendants' Cross-Motion and reply in support of their Motion. ("Plfs.' Reply Br.", ECF No. 82.) Defendants waived their right to file a reply in support of their Cross-Motion and instead stand on the arguments made in

their prior filings and at oral argument, which the Court held on March 7, 2024 ("Oral Arg. Tr.", ECF No. 91).[1] (ECF No. 92.)

The Court has carefully considered the parties' submissions and oral argument.[2] For the reasons set forth below, the Court will GRANT Defendants' Cross-Motion and DENY Plaintiffs' Motion.

I. BACKGROUND AND PROCEDURAL HISTORY

This case is one of multiple challenges to the Drug Price Negotiation Program ("Program") created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 ("IRA"), filed across several federal district courts.[3] In addition to the present case, there are three other cases challenging the Program before the undersigned. *See Bristol Myers Squibb Co. v. Becerra*, Civ. No. 23-3335 (D.N.J.); *Janssen Pharms., Inc. v. Becerra*, Civ. No. 23-3818 (D.N.J.); *Novartis Pharms. Corp. v. Becerra*, Civ. No. 23-14221 (D.N.J.). On April 29, 2024, the Court issued an Opinion granting summary judgment in favor of Defendants Becerra, Brooks-Lasure, HHS, CMS, and Ananda V. Burra against Plaintiffs BMS and Janssen's Fifth Amendment Takings Clause claim, First Amendment Compelled Speech claim, and unconstitutional conditions doctrine claim. *BMS v. Becerra*, Civ. No. 23-3335, 2024 WL 1855054 (D.N.J. Apr. 29, 2024) [hereinafter *BMS-Janssen*]. Given the parties' familiarity with the IRA and the Program, the Court incorporates by reference

[1] Given the significant overlap between the present case and the three other cases challenging the Program before the undersigned, Defendants have extensively briefed their arguments across submissions made in this case, in the three other cases, and at oral argument.

[2] Several amicus briefs have also been filed. The amici include: Intellectual Property Law and Health Law Scholars, Center for American Progress, NAACP, UnidosUS Action Fund, The Century Foundation, AARP, AARP Foundation, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Nationally Recognized Healthcare and Medicare Experts, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, and Alliance for Aging Research.

[3] *See Dayton Area Chamber of Com. v. Becerra*, Civ. No. 23-156 (S.D. Ohio); *AstraZeneca Pharms. L.P. v. Becerra*, Civ. No. 23-931 (D. Del.); *Nat'l Infusion Ctr. Ass'n v. Becerra*, Civ. No. 23-707 (W.D. Tex.); *Boehringer Ingelheim Pharms., Inc. v. HHS*, Civ. No. 23-1103 (D. Conn.); *Merck & Co., Inc. v. Becerra*, Civ. No. 23-1615 (D.D.C.).

the background of this dispute as set forth in *BMS-Janssen* and provides the relevant procedural history as follows.

Plaintiffs initiated the present action by filing a Complaint on September 29, 2023. ("Compl.", ECF No. 1.) Plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. are a part of Novo Nordisk, a global healthcare company and pharmaceutical manufacturer. (*Id.* ¶¶ 27–29.) Novo Nordisk Inc. is the U.S.-based affiliate of Novo Nordisk and it seeks to "defeat diabetes and other serious chronic disease, such as obesity, and rare blood and rare endocrine diseases." (*Id.* ¶ 27.) Novo Nordisk Pharma, Inc. "supplies unbranded biologic versions of Novo Nordisk insulin products." (*Id.* ¶ 28.) Among other medications, Plaintiffs manufacture NovoLog, NovoLog FlexPen, and NovoLog PenFill (collectively, the "NovoLog Products") and FIASP, FIASP Flextouch, and FIASP Penfill (collectively, the "FIASP Products"). (*Id.* ¶ 34.) On August 29, 2023, CMS aggregated the three NovoLog Products and the three FIASP Products as a single "selected drug" (hereinafter, "Novo's Selected Drug") subject to the first round of the Program. (*Id.* ¶ 42.)

