

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BRISTOL MYERS SQUIBB COMPANY,

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 23-3335 (ZNQ) (JBD)

OPINION

JANSSEN PHARMACEUTICALS, INC.,

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

Civil Action No. 23-3818 (ZNQ) (JBD)

OURAISHI, District Judge

THIS MATTER comes before the Court upon Cross-Motions for Summary Judgment. Plaintiff Bristol Myers Squibb Company (“BMS”) and Plaintiff Janssen Pharmaceuticals, Inc. (“Janssen”) (collectively, “Plaintiffs”) each filed a Motion for Summary Judgment. (“BMS’s Motion”, ECF No. 36; “Janssen’s Motion”, ECF No. 30) (collectively, “Plaintiffs’ Motions for Summary Judgment”). Defendants Xavier Becerra, Chiquita Brooks-Lasure, U.S. Department of Health & Human Services (“HHS”), Centers for Medicare & Medicaid Services (“CMS”), and Ananda V. Burra (collectively, “Defendants”) filed Cross-Motions for Summary Judgment

(“Defendants’ Cross-Motion for Summary Judgment”) against BMS (ECF No. 38) and Janssen (ECF No. 33.) The Court has under consideration the following submissions:¹

- BMS’s brief in support of its Motion. (“BMS Moving Br.”, ECF No. 36-3.)
- Janssen’s brief in support of its Motion. (“Janssen Moving Br.”, ECF No. 30-1.)
- Defendants’ combined brief in opposition to Plaintiffs’ Motions and in support of their Cross-Motion. (“Defs.’ Cross-Br.”, ECF No. 38-1.)²
- BMS’s combined brief in opposition to Defendants’ Cross-Motion and reply in support of its Motion. (“BMS’s Resp. Br.”, ECF No. 80.)
- Janssen’s combined brief in opposition to Defendants’ Cross-Motion and reply in support of its Motion. (“Janssen’s Resp. Br.”, ECF No. 71.)
- Defendants’ reply in support of their Cross-Motion. (“Defs.’ Reply Br.”, ECF No. 84.)³

The Court has carefully considered the parties’ submissions and held oral argument on March 7, 2024 (“Oral Arg. Tr.”, ECF No. 107). For the reasons set forth below, the Court will GRANT Defendants’ Cross-Motions for Summary Judgment and DENY Plaintiffs’ Motions for Summary Judgment.

I. BACKGROUND AND PROCEDURAL HISTORY

A. GENERAL BACKGROUND

This action arises out of BMS and Janssen’s claims challenging the constitutionality of the Drug Price Negotiation Program (“Program”) created by the Inflation Reduction Act of 2022, Pub. L. No. 117-169 (“IRA”). *See* 42 U.S.C. § 1320f *et seq.* In considering a challenge against the Program brought by Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB, our sister court in Delaware carefully and meticulously provided a general background of the Program. *See*

¹ There are also several amicus briefs filed in both cases. The amici include: Fresenius Kabi USA, LLC, Public Citizen, Patients for Affordable Drugs Now, Doctors for America, Protect Our Care, Families USA, AARP and AARP Foundation, Intellectual Property Law And Health Law Scholars, American Public Health Association, American College of Physicians, Society of General Internal Medicine, American Geriatrics Society, American Society of Hematology, Constitutional Accountability Center, Economists and Scholars of Health Policy, Abrams Institute for Freedom of Expression, Alliance for Aging Research, and Nationally Recognized Healthcare and Medicare Experts.

² Defendants filed identical Cross-Briefs against BMS and Janssen, ECF Nos. 38-1 and 33-1, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 38-1.

³ Defendants similarly filed identical Reply briefs against BMS and Janssen, ECF Nos. 84 and 75, respectively. For the purpose of this Opinion, the Court cites to the brief filed at ECF No. 84.

AstraZeneca Pharms. LP v. Becerra, Civ. No. 23-931, 2024 WL 895036, at *1–5 (D. Del. Mar. 1, 2024) (explaining the history, enactment, and functions of the Program). Given the thoroughness of the court’s factual background, and for judicial economy, this Court incorporates by reference the background of the Program set forth by the Delaware District Court.

B. PLAINTIFF SPECIFIC BACKGROUND & PROCEDURAL HISTORY

BMS initiated this action by filing a Complaint on June 16, 2023. (“BMS Compl.,” ECF No. 1.) Janssen filed its Complaint on July 18, 2023. (“Janssen Compl.,” ECF No. 1.) BMS and Janssen are both pharmaceutical manufacturers with their principal place of business in New Jersey. (BMS Compl. ¶ 11; Janssen Compl. ¶¶ 17–18.) Among other medications, BMS manufactures and sells Eliquis; Janssen manufactures and sells Xarelto. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Both medicines are used to prevent blood clots and reduce the risk of strokes. (BMS Compl. ¶ 12; Janssen Compl. ¶ 18.) Notably, Eliquis and Xarelto are both subject to the first round of Program as “negotiation eligible” drugs.⁴ (BMS Compl. ¶ 12; Janssen Compl. ¶ 77.)

BMS and Janssen allege three claims in their Complaints. First, Plaintiffs allege that the Program is an uncompensated physical taking of personal property in violation of the Fifth Amendment’s Taking Clause (“Takings Clause claim”). (BMS Compl. ¶¶ 93–101; Janssen Compl. ¶¶ 129–39.) Next, Plaintiffs allege that the Program compels their speech in violation of the First Amendment (“Compelled Speech claim”). (BMS Compl. ¶¶ 102–07; Janssen Compl. ¶¶ 140–49.) Finally, Plaintiffs allege that the Program is an unconstitutional condition on Medicare and Medicaid participation.⁵ (BMS Compl. ¶ 88; Janssen Compl. ¶¶ 150–55.)

⁴ To be consistent with the language of the Program, for the purposes of this Opinion, the Court will use the term “drug” or “drugs” to refer to Eliquis and Xarelto.

⁵ For the purposes of this Opinion, the Court uses the term Medicare when it refers to both Medicare and Medicaid.

Plaintiffs and Defendants in both cases have “conferred, and agree that these cases present sufficiently similar legal questions about the constitutionality of a federal statute that can—and should—be resolved through coordinated dispositive motions, without the need for discovery.” (ECF No. 34 at 1.) Accordingly, the Court dispensed with any submission of statements of disputed facts by the parties given they are strictly challenging the constitutionality of the Program. (ECF No. 35.)

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. DISCUSSION⁶

The Court will address the following three issues raised by the parties. First, the Court will consider whether the Program is a physical taking in violation of the Fifth Amendment’s Taking Clause. Next, the Court will consider whether the Program compels speech in violation of the First Amendment. Finally, the Court will consider whether the Program violates the unconstitutional conditions doctrine.

⁶ Given the substantial similarity between BMS and Janssen’s legal claims, arguments, and briefs, for the purpose of this Opinion, the Court will primarily cite to the briefs filed by BMS.

A. FIFTH AMENDMENT TAKINGS CLAUSE CLAIM

1. Parties' Positions

a) *Plaintiffs*

Plaintiffs' main position is that the Program effects a physical taking of Plaintiffs' drugs in violation of the Fifth Amendment. (BMS Moving Br. at 12.) Plaintiffs argue that their drugs are private property protected by the Takings Clause. (*Id.* at 24; Janssen Moving Br. at 26.) Next, Plaintiffs claim that the Program is not "a mere price cap" but rather a "forced transfer dressed up as a 'sale.'" (BMS Moving Br. at 13, 16.) Accordingly, Plaintiffs contend that "the Program's forced sales are functionally equivalent to physically seizing the medicine from the warehouse." (BMS Resp. Br. at 4.) Ultimately, Plaintiffs assert that "[t]he whole point of [the Program] is for the Government to avoid paying just compensation by paying far less than the fair market price" for the selected drugs. (BMS Moving Br. at 14–15.)

Plaintiffs explain that this compelled transfer occurs through the following scheme. First, pharmaceutical companies, like Plaintiffs, that are selected to participate in the Program must comply and agree to sell the selected drugs at the maximum fair price. (*Id.* at 7.) If Plaintiffs do not agree with the maximum fair price and want to sell the selected drug to Medicare at a different price, then Plaintiffs will incur a very high tax⁷ on all of their drug sales from all sources. (*Id.* at 8.) Second, the only way a manufacturer could avoid the tax is if they withdraw from all Medicare sales entirely.⁸ (BMS Resp. Br. at 6.) Finally, even if Plaintiffs withdraw from selling to

⁷ The parties view the excise tax differently. Plaintiffs' position is that the excise tax starts at 186% and can go up to 1900%. (See BMS Moving Br. at 8.) In contrast, Defendants claim that the excise tax is 95%. (See BMS Moving Br. at 8.)

⁸ Plaintiffs claim that they could not withdraw from the Program within adequate time to avoid the tax because the Program requires a manufacturer to give at least 11 months, and as many as 23 months, notice of termination; this deadline would have been January 2022, months before the Program was even enacted. (BMS Moving Br. at 32.) Defendants explain that there two ways in which Defendants can still withdraw from the Program. First, Defendants explained that under the 11-to-23-month statutory period, Plaintiffs remain eligible to file their notice of termination by "no later than January 30th, 2025 to be out of Medicare in time for the first sales that are actually subject to the

Medicare, it would not defeat their argument the Program is still a physical taking under Supreme Court precedent set by *Horne v. Department of Agriculture*, 576 U.S. 350 (2015). Plaintiffs argue that just because this forced transfer is “dressed-up” as a sale does not protect it from a Takings Clause claim. (BMS Moving Br. at 13.)

b) Defendants

In contrast, Defendants argue that the Program is not a physical taking and Plaintiffs incorrectly characterize it as a forced transfer. Instead, Defendants underscore that “neither the [Program] nor any other part of Medicare ‘legally compel[s]’ manufacturers to negotiate with CMS or sell their drugs to Medicare beneficiaries.” (Defs.’ Cross-Br. at 11 (quoting *Dayton Area Chamber of Com. v. Becerra*, No. 3:23-cv-156, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023))). For a claim to be valid under the Takings Clause, a property owner must be “legally compelled” to participate in a price-regulated activity. (*Id.* at 12, 19.) Here, pharmaceutical manufacturers can “opt out” of the Program in several ways, including (1) fully divesting “their interests in the drugs subject to negotiation before 2026” or (2) withdrawing from the Medicare markets. (*Id.* at 2.)

Instead, Defendants argue that participation in Medicare is voluntary. (*Id.* at 12 (quoting *Livingston Care Ctr., Inc. v. United States*, 934 F.2d 719, 720 (6th Cir. 1991))). Further, Defendants explain that the Program is a “valid exercise of Congress’s constitutional authority to control the government’s spending as a market participant.” (*Id.* at 11.)

maximum fair price.” (Oral Arg. Tr. 61:22–62:6.) Second, pursuant to CMS’s Revised Guidance, the HHS Secretary can terminate a manufacturer’s agreement “before the manufacturer would incur liability for any excise tax, so long as the manufacturer notifies CMS of its desire to withdraw at least 30 days in advance of when that tax would otherwise begin to accrue.” (Defs.’ Cross-Br. at 7.) Defendants also explained that a manufacturer can satisfy the good cause requirement under the second method of withdrawal by simply expressing their desire to no longer participate in the Program. (Oral Arg. Tr. 62:19–23.)

Defendants distinguish *Horne* on the basis that Plaintiffs in this case can avoid the statutory regime. Defendants explain that unlike the plaintiffs in *Horne*, Plaintiffs can sell their drugs to the wider market at their discretion if they do not choose to participate in the Program. Defendants also note that no statutory provision requires entities to sell their property to a government, especially when the government is acting as a market participant. (*Id.* at 12–13.) As such, when the government determines the price it is willing to pay, or “imposes caps on the amount the government will reimburse,” the government “deprives [entities] of no property interest for the purposes of the Fifth Amendment.” (*Id.* at 13.)