Plaintiffs allege four claims in their Complaint. (*Id.* ¶¶ 152–94.) Counts I and II comprise of Plaintiffs' constitutional challenges to the IRA. In Count I, Plaintiffs allege that the IRA violates separation of powers ("Separation of Powers" claim) and the Fifth Amendment's Due Process Clause ("Due Process Clause" claim). (*Id.* ¶¶ 152–67.) In Count II, Plaintiffs allege that the IRA violates the First Amendment because the Program compels Plaintiffs' speech ("First Amendment claim"). (*Id.* ¶¶ 168–76.) Counts III and IV comprise of Plaintiffs' statutory challenges. In Count III, Plaintiffs allege that CMS violated the Administrative Procedure Act ("APA") and the Social Security Act by imposing new legal obligations without complying with notice-and-comment rulemaking procedures. (*Id.* ¶¶ 177–86.) Finally, in Count IV, Plaintiffs allege that CMS's

actions, including aggregating and combining the NovoLog Products and the FIASP Products as a single drug, are ultra vires and violate express mandates of the IRA. (*Id.* ¶¶ 178–94.)

The parties "conferred and agree that this case raises legal questions that are properly resolved through dispositive motions, without the need for discovery or trial." (ECF No. 16 at 1.) Accordingly, the Court exempted the parties from filing statements of fact under Local Civil Rule 56.1(a) and set a briefing schedule for the instant summary judgment motions. (ECF No. 24.)

II. JURISDICTION

The Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331.

III. LEGAL STANDARD

A motion for summary judgment may be granted when "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If there is "no genuine dispute over material facts," then courts "will order judgment to be entered in favor of the party deserving judgment in light of the law and undisputed facts." *Iberia Foods Corp. v. Romeo*, 150 F.3d 298 (3d Cir. 1998).

IV. DISCUSSION

A. STATUTORY CHALLENGES

Plaintiffs accuse the Program of violating the IRA's own express mandates in four ways. First, CMS's method of grouping Plaintiffs' products effectively exceeds the total limit of ten products set by the statute. (Plfs.' Moving Br. at 17–20.) Second, the selection runs afoul of the statute's prohibition against imposing price controls on biological products that have not been approved for at least eleven years. (*Id.* at 22.) Third, the improper aggregation of Plaintiffs' products reaches the wrong result with respect to them being sufficiently "high-spend" to merit selection for price control. (*Id.* at 23.) Finally, CMS's treatment of Plaintiffs' products blurs the

line between their products that are reimbursable under distinct Medicare Parts B and D. (*Id.*) The distinction is meaningful to Plaintiffs because, while Part B products are eligible for price controls in 2026, Part D products are not eligible until 2028. (*Id.*)

Defendants respond that Plaintiffs lack standing to seek relief with respect to the total number of products that CMS chose for price controls. (Defs.' Cross-Br. at 14 n.3.) As to Plaintiffs' remaining arguments, Defendants asserts that this Court lacks subject matter jurisdiction. (*Id.* at 13–20.)

1. Subject Matter Jurisdiction to Consider Statutory Challenges

It is undisputed that the IRA includes a provision that expressly precludes "administrative or judicial review" of:

> (2) The selection of drugs under section 1320f-1(b) of this title, the determination of negotiation-eligible drugs under section 1320f-1(d) of this title, and the determination of qualifying single source drugs under section 1320f-1(e) of this title the application of section 1320f-1(f) of this title,

42 U.S.C. § 1320f-7. By this provision, Congress has divested this Court of jurisdiction to consider challenges under the APA to CMS's determinations under 1320f-1(b),(d),(e), and (f). Moreover, because it is an express statutory preclusion it also effectively prohibits this Court from reviewing those determinations on so-called *ultra vires* principles. *See Fed. Express Corp. v. United States Dep't of Com.*, 39 F.4th 756, 764 (D.C. Cir. 2022) (judicial review of ultra vires agency action is available only "where (i) there is *no express statutory preclusion* of all judicial review; (ii) there is no alternative procedure for review of the statutory claim; and (iii) the agency plainly acts in excess of its delegated powers and contrary to a specific prohibition in the statute that is clear and mandatory.") (emphasis added); *see also Leedom v. Kyne*, 358 U.S. 184, 188 (1958).