Further, Defendants argue that when Congress enacted the IRA, it did so pursuant to its powers under the Spending Clause, which “operates based on consent: in return for federal funds, the [recipients] agree to comply with federally imposed conditions.” (*Id.*; quoting *Cummings v. Premier Rehab Keller, PLLC*, 142 S. Ct. 1562, 1570 (2022)). Finally, Defendants contend that Plaintiffs’ argument that they cannot withdraw from the programs are “academic” because neither Plaintiff has expressed intent to withdraw from the program. (*Id.* at 15.)

2. Analysis

The Fifth Amendment’s Takings Clause prohibits the government from taking private property for public use without just compensation. *River Valley Heights Corp. v. Twp. of W. Amwell*, Civ. No. 21-2042, 2023 WL 1433634, at *2 (3d Cir. Feb. 1, 2023); *see also* U.S. Const. amend. V. (“nor shall private property be taken for public use, without just compensation”). “The paradigmatic taking requiring just compensation is a direct government appropriation . . . of private property.” *Horne*, U.S. at 358 (quoting *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 537 (2005)). Requirements that a private owner “reserve” portions of their personal property for the use of the government are a “clear physical taking.” *Id.* at 361. Property owners subject to a reserve requirement “lose the entire ‘bundle’ of property rights in the appropriated [property]—

‘the rights to possess, use and dispose of’ them.” *Id.* at 361–62 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 432 (1982)).

The fact that a property owner may be entitled to net proceeds from a sale of their physical property “does not mean there has been no physical taking,” particularly when the value of any contingent interest in the property is at the “discretion of the taker.” *Id.* at 363. The government’s “categorical duty to pay just compensation” upon a governmental taking remains the same whether applied to government appropriation of personal property or real property. *Id.* at 358. Historically, patents have received the same protection in federal courts as other types of property. “[A patent] confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser.” *Id.* at 359–60 (quoting *James v. Campbell*, 104 U.S. 356, 358 (1882)).

Although courts have devised formulas and structures for evaluating claims under the Fifth Amendment, “[t]here is no abstract or fixed point at which judicial intervention under the Takings Clause becomes appropriate.” *Andrus v. Allard*, 444 U.S. 51, 65 (1979). “Resolution of each case . . . ultimately calls as much for the exercise of judgment as for the application of logic.” *Id.*

The Court’s analysis of Plaintiffs’ Taking Clause claim takes place in two stages. First, the Court addresses whether the Program constitutes a physical taking in violation of the Fifth Amendment. Second, the Court addresses whether Plaintiffs’ participation in the Program is voluntary.

a) The Program is Not a Physical Taking

The crux of Plaintiffs’ principal argument is that the Program is a physical taking. To support their position, Plaintiffs rely heavily on the Supreme Court’s decision in *Horne*. 576 U.S. 350 (2015).

The Horne family were raisin growers and handlers. *Id.* at 356. Under the United States Department of Agriculture’s California Raisin Marketing Order, the Hornes, like all growers and handlers, were required to set aside a percentage of their crop for the government’s use. *Id.* at 354. The government would not pay for this reserve, and it could choose to sell, allocate, or otherwise dispose of the reserved raisins. *Id.* The Raisin Administrative Committee (the “Raisin Committee”) determined the allocation to be set aside, and then acquired title to the reserve raisins. *Id.*

Under the Marketing Order, raisins were sold “in noncompetitive markets . . . to exporters, federal agencies, or foreign governments” or the government “donate[d] them to charitable causes; release[d] them to growers who agree to reduce their raisin production; or dispose[d] of them by any other means consistent with the raisin program.” *Id.* at 355 (internal quotation omitted). The growers retained a contingent interest in the raisins, and if they were sold, the growers received the net proceeds of the sales from the Raisin Committee. *Id.* at 363. Notably, in the years examined by the Supreme Court in *Horne*, the proceeds were either less than the cost of the production of the raisins or there were no proceeds at all. *Id.* at 355.

If growers, like the Hornes, did not create a raisin reserve for the government, they were assessed a fine “equal to the market value of the missing raisins.” *Id.* at 356. In the Hornes’ case, they refused to set aside a raisin reserve, and when trucks sent by the government came to pick up the raisins, the trucks were turned away. *Id.* The Hornes were then assessed the fine, upon which they proceeded to federal court. *Id.* Neither side in *Horne* contested that the government would have been within its powers to entirely bar the Hornes from growing raisins in the first place. *Id.* at 362.

Ultimately, the Supreme Court held that the “reserve requirement imposed by the Raisin Committee is a clear physical taking” and that the Takings Clause applied as much to personal property as it did to real property. *Id.* at 361. The Court explained that “[t]he Government’s formal demand that the Hornes turn over a percentage of their raisin crop without charge, for the Government’s control and use, is ‘of such a unique character that it is a taking without regard to other factors that a court might ordinarily examine.’” *Id.* at 362 (quoting *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419, 426–35 (1982)). The Court further held “[t]he fact that the growers retain a contingent interest of indeterminate value [in the reserve raisins] does not mean there has been no physical taking.” *Id.* at 363. The Court also observed that this physical taking made the *Horne* case entirely distinct from cases focused on the regulation of sales. *Id.* at 362. Though “a physical taking of raisins and a regulatory limit on production may have the same impact on a grower,” the “Constitution . . . is concerned with means as well as ends.” *Id.* By requiring that growers set aside portions of their crop without paying just compensation, the government transgressed its powers under the Fifth Amendment. *Id.* at 363. Finally, the requirement to relinquish “specific, identifiable property as a ‘condition’ on permission to engage in commerce effects a per se taking.” *Id.* at 365 (internal quotations omitted). The fact that the Hornes chose to participate in the raisin market was not a defense against the taking, and the Court held that it could not “reasonably be characterized as part of a . . . voluntary exchange . . . for the ‘benefit’ of being allowed to sell” the remaining raisin crop. *Id.* at 366.