Based on the foregoing, the Court concludes that it lacks subject matter jurisdiction to consider challenges to CMS's underlying determinations that led to its identification of Novo's Selected Drug.

2. Plaintiffs' Standing to Challenge the Total Number of Drugs Selected by CMS for Price Control

What remains is Plaintiffs' challenge based on their assertion that CMS has effectively identified fifteen products, way beyond the ten products authorized by the IRA for price control in 2026. Assuming for the sake of argument that Plaintiffs are correct,[4] the ten-product limit is set forth in 42 U.S.C. § 1320f-1(a)(1), which is not exempted from judicial review by the IRA. *See* 42 U.S.C § 1320f-7. Plaintiffs' challenge on this issue, however, raises the question of their standing to do so.

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" and "Controversies." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559 (1992). "Part of the case-or-controversy requirement is the requirement that plaintiffs have standing to sue." *Yaw v. Delaware River Basin Comm'n*, 49 F.4th 302, 310 (3d Cir. 2022). To establish standing "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 594 U.S. 413, 423 (2021). The plaintiff, as the party invoking federal jurisdiction, bears the burden of establishing standing. *Id.* Because "standing is not dispensed in gross, a plaintiff who raises multiple causes of action must demonstrate standing for each claim he seeks to press." *In re Schering Plough Corp.*, 678 F.3d 235, 245 (3d Cir. 2012) (internal quotation marks and citation omitted).

[4] If Plaintiffs' premise is incorrect (or CMS's determination is unreviewable), it leads to a relatively straightforward conclusion: Plaintiffs have suffered no injury because CMS properly identified its six products as a single drug, and ten drugs in total were identified in compliance with the IRA.

As set forth above, Defendants challenge Plaintiffs' standing to ask the Court to set aside the selection of other companies' drugs for price controls, i.e., CMS's selection of all ten (or fifteen) drugs. Plaintiffs' Complaint does not seek individual relief based on each of its claims. Rather, the Complaint concludes with a ten-paragraph general prayer for relief based on all of their claims. (*See* Prayer for Relief ¶¶ A–J, Compl. at 59.) Nevertheless, based on its review, the Court agrees with Defendants that the relief sought by Plaintiffs that can be tied to their statutory challenge based on 42 U.S.C. § 1320f-1(a)(1) is overbroad insofar as they seek to enjoin the IRA program as a whole and to declare invalid CMS's entire guidance. (Prayer for Relief ¶¶ C, D, and F.[5]) Accordingly, the Court concludes that Plaintiffs have failed to demonstrate the standing required for their final statutory challenge. *See Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000) ("[A] plaintiff must demonstrate standing separately for each form of relief sought.")

B. CONSTITUTIONAL CHALLENGES

Plaintiffs also raise several constitutional challenges to the Program. Plaintiffs argue that (1) the IRA violates separation of powers because it lacks an "intelligible principle" in violation of the nondelegation doctrine (Plfs.' Moving Br. at 39–42) and confers "virtually unfettered" price setting discretion to CMS (*id.* at 51–54); (2) the IRA violates the Fifth Amendment's Due Process Clause (*id.* at 43–48); (3) the Program compels Plaintiffs' speech in violation of the First Amendment by requiring them to "espouse the government's preferred views" (*id.* at 48–51); and

[5] For clarity, based on the relief sought, the Court construes paragraphs A and B of the Prayer for Relief as stemming exclusively from Plaintiffs' Constitutional claims and construes paragraphs E, G, and H as stemming from Plaintiffs' challenge to CMS's unreviewable determinations with respect to drug selection. Paragraphs I and J merely seek fees and costs and a general catch-all of "other and further relief as the Court may deem appropriate."