Unfortunately for Plaintiffs in this case, *Horne* is inapposite to their plight for several reasons. Unlike *Horne*, there is no physical appropriation taking place and, setting aside their factual arguments, Plaintiffs fail to show how they are being *legally* compelled to participate in the Program.

Various sections of the Program explain that manufacturers and CMS engage in negotiations to determine “a maximum fair price for such selected drug of the manufacturer *in order for the manufacturer to provide access to such [maximum fair] price . . .*” 42 U.S.C. § 1320f-2(a)(1), (a)(2), (a)(3) (emphasis added). Plaintiffs claim that the “Program’s forced sales are functionally equivalent to physically seizing” the drug because the Program obligates the transfer of drugs to “Medicare at rates the Government dictates and to which [Plaintiffs] would never ordinarily agree.” (BMS Resp. Br. at 4–5.) Plaintiffs also contend that to “provide ‘access’ to the ‘maximum fair price’” for the drug, Plaintiffs “must physically provide [the drug] at that price.” (*Id.* at 7.) In other words, “[y]ou can’t have access to a price without access to a [drug].” (Oral Arg. Tr. 19:6–7.) Defendants, however, characterize Plaintiffs’ interpretation of the Program as “a fairly thin read on which to infer that actual commercial transactions need to take place at that price.” (*Id.* 59:12–14.) Pointing to § 1320f-6 of the Program, Defendants explain that it creates an “if-then” relationship: if a manufacturer sell a drug, then the manufacturer can only charge a price at or below the negotiated maximum fair price for that drug. (*Id.* 60:6–12.)

Despite Plaintiffs’ attempts to liken the Program to the reserve requirement in *Horne*, the two are markedly different. Plaintiffs in this case distort their position to liken it to the passive role of the raisin growers who are *required* to “give a percentage of their crop to the Government, free of charge” by way of an agricultural regulatory program marketing order. *Horne*, 576 U.S. at 354. The regulatory program in *Horne* markedly differs in that it “regulated all sales of raisins on the open market” and compelled raisin growers to set aside reserve raisins for the government’s use if growers sold their raisins at all. (Oral Arg. Tr. at 67:4–5.) Thus, Plaintiffs’ reliance on *Horne* strategically overlooks the obvious point that the only way for raisin growers to avoid the reserve requirement was to stop selling raisins altogether. *Horne*, 576 U.S. at 365. That is not the

case here. The Program applies solely to sales to Medicare. There is no statutory provision that imposes a requirement that pharmaceutical manufacturers must set aside, keep, or otherwise reserve any of their drugs for the government’s use, for the use of Medicare beneficiaries, or any other entity’s use. Nor, as Plaintiffs conceded at oral argument, does the Program require a manufacturer to physically transmit or transport drugs at the agreed price. (Oral Arg. Tr. 58:12–13.)

Plaintiffs repeatedly highlight the tax penalties that a manufacturer will incur if it does not sell the drug at the agreed price.⁹ However, as they also admitted at oral argument, Plaintiffs are free to opt out of Medicare entirely and sell their drugs to anyone but the government, or to divest their interest in the selected drug, or to remain in the Program but not make any sales to Medicare. (*Id.* 72:4–6.)

Plaintiffs separately argue that the Program is a Fifth Amendment violation under the *per se* takings rule expressed in *Cedar Point Nursery v. Hassid*. 594 U.S. 139 (2021). According to their theory, “a ‘classic’ or *per se* taking occurs when the Government forces a property owner to transfer possession or title, whether to ‘itself or someone else.’” (BMS Moving Br. at 13 (quoting *Cedar Point*, 594 U.S. at 146). The statutory access to their drug at specific prices set by the government, in their view, “forces” the manufacturers to transfer the selected drugs “to those third parties at the price demanded by the Government—[the manufacturers] cannot refuse to deal on those terms.” (*Id.* at 24.)

⁹ Janssen relies on *Horne* for the proposition that legal compulsion is not required to establish a constitutional violation. (Janssen Resp. Br. at 2.) And, even if legal compulsion was required, Plaintiffs contend that they have satisfied that showing because the Program compels Plaintiffs to “comply with the Program’s requirements for at least a minimum period or else pay the excise tax.” (*Id.* at 2–3.) However, as the Court explained, there are still several opportunities for Janssen to withdraw from the Program and avoid any excise tax.

Cedar Point Nursery is another agricultural case. The eponymous nursery grew strawberries. 594 U.S. at 144. At issue was whether a state labor relations board regulation effected an impermissible taking because it provided a “right of access to union organizers to the premises of an agricultural employer for the purpose of meeting and talking with employees and soliciting their report.” 594 U.S. at 144 (quoting Cal. Code Regs., tit. 8, § 20900(e).) The Supreme Court succinctly clarified that the “essential question” underlying a physical takings claim is “whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner’s ability to use his own property.” 594 U.S. at 149. Here, the Program neither requires nor forces Plaintiffs to give or sell their drugs to Defendants. As Defendants correctly note, the Program “does not authorize the government to requisition a manufacturer’s drugs or other property. Nor does the IRA require a manufacturer to relinquish any drug it does not wish to sell.” (Defs.’ Cross-Br. at 2.) As such, the Court finds that the Program does not qualify as a *per se* taking under *Cedar Point*.

b) Plaintiffs’ Participation in the Program is Voluntary

For their part, Defendants largely argue that the Program is not a taking because Plaintiffs’ participation in the Program is voluntary. (See generally Defs.’ Cross-Br; Defs.’ Reply Br.) Plaintiffs disagree. Plaintiffs reiterate that their takings claim is premised on a physical taking, not a regulatory taking. (Oral Arg. Tr. 29:4–7.) Accordingly, Plaintiffs argue that because the Program effectuates a physical taking, it should not be treated as a condition on participation and the voluntariness principles set forth in *Horne* and *Valancourt Books, LLC v. Garland*, 82 F.4th 1222 (D.C. Cir. 2023), are applicable. (*Id.* 25:16–26:5.)

Before addressing Plaintiffs’ narrow arguments specifically relating to the Program, the Court will first review the voluntary nature of participation in Medicare more broadly. As an initial matter, the parties have not identified any authority holding that participation in the

Medicare system is involuntary. (*See, e.g., id.* 12:8–11 (The Court asked Plaintiffs if they had “found any case law in this circuit or any other that holds that the participation in the Medicare system is not voluntary?” and Plaintiffs responded, “No”). The Court, despite diligent efforts, was likewise unable to identify any such authority. If anything, the contrary appears true; at least one court of appeals has consistently held that participation by healthcare providers in Medicare is voluntary. *See Livingston Care Ctr., Inc. v. U.S.*, 934 F.2d 719, 720 (6th Cir. 1991) (“[P]articipation in the Medicare program is a voluntary undertaking.”); *Baptist Hosp. East v. Sec’y of HHS*, 802 F.2d 860, 869–70 (6th Cir. 1986) (“[P]articipation in the Medicare program is wholly voluntary.”).

More recently and more to the point, other district courts that have considered the same challenge to the Program have found that a manufacturer’s participation in the Program is voluntary.¹⁰ The Southern District of Ohio considered challenges to the Program in the context of an emergent preliminary injunction seeking to enjoin the implementation of the Program. *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *1. The district court stated that “participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice.” *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11 (S.D. Ohio Sept. 29, 2023) (citing *Baptist Hosp.*, 802 F.2d 860 at 869). The court further found that “[a]s there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation.” *Dayton Area Chamber of Com.*, 2023 WL 6378423, at *11.

¹⁰ There have been several challenges brought against the Program across various district courts. In this Opinion, the Court specifically refers to the district court decisions from the Southern District of Ohio in *Dayton Area Chamber of Com. v. Becerra*, Civ. No. 3:23-cv-156, 2023 WL 6378423 (S.D. Ohio Sept. 29, 2023), and the District of Delaware in *AstraZeneca Pharms. LP v. Becerra*, Civ. No. 23-931, 2024 WL 895036 (D. Del. Mar. 1, 2024). The Court clarifies that though the courts in *Dayton Area Chamber of Com.* and *AstraZeneca* did not address the identical constitutional challenges brought by Plaintiffs in the present action, the courts’ findings regarding voluntariness are nevertheless relevant and applicable here.

More recently, as noted above, our sister court in Delaware heard another challenge to the Program. *AstraZeneca Pharms.*, 2024 WL 895036. It agreed with the Southern District of Ohio. In that case, plaintiff AstraZeneca Pharmaceuticals LP claimed, inter alia, that the Program violated its Fifth Amendment due process rights. *Id.* at *13. In relevant part, the district court found that “[n]either the IRA nor any other federal law requires AstraZeneca to sell its drugs to Medicare beneficiaries. On the contrary, ‘participation in the Medicare program is a voluntary undertaking.’” *Id.* at *15 (quoting *Livingston Care Ctr.*, 934 F.2d at 720.)

Plaintiffs emphasize the “massive penalty” they would incur should they reject the maximum fair price. Plaintiffs argue that the government has total control over the market for pharmaceuticals and that “[c]ompletely withdrawing from almost half the domestic pharmaceutical market is not commercially feasible.” (Janssen Moving Br. at 11.) Courts have roundly rejected such arguments. *See Baptist Hosp.*, 802 F.2d 860 at 869–70 (“If any provider fears that its participation will drive it to insolvency, it may withdraw from participation.”); *Livingston Care Ctr.*, 934 F.2d 719, 721 (6th Cir. 1991) (“Providers of health care who choose to participate in the federally sponsored program for the aged and disabled do so with no guarantee of solvency. Just as those who choose to serve individuals not covered by Medicare assume the risks of the private market, those who opt to participate in Medicare are not assured of revenues.”) (citation omitted); *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) (“Despite the strong financial inducement to participate in Medicaid, a nursing home’s decision to do so is nonetheless voluntary. This voluntariness forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation”).

Nonetheless, Plaintiffs are dismissive of the adverse case law. They argue that it is not applicable because the cases are (1) “outdated” given of the Supreme Court’s decision in *Horne*, (2) “off-point” because the cases do not address schemes that resemble the Program, and (3) “limited” because they analyzed voluntariness in the context of Due Process and regulatory takings claims. (BMS Resp. Br. at 23–26.) Instead, Plaintiffs urge the Court to view the Program as a “physical taking backed by a penalty,” not a condition, and to again find *Horne* instructive. (Oral Arg. Tr. 25:21–22.) To the extent Plaintiffs argue that *Horne* is instructive and that the Court should analyze the Program as a physical taking, the Court has already rejected that analogy.

Plaintiffs also point to *Valancourt*, a recent D.C. Circuit case finding that the “mandatory deposit requirement” of Section 407 of the Copyright Act was a physical taking in violation of the Takings Clause. 82 F.4th at 1231. Section 407 states that “the owner of copyright or of the exclusive right of publication in a work published in the United States shall deposit, within three months after the date of such publication . . . two complete copies of the best edition” of the work “for the use or disposition of the Library of Congress.” *Id.* at 1227 (quoting 17 U.S.C. § 407(a)(1), (b)). A copyright owner who fails to make the “required deposit” faces several fines. *Id.* (citing 17 U.S.C. § 407(d)(1)–(2), (d)(3)). The court of appeals held this constituted an impermissible taking. Notably, the court’s decision is narrow, and in its own words “is tied to the particular circumstances” of Section 407. *Id.* at 1239.