(4) the Program coercively compels Plaintiffs' participation and violates the unconstitutional conditions doctrine (*id.* at 54–60).[6]

In *BMS-Janssen*, the Court addressed nearly identical constitutional challenges that the Plaintiffs make here. Specifically, the Court considered whether the Program violates the Fifth Amendment's Takings Clause, whether the Program compels speech in violation of the First Amendment, and whether the Program violates the unconstitutional conditions doctrine. *BMS-Janssen*, 2024 WL 1855054, at *2–12.

First, the Court found that the Program is neither a physical taking nor a *per se* taking of a manufacturer's drugs. *Id.* at *2–7. Here, Plaintiffs have not alleged a Takings Clause claim but much like the plaintiffs in *BMS-Janssen*, Plaintiffs generally argue that the "IRA's constitutional problems cannot be excused by pretending that manufacturers have voluntarily embraced price controls by virtue of their continued participation in the Medicare and Medicaid programs." (Plfs.' Moving Br. at 54.) To that end, Plaintiffs contend that their participation in the Program is coercive, not voluntary, and that even if Plaintiffs had a "meaningful choice" to participate, the Program nevertheless requires the "surrender of constitutional rights in return for a government benefit." (*Id.* at 54–60.) However, the Court rejected these same arguments in *BMS-Janssen*. The Court concluded that participation in Medicare broadly, and participation in the Program specifically, is voluntary. *BMS-Janssen*, 2024 WL 1855054, at *6–9. The Court explained that "[s]elling to Medicare is a choice Plaintiffs can accept or not accept" and manufacturers have alternative options should they choose not to participate in the Program. *Id.* at *8.

[6] The Court notes that the Complaint neither references the "unconstitutional conditions doctrine" nor does it specifically allege a distinct unconstitutional conditions doctrine claim. (*See generally* Compl.) Similarly, Plaintiffs do not specifically state a claim that the Program is involuntary. (*Id.*) But given the Parties extensively brief these arguments in their submissions, the Court will consider the arguments in the context of Plaintiffs' constitutional challenges.

Next, the Court concluded that the Program does not compel speech in violation of the First Amendment. *Id.* at *9–12. The Court explained that the IRA regulates conduct, not speech, given that the purpose of the IRA is "to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare." *Id.* at *10–11. Any "speech" aspects of the Program, such as the agreements and negotiations, are merely incidental mechanisms used during the price-setting process. *Id.* at *11. Further, the Court concluded that a manufacturer's signature on the agreements does constitute expressive conduct because the agreements are ordinary commercial contracts executed during the various stages of the Program.[7]

Finally, the Court swiftly rejected the plaintiffs' unconstitutional conditions doctrine claim because the plaintiffs failed to demonstrate how the Program violated either BMS's or Janssen's First or Fifth Amendment rights. *BMS-Janssen*, 2024 WL 1855054, at *12. Given a manufacturer's participation in the Program is a voluntary, and not coerced, undertaking that neither constitutes a physical taking nor compels speech, the Program does not infringe on a manufacturer's constitutional rights. *Id.*

Here, the Court declines to disturb its prior holdings and applies its reasoning and conclusions to the present action. Accordingly, the Court concludes that (1) Plaintiffs' participation in the program is voluntary, (2) the Program does not compel Plaintiffs' speech, and (3) for the reasons discussed below, the Program does not violate the unconstitutional conditions doctrine given the Due Process Clause does not protect Plaintiffs' desired, but not inherent, right to continue selling its drugs to Medicare at a "fair market value." The Court therefore finds that Plaintiffs' First Amendment claim and its claims challenging the voluntary nature of the Program

[7] *See also Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *15–17 (finding that the Program's agreements regulate conduct, not speech, and that the agreements do not force manufacturers to convey any preferred government message).

fail. As such, only two constitutional challenges remain that the Court must address: whether the Program violates separation of powers and whether the Program violates the Due Process Clause.