Setting aside the express narrowness of the *Valancourt* decision, it is also readily distinguishable from Plaintiffs’ case. The mandatory deposit requirement in *Valancourt*, like the reserve requirement in *Horne*, is part of a regime that parties could not readily exit. The court explained that when the deposit occurs, the copyright owners “lose the entire ‘bundle’ of property rights” in the copies and they “receive no additional benefit for the works they forfeit.” *Id.* at

1231–32 (citations omitted). Further, the deposit requirement was enforced via a demand letter that did not indicate another “option other than surrendering the property at issue or paying a fine, and in which Valancourt had no indication from any other source of the existence of a costless option to disavow copyright protection and thereby avoid complying with the sole options described in the demand letter.” *Id.* at 1239. The Program in this case bears none of these features.

Again, manufacturers selected to participate in the Program will not face any fee, tax, or fine if they initially choose not to participate in the Program. Despite Plaintiffs’ attempts to frame their plight as such, their options go beyond either (1) participating in the Program or (2) paying a fine. There are alternatives for Plaintiffs to explore should they choose, including exiting from sales to Medicare in the first instance. Plaintiffs who do so can continue to sell their drugs to any purchaser other than the federal government. Selling to Medicare is a choice Plaintiffs can accept or not accept. This is true for any negotiation between a purchaser and a seller. The plaintiffs in *Horne* and *Valancourt* were never given that choice. Accordingly, there is no “obligatory legal framework” here that Plaintiffs can only exit by paying a fine. (Oral Arg. Tr. 69:6–20.)

Along these lines, there is a final distinguishing factor between the Program and the physical takings in the cases Plaintiffs cite. Plaintiffs contend that the Program taxes nonparticipating manufacturers and punishes private parties “by shutting them out of other markets,” which is a “quintessential exercise of sovereign power.” (BMS Resp. Br. at 20.) However, as Defendants correctly note, the Program is akin to other Medicare reimbursement limits, and reflects a valid exercise of Congress’s constitutional authority to control the government’s spending as a market participant. (Defs.’ Cross-Br. at 11.) The Program is not regulating how the market operates, it arises in the context of Congress acting as a “proprietor of its own assets as opposed to regulating how a market is going to operate.” (Oral Arg. Tr. 66:23–

67:2–3.) The government has the fundamental right to decide how it will spend taxpayer money. *South Dakota v. Dole*, 483 U.S. 203, 206–08. Likewise, Plaintiffs have the fundamental right to decide whether they want to sell their drug to a specific purchaser under the conditions set. Here, the Court is not persuaded by Plaintiffs’ arguments that its participation in the Medicare program is involuntary. The Court agrees with the courts in the Southern District of Ohio, Delaware, and the established case law across several circuits holding that there can be no taking when participating in Medicare is voluntary and it rejects Plaintiffs’ attempts to suggest otherwise.

In short, Defendants are not taking drugs from Plaintiffs. BMS and Janssen want to sell their drugs to Medicare, a significant (but not the sole) buyer of pharmaceuticals in the United States. Selling to Medicare may be less profitable than it was before the institution of the Program, but that does not make Defendants’ decision to participate any less voluntary. For the reasons provided, the Court concludes that the Program does not result in a physical taking nor direct appropriation of Plaintiffs’ drugs.

B. FIRST AMENDMENT COMPELLED SPEECH CLAIM

1. Parties’ Positions

Plaintiffs argue that unconstitutional Compelled Speech begins when the Program forces them to engage in “sham ‘negotiations’” that result in “faux ‘agreements.’” (BMS Moving Br. at 21.) Once Plaintiffs sign the agreement, they are then forced to publicly express Defendants’ preferred message that the resulting sales at below-market prices is “fair.” (*Id.*) They point to the template “Medicare Drug Price Negotiation Program Agreement” (“Template Agreement”) and argue that its use of certain terms such as “agreement,” “negotiate,” and “maximum fair price” reinforces this message, which is driven by Defendants’ political objectives. (*Id.*, Decl. of Toni-Ann Citera Ex. B, ECF No. 36-2.) Plaintiffs argue that the Program’s agreements are more than

ordinary commercial contracts because they convey an implicit agreement by Plaintiffs that they are “negotiating” and an explicit agreement by Plaintiffs that the below-market maximum fair price is actually a “fair price.” (*Id.* at 25.) Overall, Plaintiffs contend that the agreements suggest that Plaintiffs are “choosing to give the Government a massive break on the price” of the drugs, even though Plaintiffs insist they are not. (*Id.*)

Like with Plaintiffs’ Takings Claim, Defendants argue that Plaintiffs’ Compelled Speech claim fails because their participation in the Program is voluntary. Accordingly, Defendants contend that “because the Negotiation Program is entirely voluntary, it does not compel any manufacturer to do anything at all—either by signing an agreement or otherwise.” (Defs.’ Cross-Br. at 31.) Notwithstanding the voluntary nature of the Program, Defendants also argue that signing the agreements does not compel Plaintiff’s speech because the Program regulates conduct, not speech. Additionally, Defendants argue that the agreements are not expressive “merely because they were written and *could* be incorrectly understood as conveying a message.” (Defs.’ Reply Br. at 40.) Defendants maintain that the Program’s agreements are “purely commercial arrangements” that “exist solely to memorialize manufacturers’ voluntary undertaking of a commitment to participate in the [Program]—and ultimately, to charge Medicare beneficiaries no more than the negotiated prices.” (*Id.* at 37–38.)

2. Analysis

A threshold issue for their Compelled Speech claim is whether Plaintiffs are compelled to participate in the Program. Setting aside the broader issue of whether the Program itself constitutes speech for First Amendment purposes for the moment, the Third Circuit instructs that “a violation of the First Amendment right against compelled speech occurs only in the context of actual compulsion.” *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 189 (3d Cir. 2005). “In order to

compel the exercise . . . of speech, the governmental measure must punish, or threaten to punish, protected speech by governmental action that is ‘regulatory, proscriptive, or compulsory in nature.’ *Id.* (quoting *Phelan v. Laramie Cnty. Cmty. Coll. Bd. of Trs.*, 235 F.3d 1243, 1244–47 (10th Cir. 2000)). At oral argument, Plaintiffs posited that the excise tax penalty is “what creates the First Amendment problem” and that if that penalty is stricken, then Plaintiffs no longer have a First Amendment claim. (Oral Ag. Tr. 124:4–9.) Like their Takings Clause claim, Plaintiffs’ Compelled Speech claim is premised on the theory that the Program is inherently involuntary and that Plaintiffs do “*not* voluntarily agree” with any aspect of the Program. (BMS Moving Br. at 24.) However, for the reasons provided, the Court has already concluded that the Program is voluntary and that Plaintiffs are not being compelled or forced to participate in the Program. Accordingly, the Court rejects Plaintiffs’ arguments that rely on involuntariness as the basis of their compelled speech claim.

a) The Program Regulates Conduct, Not Speech

First, contrary to Plaintiffs’ interpretation, the Program regulates conduct, not speech. Any effect on Plaintiffs’ speech in this case is merely incidental.¹¹

“It is settled law that ‘[g]overnment action that . . . requires the utterance of a particular message favored by the Government, contravenes th[e] essential right’ to refrain from speaking protected by the First Amendment.” *Ridgewood Bd. of Educ.*, 430 F.3d at 187 (quoting *Turner Broad. Sys., Inc. v. F.C.C.*, 512 U.S. 622, 641 (1994)). “[L]eading First Amendment precedents have established the principle that freedom of speech prohibits the government from telling people

¹¹ Plaintiffs’ own inconsistent positions as to the Program’s purpose reflects their strained Compelled Speech claim. Initially, with respect to their Takings Cause claim, Plaintiffs argued that the Program mandated and compelled the transfer of the physical drugs themselves. In contrast, with respect to their Compelled Speech claim, Plaintiffs argue that the “only thing the statute mandates is the agreement, the speech, and then that is what gives rise to the obligation relating to pricing and conduct.” (Oral Arg. Tr. 100:9–11.)

what they must say.” *Rumsfeld v. F. for Acad. & Institutional Rts., Inc.*, 547 U.S. 47, 61 (2006). Separately, courts have also routinely found that a statute regulates “conduct, not speech” when it affects what someone “must *do* . . . [and] not what they may or may not *say*.” *FAIR*, 547 U.S. at 60 (emphasis in original); *see also Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011) (“It is true that restrictions on protected expression are distinct from restrictions on economic activity or, more generally, on nonexpressive conduct.”). Plaintiffs claim that the Program “fits really neatly” into the pattern of First Amendment case law holding that the government cannot “compel a person to speak its own preferred messages,” but the Court disagrees. (Oral Arg. Tr. 99:2–8; *303 Creative LLC v. Elenis*, 143 S. Ct. 2298, 2312 (2023)).

Plaintiffs point to *Expressions Hair Design v. Schneiderman* where the Supreme Court found a New York price regulation improperly regulated speech. 581 U.S. 37 (2017). The price regulation at issue, N.Y. Gen. Bus. Law § 518, prohibits merchants from imposing surcharges to customers who pay with a credit card but permits merchants to offer discounts to customers who pay with cash. *Id.* at 40. For example, if a merchant wants to sell an item for \$10, the merchant can charge \$10 to a buyer paying with cash. *Id.* at 47. However, if the merchant wants to charge a buyer paying with a credit card an additional 3% surcharge to account for a credit transaction fee, the merchant must convey that price as a single sticker price of \$10.30 as opposed to “\$10, with a 3% credit card surcharge.” *Id.* On appeal, the Second Circuit concluded that § 518 did not violate the First Amendment because it regulated conduct, not speech. *Id.* at 46–47. The Second Circuit opined that “price controls regulate conduct alone” and that a “law regulating the relationship between two prices regulates speech no more than a law regulating a single price.” *Id.* The Supreme Court agreed with the Second Circuit that “§ 518 regulates a relationship between a sticker price and the price charged to credit card users.” *Id.* at 47–48. However, the Supreme

Court drew a different conclusion: “[i]n regulating the communication of prices rather than prices themselves, § 518 regulates speech.” *Id.* at 48. The Supreme Court distinguished § 518 from a “typical price regulation” because the law does not simply regulate the amount of money a merchant could collect for a sale. *Id.* at 47. In that scenario, the law regulates the merchant’s conduct and any “written or oral communications” the merchant uses to collect the money, such as identifying an item’s price on a menu, are “only incidental to its primary effect on conduct.” *Id.*

Critical to the holding in *Expressions*, though, is that § 518 “tells merchants nothing about the amount they are allowed to collect from a cash or credit card payer” but rather the law regulates how merchants communicate their prices. *Id.* Section 518 did not restrict what merchants could charge. Instead, the law constrained the ways that merchants could communicate their prices to buyers. The case before this Court is arguably the inverse of the one in *Expressions*. The primary purpose of the Program is to determine the price manufacturers may charge for those specific drugs they choose to sell to Medicare. The agreements and negotiations are incidental mechanisms the government is using to set those prices. In sum, the Court finds that the Program permissibly regulates Plaintiffs’ commercial conduct, not their communication of information.

b) *Signing the Program’s Agreements does not Constitute Expressive Conduct*

Plaintiffs’ real issue, then, is with the terminology Congress used within the Program’s agreements. Plaintiffs object to several terms used in the Template Agreement, including “negotiate,” “agree,” and “maximum fair price.” Plaintiffs’ key concern is that by agreeing to the final drug price, they are openly admitting that the price is the “maximum fair price.” (BMS Resp. Br. at 30.) That “message” runs against Plaintiffs’ sincere belief that the drug prices are not fair. Therefore, unlike a traditional price regulation that would merely communicate a price, Plaintiffs

contend that the agreements are expressive because they convey the government's preferred message. The Court, however, rejects Plaintiffs position for several reasons.