3. Due Process Clause Claim

Plaintiffs argue that the Program violates the Fifth Amendment's Due Process Clause in two ways. First, Plaintiffs note that due process must ensure that the "executive acts 'as authorized by law'" and protect individuals from arbitrary acts of government. (Plfs.' Moving Br. at 43 (citing *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 276 (1855); *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974))). To that end, Plaintiffs argue that the Program "invites arbitrary action by withdrawing judicial review from the price-setting regime's core features, including choosing what prices to set." (*Id.*)

Second, Plaintiffs contend that they have a "property interest both in the drug it creates and in the confidential information that CMS is forcing it to disclose," a right to "possess, use and dispose of" their property, a right to sell their drugs at a fair market value, and finally, a "property interest in its expectation that [Plaintiffs] may sell [their] drugs at a fair market value." (Plfs.' Reply Br. at 30–31.) Plaintiffs argue that the Program deprives them of their rights without any procedural protections such as judicial and administrative review. (Plfs.' Moving Br. at 44.) In particular, they note that CMS is not required to disclose any evidence that it relies on in determining the maximum fair prices, and as a result, Plaintiffs have no meaningful opportunity to respond to the evidence that CMS might rely on. (*Id.* at 46.) Therefore, without "traditional procedural safeguards" especially in the price setting context, Plaintiffs argue that their due process rights have been violated.

Defendants argue that Plaintiffs' Due Process Clause claim faces the same fatal law as their other constitutional claims: Plaintiffs have not, and cannot, identify any protected interest at risk of being deprived. (Defs.' Cross-Br. at 54, 56; Oral Arg. Tr. at 172:14–18.) Defendants argue that

while Plaintiffs have a physical property interest in their physical drug, the Program does not infringe on that right given Plaintiffs' participation in the Program is voluntary and they are not forced to make any sales to Medicare in the first place. (Defs.' Cross-Br. at 55.) Further, Defendants emphasize that Plaintiffs do not have a property interest to sell their drugs to Medicare at a particular price nor do they have a right to continued business with the Government. (*Id.* at 54–56.)

The Court can dispose of Plaintiffs' Due Process Clause claim quickly because the Due Process Clause is not implicated here. "The first inquiry in every due process challenge is whether the plaintiff has been deprived of a protected interest in 'property' or 'liberty.'" *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 59 (1999) (citing U.S. Const. amend. XIV). Here, the Court must first conclude that Plaintiffs have been deprived of a protected interest before it can consider whether the IRA and the Program comport with due process. *Id.* The Court will not reach the second question because Plaintiffs cannot demonstrate any deprivation of a protected interest.[8]

Plaintiffs argue that they have three protected interests: a property interest in their physical drugs, a property interest to sell their drugs at a fair market value, and a property interest in continued sales with Medicare at a fair market value. (Plfs.' Reply at 30–31.) At best, Plaintiffs can establish only one cognizable property right—a protected interest in the physical drugs—which Defendants do not dispute. (Defs.' Cross-Br. at 54.) However, it is unclear to the Court, and Defendants, how Plaintiffs are deprived of that right given that their participation in the

[8] The Third Circuit has noted that "determining what constitutes the impairment of a protected property interest for purposes of due process . . . is a distinct inquiry from determining what constitutes a taking for the purposes of the Takings Clause." *Burns v. Pa. Dep't of Correction*, 544 F.3d 279, 287 n.3 (2008). The Third Circuit sought to clarify that "property" is defined more narrowly in the Takings Clause context than in a due process challenge. *Id.* (internal citations omitted). The Court acknowledges this distinction but confirms that Plaintiffs' participation in the Program is voluntary under the contexts of both a Takings Clause and due process challenge. As such, "voluntary participation in a government program should [not] amount to a deprivation of property any more than it amounts to a taking of property." *Boehringer Ingelheim Pharms.*, 2024 WL 3292657, at *14.