First, the Program's agreements are ordinary commercial contracts. Here, pharmaceutical manufacturers, like Plaintiffs, choose to participate in the Program. They accordingly execute the required contracts to confirm their agreement with Defendants. While it is true that the "creation and dissemination of information are speech for First Amendment purposes," Plaintiffs do not point to any authority supporting the proposition that a contract is expressive simply because it contains information. *Sorrell*, 564 U.S. at 570. Even Plaintiffs acknowledge that "many contracts do not express views or convey beliefs." (BMS Moving Br. at 25.) Nor do manufacturers' signatures on the agreements evidence any expressive conduct. Plaintiffs strain to analogize the impact of a manufacturer's signature on the Template Agreement to an individual's signature on a voting referendum. (BMS Resp. Br. at 33 (citing *John Doe No. 1 v. Reed*, 561 U.S. 186 (2010))). A voter's signature on a political petition, however, is unique because an "individual expresses a view on a political matter when he signs a petition." *Reed*, 561 U.S. at 194. "Even if the signer is agnostic as to the merits of the underlying law, his signature still expresses the political view that the question should be considered 'by the whole electorate.'" *Id.* at 195. Given that the Template Agreement itself is not expressive, the Court finds that a manufacturer's signature does not convey any message beyond its agreement with Defendants to the terms of the contract.

Importantly, the terms that Plaintiffs object to are statutory terms of art that are defined in the Program's statutory text. (Oral Arg. Tr. 107:21–108:9.) To accept Plaintiffs' position that the terminology used in the agreements forces Plaintiffs to convey a message requires construing the terms beyond the context of the agreement and beyond their statutorily defined meanings. As Defendants explained at oral argument, the terms are "ported over from the statute, they are defined

by the statute, and they are [in the agreements] to make clear that manufacturers are agreeing to abide—they are contracting to abide by the same technical understanding of these terms.” (*Id.* 108:5–8.) The term “maximum fair price” is defined in § 1320f(c)(3). When “maximum fair price” is used in the agreements, its meaning reflects its statutorily defined definition, not a colloquial meaning of “maximum fair price.” *See Meese v. Keene*, 481 U.S. 465, 484 (1987) (“It is axiomatic that the statutory definition of the term excludes unstated meanings of that term.”). In *Meese*, the Supreme Court rejected a First Amendment challenge against a statute that used the term “political propaganda” as the statutory name to categorize certain films. *Id.* at 467. In holding that the term be interpreted by its statutory definition, the Supreme Court warned that legislation should be construed “as it is written, not as it might be read by a layman, or as it might be understood by someone who has not even read it.” *Meese*, 481 U.S. at 485. Consistent with this guidance, the Court here similarly declines Plaintiffs’ invitation to interpret the Program’s terms beyond the scope of their statutory meaning.

Notably, nothing in the statute prevents Plaintiffs from publicly criticizing the Program or the final drug prices. Plaintiffs say they fear a “counternarrative” that they “would charge *more* than a ‘fair’ price for [the selected drugs] if not for the [Program’s] mandated ‘negotiations.’” (BMS Moving Br. at 26.) These, however, are public relations problems not constitutional problems.¹²

For the above reasons, the Court finds that the Program regulates conduct, not speech, and Plaintiffs are not engaging in expressive conduct by participating in the Program or by signing the

¹² Plaintiffs also claim that the disclaimer in the Template Agreement “does nothing to solve the compelled speech problem.” (BMS Resp. Br. at 36.) Plaintiffs’ argument assumes that the agreements are expressive and that the disclaimer is curing a potential compelled speech violation. However, the agreements are not expressive and the disclaimer clarifies that the “[u]se of the term “maximum fair price” and other statutory terms throughout this Agreement reflects the parties’ intention that such terms be given the meaning specified in the statute and does not reflect any party’s views regarding the colloquial meaning of those terms.” (Template Agreement at 4.)

agreements. As a result, the Court does not address whether the Program survives First Amendment scrutiny. *Expressions*, 581 U.S. at 48.

C. UNCONSTITUTIONAL CONDITIONS DOCTRINE CLAIM

Having concluded that the Program is not a physical taking, that the Program does not compel Plaintiffs' speech, and that Plaintiffs' participation in the Program is voluntary, the Court next considers whether the Program violates the unconstitutional conditions doctrine.

Plaintiffs argue that, even if their participation in the Program were voluntary, the Program would still violate the unconstitutional conditions doctrine. They contend that the Program "is not immunized from constitutional scrutiny merely because it's labeled as a condition on participation in a voluntary program." (Oral Arg. Tr. 41:3-5.) Specifically, participating in the Program mandates Plaintiffs to (1) publicly endorse the government's preferred message, in violation of the First Amendment, and (2) transfer the right to access Eliquis and Xarelto to third parties on government-dictated terms, in violation of the Fifth Amendment. (BMS Moving Br. at 39.) These, Plaintiffs insist, represent unconstitutional conditions.

The unconstitutional conditions doctrine "vindicates the Constitution's enumerated rights by preventing the government from coercing people into giving them up." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 604 (2013). Plaintiffs' doctrine claim suffers a fatal flaw: as Defendants succinctly observed at oral argument, "there's no constitutional right in danger of being trampled." (Oral Arg. Tr. 58:2-4.) "A predicate for any unconstitutional conditions claim is that the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure that person into doing." *Koontz*, 570 U.S. at 612. Here, for the various reasons discussed, the Court has already found that the Program does *not* constitute a physical taking in violation of the Fifth Amendment, nor does the Program regulate speech or

compel Plaintiffs to convey any government message in violation of the First Amendment. *See, e.g., Sanofi-Aventis U.S., LLC v. HHS*, 570 F. Supp. 3d 129, 210 (D.N.J. 2021), *rev'd in part on other grounds*, 58 F.4th 696 (3d Cir. 2023) (“To the extent that [plaintiff] has not established either a physical or regulatory taking under the Violation Letters, as I find here, the unconstitutional conditions doctrine is inapplicable.”). On that basis, the Court finds the unconstitutional doctrine does not apply under these circumstances and declines to consider Plaintiffs’ claim further.

V. CONCLUSION

For the reasons stated above, the Court will GRANT Defendants’ Cross-Motions for Summary Judgment and DENY Plaintiffs’ Motions for Summary Judgment. An appropriate Order will follow.

Date: April 29, 2024

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