Program is voluntary. As the Court explained at length in *BMS-Janssen*, a pharmaceutical manufacturer's participation in the Program, and its choice to sell to Medicare generally, is voluntary. *BMS-Janssen*, 2024 WL 1855054, at *6–9. Plaintiffs cannot conflate any financial or practical compulsion that participation in Medicare might exact with legal compulsion that obligates participation in either Medicare or the Program. Therefore, Plaintiffs cannot plausibly maintain that Defendants are depriving Plaintiffs of their physical drugs if they are not being coerced or compelled to give them up in the first instance.

Plaintiffs' two remaining "protected interests" are not cognizable rights. Notably, Plaintiffs provide no authority, statute, or regulation stating that they are inherently entitled to continue Medicare sales at their preferred price. This is because courts have routinely held otherwise. "The government has the fundamental right to decide how it will spend taxpayer money. Likewise, Plaintiffs have the fundamental right to decide whether they want to sell their drug to a specific purchaser under the conditions set." *BMS-Janssen*, 2024 WL 1855054, at *8 (internal citations omitted); *see also AstraZeneca Pharms.*, 2024 WL 895036, at *15 ("No one . . . is entitled to sell the Government drugs at prices the Government won't agree to pay." (citing *Coyne-Delany Co., Inc. v. Cap. Dev. Bd. of State of Ill.*, 616 F.2d 341, 342 (7th Cir. 1980))). In *AstraZeneca*, the district court addressed a similar due process challenge against the Program and found that plaintiff AstraZeneca Pharmaceutical LP's "'desire' or even 'expectation' to sell its drugs to the Government at the higher prices it once enjoyed does not create a protected property interest" and that "because AstraZeneca has no legitimate claim of entitlement to sell its drugs to the Government at any price other than what the Government is willing to pay, its due process claim fails as a matter of law." 2024 WL 895036, at *15 (citing *Town of Castle Rock, Colo. v. Gonzales*, 545 U.S. 748, 756 (2005)). Consistent with the Court's holding in *BMS-Janssen*, here,

the Court again concludes that because Plaintiffs' participation in the Program is voluntary, Plaintiffs do not have a protected property interest to sell drugs to Medicare at their professed "fair market value" nor do they have a property interest in their expectation that they will continue selling their drugs to Medicare at a fair market value.[9] Accordingly, Plaintiffs cannot demonstrate that the Program deprives them of a protected interest and therefore their Due Process Clause claim fails as a matter of law.

4. Separation of Powers

Plaintiffs' Separation of Powers claim is largely premised on the nondelegation doctrine. Plaintiffs argue that the IRA violates the nondelegation doctrine because when Congress enacted the IRA, it failed to articulate an "intelligible principle to which" CMS "is directed to conform." (Plfs.' Moving Br. at 39 (quoting *Touby v. United States*, 500 U.S. 160, 165 (1991)). Plaintiffs recognize that the IRA defines maximum fair price and that it provides a list of factors that CMS must consider in reaching the maximum fair price, but they argue that the IRA does not explain how CMS should determine the prices or how to weigh and consider each factor. (*Id.* at 41.) Further, Plaintiffs argue that nondelegation concerns are heightened by "Congress's decision to withdraw judicial review of CMS's price-setting decisions" because the IRA's price-setting scheme lacks a standard mechanism of ensuring accountability. (*Id.* at 42.) Along these lines, Plaintiffs suggest that the IRA is "unlike any price-setting scheme Congress has ever created." (*Id.* at 51.) They claim that the IRA confers "virtually unfettered" discretion on CMS to "control large

[9] Unlike Plaintiffs in this case, the plaintiff in *Boehringer Ingelheim Pharmaceuticals* did not argue that it had a protected property interest to sell its drugs through Medicare or that it was entitled to a particular rate of reimbursement. 2024 WL 3292657, at *14 n.3. The district court nevertheless clarified that the plaintiff could not even make such an argument "because no statute or regulation entitles it to sell its products to the government at all, let alone to do so at a particular rate of reimbursement." *Id.*

parts of the economy" and argue that it should be invalidated. (*Id.* at 53 (citing *A.L.A Schechter Poultry Corp. v. United States*, 295 U.S. 495, 542 (1935))).

Here, the Court disagrees and concludes that Plaintiffs' arguments, and the IRA generally, does not run afoul of the nondelegation doctrine for the reasons set forth below.

Article I of the Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States" and "[a]ccompanying that assignment of power to Congress is a bar on its further delegation." *Gundy v. United States*, 558 U.S. 128, 135 (2019) (plurality opinion). Though Congress may not transfer to the Executive or Judicial branch "powers which are strictly and exclusively legislative," *Wayman v. Southard*, 23 U.S. (10 Wheat.) 1, 42–43 (1825), the Constitution permits Congress the "necessary resources of flexibility and practicality to perform its function." *Yakus v. United States*, 321 U.S. 414, 425 (1944) (internal quotation marks omitted). To that end, "Congress may 'obtain the assistance of its coordinate Branches'—and in particular, may confer substantial discretion on executive agencies to implement and enforce the laws.'" *Gundy*, 588 U.S. at 135 (plurality opinion) (quoting *Mistretta v. United States*, 488 U.S. 361, 372 (1989)). The Supreme Court has "held, time and again, that a statutory delegation is constitutional as long as congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'" *Id.* (quoting *Mistretta*, 488 U.S. at 372).

The Supreme Court has consistently explained that the standards to satisfy an intelligible principle to guide an agency's exercise of authority "are not demanding." *Id.* at 146 (plurality opinion). It is well accepted that it is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946). Accordingly, to determine

whether Congress has articulated an intelligible principle to CMS, the Court must review the statutory language of the IRA to determine "what task it delegates and what instructions it provides." *Gundy*, 588 U.S. at 135–36 (plurality opinion). "[O]nce a court interprets the statute, it may find that the constitutional question all but answers itself." *Id.* at 136.

The Court rejects Plaintiffs' position that the IRA fails to articulate an intelligible principle and that it lacks necessary safeguards that leaves CMS with unfettered power. The IRA is a statute that directs the Secretary of HHS, acting through CMS, to establish the Program. 42 U.S.C. § 1320f(a). The IRA then describes the core functions and elements of the Program, including instructing CMS to: (1) publish a list of selected drugs; (2) enter into agreements with the manufacturers of the selected drugs; and (3) negotiate and renegotiate maximum fair prices for the selected drugs. § 1320f(a)(1)–(3). Arguably, the Court could find that Congress satisfied the constitutional standard setting forth an intelligible principle to CMS within just the first subsection of the IRA. *See Am. Power & Light Co.*, 329 U.S. at 105.

However, a review of the IRA reveals that the statute provides significantly much more guidance than Plaintiffs claim. In particular, § 1320f-3 focuses on the "negotiation and renegotiation process." Specifically, § 1320f-3(c) explains how CMS shall determine the ceiling for the maximum fair price and § 1320f-3(e) sets forth specific criteria that CMS "shall consider . . . as the basis for determining the offers and counteroffers" for the maximum fair price of a selected drug. There are two categories of factors. The first category of factors covers "manufacturer-specific data" for a particular drug, including research and development costs, production and developments costs, patent application data, market data, revenue, and sales volume data. § 1320f-3(e)(1). The second category of factors covers "evidence about alternative treatments" and includes evidence such as whether a selected drug "represents a therapeutic

advance as compared to existing therapeutic alternatives," FDA approved prescribing information for the selected drug and its therapeutic alternatives, and the comparative effectiveness of the selected drug and its therapeutic alternatives. § 1320f-3(e)(2). Having considered and reviewed the statute, the Court finds that Congress's delegation in the IRA easily passes constitutional muster because it articulates an "intelligible principle" to guide CMS during the negotiation process. The IRA conveys a specific, delineated task to CMS, and it explains the scope and parameters of the delegation throughout the statute. The statute sets forth a broad delegation to CMS to negotiate maximum fair prices for selected drugs, but it also narrowly defines relevant terms, sets forth the timelines for the various applicability periods, and provides CMS with guidance during the price negotiation phase.

It is undisputed that since 1935, the Supreme Court "has uniformly rejected nondelegation arguments and has upheld provisions that authorized agencies to adopt important rules pursuant to extraordinarily capacious standards." *Gundy*, 588 U.S. at 148–49 (Alito, J., concurring). Notably, the Supreme Court has found a delegation to be excessive in only two cases, both in 1935, where "Congress had failed to articulate *any* policy or standard" to confine discretion. *Mistretta*, 488 U.S. at 373 n.7 (emphasis added); *see Schechter*, 295 U.S. 495 (1935); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935). Given the various directions and considerations set forth in the IRA, it certainly cannot be said that Congress failed to articulate *any* intelligible principle in the IRA and Plaintiffs' attempts to compare the IRA to the delegations in *Schechter* or *Panama Refining* are not successful. Finding that the IRA fails to delegate an intelligible principle to CMS would disturb nearly century-long precedent upholding very broad delegations to agencies to regulate "in the public interest" and to "'set fair and equitable' prices and 'just and reasonable' rates." *See*

Gundy, 588 U.S. at 146 (plurality opinion) (first quoting *Nat'l Broad. Co. v. United States*, 319, U.S. 190, 216 (1943); then quoting *Yakus*, 321 U.S. at 427).

Further, Plaintiffs' argument that the nondelegation doctrine is violated because CMS's decisions are not subject to judicial review is misplaced. The Court agrees with Defendants that the preclusion of judicial review is not related to the nondelegation doctrine. (Defs.' Cross-Br. at 67.) As Defendants note, the nondelegation doctrine focuses on "the power Congress has delegated to the Executive Branch, *on the front end*—not whether the exercise of that power is subject to otherwise-unrelated constraints, *on the back end*." (*Id.*) (emphasis added). Plaintiffs do not cite to any authority that stands for the proposition that Congress's decision to preclude judicial review triggers a violation of the nondelegation doctrine issue.[10] In fact, courts have consistently considered statutes that preclude judicial review and have not indicated that such preclusion violates the nondelegation doctrine. *See, e.g.*, *Heckler v. Chaney*, 470 U.S. 821 (1985) (discussing that the APA precludes judicial review of certain decisions); *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982) (discussing that Medicare precludes judicial review of certain determinations and claims); *Yale New Haven Hosp. v. Becerra*, 56 F.4th 9 (2d Cir. 2022) (same). Given the Court does not find that the IRA violates the nondelegation doctrine under the traditional intelligible doctrine test, the Court declines to extend the nondelegation doctrine to find that the IRA's lack of judicial review creates a nondelegation doctrine violation. Accordingly, for the reasons provided, the Court concludes that the IRA does not violate the nondelegation doctrine and it does not violate separation of powers.

[10] Rather, Plaintiffs merely cite to an Eighth Circuit case for the proposition that "[j]udicial review is a factor weighing in favor of upholding a statute against a nondelegation challenge." *United States v. Garfinkel*, 29 F.3d 451, 459 (8th Cir. 1994) (quoting *United States v. Bozarov*, 974 F.2d 1037, 1042 (9th Cir. 1992)).

V. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants' Cross-Motion for Summary Judgment (ECF No. 37) and DENY Plaintiffs' Motion for Summary Judgment (ECF No. 28). An appropriate Order will follow.

Date: **July 31, 2024**

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE