IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., and MERCK SHARP & DOHME LLC, Plaintiffs, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	Civil Action No. 23-cv-1615-CKK

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

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INTRODUCTION

Congress decided that Medicare "spend[s] far too much" on prescription drugs. ECF 25 (Govt. Br.) at 21. So it enacted a law ordering pharmaceutical manufacturers to turn over their most valuable products to Medicare beneficiaries at steep discounts from market prices—or else pay massive tax penalties. And to conceal that top-down takeover of the pharmaceutical industry, Congress directed manufacturers to "agree" in writing that those discounts reflect the "maximum fair prices" for their products. The Administration then sold the Program to the American people as a "voluntary" system of "negotiations" with drug manufacturers.

The Program is, on its face, a straightforward violation of the Fifth and First Amendments. Seizing property for public benefit without paying its market value is exactly what the Takings Clause prohibits. And conscripting regulated parties to obscure reality by parroting the Government's agenda is precisely what the compelled speech doctrine forbids. But the Government insists this is all permissible, because manufacturers are not "obligated to participate," ostensibly making the Program's property and speech burdens purely "voluntary." Govt. Br. 2.

This is a shell game. Yes, manufacturers have "choices." If they do not want to hand over their property, they can "choose" to pay enormous penalties. That does not *solve* the constitutional problem—it *creates* it. Alternatively, the Government says, manufacturers can "choose" to "divest" selected drugs from their portfolio. Govt. Br. 23. But *abandoning* property to avoid its appropriation is obviously not a solution either; that just imposes a different burden on property rights.

Last, but foremost for the Government, the manufacturer can "suspend" the tax if it withdraws *all* its products from Medicare and Medicaid—forfeiting nearly half the U.S. market and abandoning millions of patients. The Government says that makes the Program just a "condition" on coverage under these federal insurance programs. But that does not somehow immunize the Program from scrutiny; the "unconstitutional conditions" doctrine forbids the abuse of federal spending powers to coerce the abandonment of constitutional rights. And the Program flunks that doctrine on multiple levels—it holds hostage a pre-existing funding stream that no manufacturer can afford to lose, one intended to pay for *other* products, to induce the companies to hand over their property and to pretend they did it willingly. That is a textbook example of a *coercive* condition (not a voluntary one), a *disproportionate* exaction (not a reasonable one), and an *illusory* exchange (not a genuine one).

To be very clear, nobody has a right to force others to buy their products at any particular price. But nor does anyone have a right to *force others to sell* their products at any particular price. Congress is thus free to impose "limits on how much federal agencies pay for prescription drugs." Govt. Br. 1. Congress is also free to authorize agencies to "negotiate prices," like any market participant. *Id.* But what Congress *cannot* do is use draconian penalties or exclusion from government benefits to punish manufacturers who do not "agree" to sell at bargain-basement prices. That is not "negotiation" (*id.*), "ordinary price regulation" (Govt. Br. 30), or anything remotely resembling the behavior of "any well-funded market participant" (Govt. Br. 20). It is an abuse of the Spending Clause to circumvent the Constitution.

Yet that is exactly what the Program does. In so contending, Merck is not laboring under any "misunderstandings" of the statute. Govt. Br. 2. Rather, it is the Government that has tried at every turn to rewrite the IRA's text, to "fix" its constitutional flaws, to downplay its obligations, and to contort its penalties. But no amount of administrative maneuvering or lawyerly semantics can transform the Program into just a "voluntary" system for price "negotiation."

Merck understands Congress's desire "to reduce government spending" on prescription drugs (Govt. Br. 1), and shares the goal of *amici* to expand access to those products. But the Constitution puts constraints on how those goals can be advanced, and the Program's unprecedented framework crosses constitutional lines.

ARGUMENT

I. THE GOVERNMENT'S STANDING OBJECTION IS BOTH MERITLESS AND MOOT.

The Government's lead submission is that this case should be dismissed on prudential standing grounds because, under guidance issued *after* Merck sued, the plaintiff supposedly should instead be one of Merck's wholly owned subsidiaries—Merck Sharp & Dohme LLC (MSD). Govt. Br. 8–12. The Government's resort to this formalistic extreme to avoid engaging on the merits is certainly conspicuous. But its objection is misguided. The Supreme Court and D.C. Circuit have allowed corporate parents to challenge laws that regulate their subsidiaries. Plus, the Program imposes independent injuries on Merck too. Regardless, the Government's objection is easily addressed by adding MSD as a plaintiff, as Merck has now done by amending its complaint (ECF 51). So, one way or the other, this action can proceed.

A. Merck Itself Has Standing To Challenge the Program.

The Government admits that one of Merck's products, Januvia, has now been selected for the first round of the Program, just as Merck alleged. *See* Govt. Br. 8. Nonetheless, the Government says that CMS announced, in guidance issued *after* Merck sued, that the agency would treat the IRA as imposing obligations only on the drug's so-called "primary manufacturer," which CMS defines as the entity that holds the "new drug application" (NDA) for FDA purposes. Govt. Br. 9; ECF 23-5 (Revised Guidance) at 118. For Januvia, the NDA holder happens to be MSD, a wholly owned Merck subsidiary. *See* Govt. Br. 9; Supp. Decl. of Patrick Davish (Davish Supp. Decl.) ¶ 5. So, the Government maintains, "Merck lacks standing" and only MSD would be a proper plaintiff. Govt. Br. 8. That argument is wrong on multiple levels.

To start, the Government does not dispute that Merck has *Article III* standing to sue based on harm to its wholly owned subsidiary. The very case the Government cites (Govt. Br. 10) says so: "We think that the Court of Appeals was quite right in holding that respondents have Article III standing to challenge the taxes that their wholly owned subsidiaries are required to pay." *Franchise Tax Bd. of Cal. v. Alcan Aluminum Ltd.*, 493 U.S. 331, 336 (1990). And the D.C. Circuit has cited that case to allow "the sole shareholder of two affected corporations" to pursue a constitutional challenge. *BellSouth Corp. v. FCC*, 144 F.3d 58, 62 (D.C. Cir. 1998). Instead, the Government claims that Merck lacks "prudential" standing under the "shareholder standing rule," which can restrict shareholders from asserting certain rights on the corporation's behalf. *Alcan*, 493 U.S. at 336. That theory fails for four reasons.

First, the Government does not dispute that Merck *had* standing when it filed its complaint; it simply contends that *subsequent* CMS guidance narrowed the entry to the courthouse. At most, this is therefore an issue of mootness. And because the supposed mootness as to Merck was caused by the Government's own conduct, such "maneuvers designed to insulate" agency action "from review by this Court must be viewed with a critical eye." *Knox v. SEIU*, 567 U.S. 298, 307 (2012). The Government in those circumstances "bears the burden" to prove that it is "absolutely clear" that any threat of injury has abated. *West Virginia v. EPA*, 142 S. Ct. 2587, 2607 (2022). It cannot carry that burden here. CMS's guidance is just that—guidance—and it can be revised at any time without even the hindrance of notice-and-comment procedures. *See* Govt. Br. 6. Because Merck itself is thus not out of the woods, the issuance of the Revised Guidance does not moot the claims that Merck asserted.

Second, even taking CMS's guidance at face value, the agency is trying to have it both ways. In the very same guidance the Government invokes for its claim that only MSD may sue, CMS indicated it would *not* recognize a transfer of ownership of rights in a selected drug to a "related" corporate entity—in other words, the agency would look past corporate form in implementing the Program. The force of such a "transfer of ownership," the agency said, will "depend on whether" it "was made to an entity *that is not a related party (e.g., not treated as part of the same employer* under [26 U.S.C. § 52(a)–(b)])." Revised Guidance at 132 (emphasis added). The referenced tax provision, 26 U.S.C. § 52, treats entities under common control—like Merck and MSD—as a single unit. And the IRA itself cross-references that same tax law to treat

affiliates "as one manufacturer" for other Program purposes. *See* 42 U.S.C. § 1320f–1(d)(2)(B)(i); *id.* § 1320f–1(f)(1)(C)(i). Even under the CMS guidance, the bottom line is that it does not matter which entity under the Merck umbrella holds the NDA; all "related" parties are equally swept up. For that reason, Merck retains standing.[1]

Third, even if MSD were the only entity subject to the Program's obligations, the concerns animating the shareholder standing rule have no relevance here. The "'rule serves the noble function of preventing parent corporations from having their cake and eating it too.'" Govt. Br. 11. But the Government cannot identify a single strategic reason why Merck would prefer to be the named plaintiff in lieu of MSD. There is none. Merck was the plaintiff in the complaint simply because it sued *before* CMS announced its "primary manufacturer" test. Because "none of the principles underlying the shareholder-standing rule" would be "offended by allowing [Merck's] suit to proceed," this Court should reject the prudential standing objection. *Gilardi v. HHS*, 733 F.3d 1208, 1216 n.5 (D.C. Cir. 2013); *see also, e.g.*, *Bellsouth*, 144 F.3d at 62 (allowing parent corporation to proceed with constitutional challenge on behalf of wholly owned subsidiaries subject to the regulatory action).

[1] CMS has also taken the same position on corporate aggregation in related contexts. For Medicaid's drug rebate program, for example, it has proposed to define "manufacturer" "to include parent, brother-sister, or subsidiary corporations," and entities "under common corporate ownership or control." 88 Fed. Reg. 34238, 34256 (May 26, 2023). The agency said that broader definition was necessary to respect "Congressional intent" and to prevent a manufacturer from "exclud[ing] some of its drugs from the drug rebate program" by "forming a subsidiary corporation." *Id.* There is little doubt, especially given its position in the Revised Guidance, that CMS would take the same view with respect to the Program.

Finally, even the Government admits there is an exception to the shareholder standing rule if the parent has its own "direct" interest in the claim. *See* Govt. Br. 10; *see also Gilardi*, 733 F.3d at 1216. Here, the Program imposes separate, distinct burdens on Merck itself. Specifically, a manufacturer can suspend the IRA's penalty only by withdrawing entirely from Medicare and Medicaid. Govt. Br. 15. But the Medicaid agreement with CMS identifies *Merck itself* as the "manufacturer." Davish Supp. Decl. ¶ 4 & Exh. A. That not only exposes the Government's own inconsistency, but shows that the Program impairs Merck's independent interests, because Merck would need to terminate that Medicaid agreement—in its own name—in order to suspend the Program's tax on MSD. That link suffices to defeat the Government's prudential standing objection a fourth time over.

B. Regardless, MSD's Joinder Has Cured Any Defect.

Even though the Government's standing objection is misguided, the Court need not confront this issue. The Government acknowledges that MSD has standing, and consented to an amendment adding MSD as a plaintiff. That amendment moots any concern, since "only one plaintiff must have standing." *In re Navy Chaplaincy*, 697 F.3d 1171, 1178 (D.C. Cir. 2012); *see also, e.g.*, *Mullaney v. Anderson*, 342 U.S. 415 (1952) (allowing addition of plaintiff to cure asserted standing defect). Whether the right plaintiff is Merck or MSD, this challenge can therefore proceed.[2]

[2] The addition of MSD as a second plaintiff does not affect any of the arguments about the Program's facial constitutionality, as laid out in the pending cross-motions that are now almost fully briefed. Those motions therefore remain ripe for resolution once briefing is completed, as Merck will explain in a forthcoming motion to govern further proceedings. *See also* Davish Supp. Decl. ¶ 6.

II. THE PROGRAM EFFECTS PHYSICAL TAKINGS OF MERCK'S PROPERTY WITHOUT JUST COMPENSATION.

Merck's argument under the Takings Clause is simple. Prescription drugs are property. The Program "takes" those drugs by threatening to penalize Merck, either through a tax or by excluding it from other government benefits, unless it provides Medicare beneficiaries with "access" to drugs at discounted prices. And those prices, by definition, do not provide "just compensation" because they are capped at a *fraction* of the drugs' market price. This scheme, on its face, flouts the Fifth Amendment.

In evaluating that argument, this Court has a new precedent to guide the way. In August, the D.C. Circuit sustained a Takings Clause challenge to another federal statute that requisitions property using the threat of fines. And, in doing so, the court rejected the Government's strikingly similar attempt to recast the taking as merely a voluntary "condition" on government benefits. *Valancourt Books, LLC v. Garland*, --- F.4th ---, 2023 WL 5536195 (D.C. Cir. Aug. 29, 2023).

Valancourt involved a challenge to a provision of the Copyright Act that orders the owner of a copyright in a work to "deposit two copies of the work with the Library of Congress within three months of its publication." *Id.* at *1. If the owner fails to do so, it must "pay a fine." *Id.* The plaintiff in *Valancourt* was an independent press that publishes rare fiction. *Id.* at *3. The Copyright Office demanded that it provide copies of certain books it had published, or else pay a fine of up to $250 per book plus $2,500 for willful refusal to comply. *Id.* Valancourt instead sought a declaration that the federal statute violated the Takings Clause. *Id.* While the district court rejected the claim, a unanimous D.C. Circuit panel reversed.

Writing for the court, Chief Judge Srinivasan began by recounting that "[a] physical appropriation of property presents the 'clearest sort of taking," triggering a "simple, *per se* rule: The government must pay for what it takes.'" *Id.* at *6 (quoting *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021)). The provision at issue, amounting to "[a] government demand to turn over personal property," constituted a physical appropriation that triggered that rule. *Id.*

Of course, the owners could "pay[] a fine instead of forfeiting their property." *Id.* at *8. But that did not "affect[] the analysis," as a fine equally "burdens" property rights. *Id.* Any other rule would allow the Government to "avoid" the Takings Clause "by purporting to 'simply give the owner a choice of either surrendering property or making a payment equal to the property's value.'" *Id.* at *8–9.

The Government's defense was that "a voluntary exchange for a governmental benefit" is not a taking; it claimed depositing copies was a condition on copyright protection. *Id.* at *6. But the D.C. Circuit disagreed: Under the statute, copyright protection did not hinge on depositing the copies; rather, owners who fail to deposit "are subject to a series of fines" but "retain copyright." *Id.* at *7. The Government then argued that owners could avoid those fines by opting out of copyright protection, but the Circuit rejected that argument too. *Id.* at *9. While "a simple, seamless, and transparent way to opt out" might "arguably" render the forfeiture of property "voluntary," those conditions were not satisfied. *Id.* Among other things, the opt-out process was not "costless" to the owner—there was a $125 fee—and so turning over the property could not be deemed truly "voluntary." *Id.* at *9–10.

Although the Government largely ignores it, *Valancourt* is similar to this case in many ways. Here, as in *Valancourt*, a federal statute purports to order a transfer of property to someone else. Here, as in *Valancourt*, failure to do triggers a monetary penalty. Here, as in *Valancourt*, the Government argues that this is still a voluntary exchange because the owner can "opt-out" of the obligation or penalty by disclaiming federal benefits. But here, as in *Valancourt*, the opt-out is anything but "simple, seamless, and transparent"—and certainly is not "costless."

Indeed, this is an *a fortiori* case. The Copyright Office charged $125 to opt out of copyright protection; even that was fatal. Meanwhile, the IRA requires drug manufacturers to forfeit access to nearly half the national market to avoid the illusory choice between handing over the drug or incurring immense daily penalties. Had the Copyright Act required the owner to disclaim protection of *all his works* to avoid the penalty for failing to deposit *one* work, it would have been (more) analogous to the IRA. There is no way such a scheme would have survived the D.C. Circuit's analysis.

Repeating its failed strategy from *Valancourt*, the Government here too denies there is any taking by emphasizing the supposed "options" available to Merck. Govt. Br. 17. It opens its merits argument by claiming those "options" make the Program "voluntary." Govt. Br. 13–18. And it closes, similarly, by claiming that the Program functions as a "condition on federal funds." Govt. Br. 33–35. But walking through each of Merck's supposed "options" exposes the Government's sophistry and lays bare the Program's offense against the Constitution. A step-by-step analysis reveals there is no "choice" here—just one unconstitutional imposition or another.

A. The IRA's Compelled Sales Are Appropriations of Property.

Start with Merck's most obvious option—the one the IRA actually *commands* it to take: Cave to Congress's demands and promise to provide Medicare beneficiaries with "access" to Januvia at whatever price the agency dictates. *See* 42 U.S.C. § 1320f–3(a) (directing that manufacturer "*shall* … negotiate a maximum fair price"); *id.* § 1320f–2(a)(3) (ordering that "access to the maximum fair price … *shall* be provided" by manufacturer) (emphases added). That is where the constitutional analysis begins because, as the Government recognizes, the threshold inquiry is always whether the alleged "funding condition … could be constitutionally imposed directly." Govt. Br. 33 (quoting *Rumsfeld v. FAIR*, 547 U.S. 47, 59 (2006)).

There is no doubt that such a command—imposed directly—would constitute a physical taking. The drugs themselves are property under the Fifth Amendment. *See Horne v. Dep't of Agric.*, 576 U.S. 351, 358 (2015). A government order to provide property (drugs) to third parties (Medicare beneficiaries) is a taking of that property. *Cedar Point*, 141 S. Ct. at 2072. And the promise of payment at prices below "market value of the property" does not vitiate the taking; it merely bears on the amount of compensation owed. *Horne*, 576 U.S. at 368–69; *see also id.* at 363–64 (holding that partial recoupment of proceeds goes only to quantum of damages). The IRA may not operate through "trucks" sent to Merck's facilities to "haul away drugs." Govt. Br. 27. But the Constitution cares not how an appropriation "comes garbed." *Cedar Point*, 141 S. Ct. at 2072. A forced transfer is a taking whether effectuated by truck or by a functionally equivalent takeover of the prescription drug supply chain.

The Government's fleeting counterarguments lack merit. *See* Govt. Br. 25–28. At the first step (the property interest), the Government distracts by arguing that manufacturers have no "vested property interest in Medicare sales." Govt. Br. 25. That is the *opposite* of Merck's claim. The Program effects takings by *compelling* sales of the selected drug to Medicare, not by *depriving* Merck of those sales. Merck's property is not "Medicare sales"; it is the prescription drugs themselves. Merck is not trying to "*force* [its] drugs onto the government at rates the government is unwilling to pay" (Govt. Br. 26); it is trying to resist the obligation to *sell* its drugs to Medicare at rates the Government dictates. A defense contractor cannot force the Pentagon to buy its aircraft carrier, but if the Pentagon demanded "access" to the vessel at 70% off list price, that would be a classic, physical, *per se* taking. By the same token, it matters little whether the President commandeers American steel mills or instead orders them to provide steel at a price of his choosing. *Cf. Youngstown Sheet & Tube Co. v. Sawyer*, 343 U.S. 579, 631 (1952) (Douglas, J., concurring).

At the second step (the taking), the Government denies that the Program "takes" drugs. It suggests that the IRA does not obligate manufacturers to provide "access" to the *drugs*, only "access" to *discounted prices*. Govt. Br. 27–28. But that is just wordplay; access to a *price* necessarily subsumes access to the *product*. If Merck were to agree to provide Medicare with "access" to Januvia at a "maximum fair price," and then refuse to sell the drug to Medicare beneficiaries at all, that would obviously not constitute compliance. It would be like a store promising a seniors' discount and then turning away every customer over 65 at the door.

Despite some vague insinuations,[3] the Government eventually acknowledges that manufacturers' "obligation" under the IRA is "to ultimately *provide their drugs* at the negotiated prices." Govt. Br. 34 (emphasis added). Likewise, in another telling slip-up, the Government admits that the Program does not just "limit the prices" at which drugs *may be sold*; it "limits the prices *at which drugs are to be made available* under the Medicare program." Govt. Br. 27 (emphasis added). The IRS recognizes the same: The Program requires manufacturers "to provide *access to selected drugs*" to eligible buyers. IRS, Notice 2023-52, at 2 (Aug. 4, 2023) (emphasis added). Indeed, the statute goes so far as to mandate that every selected drug "shall" be included in *every* Medicare Part D drug formulary, thus stripping the manufacturer of the right to withhold that drug from coverage. 42 U.S.C. § 1395w–104(b)(3)(I)(i). To comply with the IRA's "access" obligation, a manufacturer therefore must provide its drug to Medicare at the dictated price. That forced sale effectuates a taking. *See Cedar Point*, 141 S. Ct. at 2072 (law granting union "access" to property was *per se* taking).

To be clear, the IRA does not permit a manufacturer to withhold the selected drug from Medicare while continuing to receive coverage for its other products. CMS did not identify that as a viable choice in the pages of guidance that the Government repeatedly cites for its account of the manufacturers' many "options." *See* Revised Guidance at 131–32. That is because the IRA plainly forecloses such one-off withholding; any other reading of the "access" requirement would make no sense. As

[3] *See, e.g.*, Govt. Br. 15 (suggesting without explanation that manufacturer may "otherwise stop selling [selected drug] to Medicare beneficiaries").

the Government admits, the law allows a manufacturer to suspend the IRA's penalty only if it withdraws *all* its products from Medicare and Medicaid. Govt. Br. 5–6. Congress put manufacturers to that all-or-nothing choice; it provided no halfway house of continuing to enjoy Medicare coverage for other products while selling the selected drug only to those who pay privately. For a manufacturer that complies with the Program's demands rather than pay the tax or withdraw entirely from Medicare and Medicaid—the "options" addressed below, *see infra* Part II.B, II.D—the transfer of the drug to Medicare beneficiaries is thus *legally compelled*.

Undaunted, the Government tries to get to the same place through a backdoor: It suggests the IRA's tax applies only to sales *to Medicare*, so a manufacturer would face no penalty for impermissibly withholding the selected drug from Medicare. Govt. Br. 7, 17. But that is flatly contrary to the statutory text, which imposes the excise tax "on the sale … of *any designated drug*," 26 U.S.C. § 5000D(a) (emphasis added)—with no limitation based on who the buyer is. The Government's invented limit also conflicts with the statutory structure. Recall that the IRA "suspen[ds]" its tax if a manufacturer leaves Medicare entirely. *Id.* § 5000D(b)–(c). If the tax applied only to Medicare sales, there would be nothing to "suspend," as such a manufacturer would not incur any tax to begin with; the suspension regime would thus be superfluous. *But see United States ex rel. Polansky v. Exec. Health Res., Inc.*, 599 U.S. 419, 432 (2023) (applying "interpretive principle that every clause and word of a statute should have meaning"). This would be akin to a law "suspending" the federal income tax for years when an individual earns no income.

Clearly, Congress did not put manufacturers to a painful all-or-nothing choice, holding hostage all Medicare and Medicaid coverage for all of their products, only to allow them to circumvent that choice through an obscure tax loophole. In suggesting otherwise, the Government rests exclusively on a few unclear words in a vague IRS Notice that merely advises of a supposed *intent* to *propose* regulations on this issue in the future. This is part of a pattern: The Government knows the statute as enacted is indefensible, so it tries to rewrite it—and even to undercut its coherence—in a futile effort to save it. *See also infra* at 18 n.5, 23, 41 (other examples).

In short, the IRA compels manufacturers to provide "access" to their drugs, and that distinguishes this novel regime from mere price regulation. Complying with the Program means a manufacturer must make its drugs available at the discounted prices, and provide them at that price to any Medicare-eligible individual. Companies are thus "'*legally compelled* to engage in price-regulated activity,'" which even the Government agrees triggers the obligation to pay just compensation. Govt. Br. 13.

And that brings us to the final step of the Takings Clause analysis: Does the scheme provide for just compensation? On this front, the Government never disputes that the Program's ceiling prices do not represent the "market value" of the drugs and thus do not satisfy the constitutional guarantee. *Horne*, 576 U.S. at 368–69. That is why Merck's challenge is a facial one—in all applications, the Program provides below-market compensation for the property it takes. There is no need in this case to determine the actual market value of any particular drug, because Merck seeks only declaratory relief on this claim. *See* Merck MSJ Br. 19–22.

Confusingly, the Government nonetheless argues that, in the context of public utilities—which are likewise compelled by law to serve the public, and therefore are entitled to just compensation, *Garelick v. Sullivan*, 987 F.2d 913, 916 (2d Cir. 1993)—any takings challenge must be directed toward "rates, not methods." Govt. Br. 28 (quoting *Verizon Commc'ns Inc. v. FCC*, 535 U.S. 467, 525 (2002)). But Merck is not challenging a price-setting "method" in the abstract. Its point is that the "rates" capped by the IRA are pegged to a *fraction* of market price and so *necessarily* do not provide market value. *See United States v. Gen. Motors*, 323 U.S. 373, 385 (1945) (Douglas, J., concurring in part) (finding it "difficult to see" how "allow[ing] the Government to … pay only a part of the rent" for occupied leasehold would provide just compensation). Unlike in *Verizon*, here the face of the statute makes clear that the IRA's prices will fall below "just compensation." So there is no need or reason to wait for "any specific rate" to be selected. Govt. Br. 28.[4]

In sum, if the IRA's compelled sales constitute takings (as they do), there is no dispute that the IRA fails to provide the market-based compensation that the Fifth Amendment demands. That warrants the declaratory relief that Merck seeks.

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[4] While the Government does not dispute that the IRA's ceiling prices fail to provide just compensation, a set of *amici* argue that the market prices of prescription drugs are not "fair" because manufacturers enjoy a period of exclusivity under patent and FDA law. *See* Public Citizen Br. 8–9. *Amici*, however, cannot raise issues that the parties forfeited. *See Boehner v. Anderson*, 809 F. Supp. 138, 139 (D.D.C. 1992). Regardless, the Supreme Court has long endorsed "market price" as the measure of compensation for property that is bought and sold in an established market. *Kimball Laundry Co. v. United States*, 338 U.S. 1, 6 (1949). *Amici* cite no authority suggesting any different standard. Nor should there be one: Properly understood, the exclusivity to which they object is an innovation-inducing *feature* of this market—not a *bug*.

B. The Government Cannot Circumvent the Takings Clause by Penalizing the Refusal To Forfeit Property.

Although the IRA uses the mandatory term "shall" to describe the obligation to "negotiate" with the Government and "agree" to its dictated price, the statute does provide one implicit alternative: A manufacturer can instead pay an excise tax for each day of "[n]oncompliance" with the Program's obligations. 26 U.S.C. § 5000D(b). The Government cites this as one of the "options" that supposedly renders the Program voluntary: "A manufacturer that does not wish to sign such an agreement" or "to otherwise participate" in the Program can just "pay an excise tax." Govt. Br. 5.

This "option" does not *remedy* the taking; it *enforces* it. If there were no penalty for refusal to transfer the drugs, perhaps the toothless command alone would not warrant relief. But the IRA backs its demand with monetary sanctions; that amounts to legal compulsion. *See Horne*, 576 U.S. at 356 (demand for raisins enforced through penalties was a taking). On this point, Merck cannot do any better than Chief Judge Srinivasan, writing for the D.C. Circuit in *Valancourt*:

> It is true that copyright owners can satisfy Section 407 by paying a fine instead of forfeiting their property. But the government understandably does not contend that the "option" of paying a fine affects the analysis. A statute can effect a taking even if the property owner never actually forfeits property and is instead subject to a fine. … Just as the alternative of a fine in *Horne* did not save the statute from constituting a taking, Section 407's scheme of fines does not save the statute here, either. A "demand for money" that "operate[s] upon ... an identified property interest" can violate the Takings Clause because a "monetary obligation burden[s]" ownership of property. Were we to find otherwise, the government could avoid the strictures of the Takings Clause by purporting to "simply give the owner a choice of either surrendering [property] or making a payment equal to the [property's] value."

2023 WL 5536195, at *8-9 (citations omitted).

In short, the IRA by its terms directs manufacturers either to provide "access" to their products at a discount, or pay monetary penalties. That "choice" itself violates the Constitution.[5]

C. The Manufacturer's Power To Dispose of Its Property Before the Taking Does Not Cure the Constitutional Problem.

Next, the Government offers another "option" that is implicit in the scheme—manufacturers can "divest their interest in the selected drug(s)." Govt. Br. 7; *see also* Govt. Br. 2, 17, 22, 23, 23 n.11 (similar). As noted above, CMS guidance clarifies that such divestment would have to involve an unrelated party; this is not as easy as spinning off the selected drug to a subsidiary or affiliate. *See supra* at 5-6; Revised Guidance at 131–32. Keeping that caveat in mind, the Government's point is apparently that manufacturers can abandon their interests in the property before Medicare takes it, and thereby escape the taking.

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[5] The Government claims that Merck "misunderstands" the *amount* of the tax. Govt. Br. 22 n.10. The amount of the tax makes no constitutional difference; imposing a penalty on the refusal to abandon property rights violates the Fifth Amendment in any case. Indeed, the fine in *Valancourt* was just $250, and that sufficed to make the scheme unconstitutional. *See* 2023 WL 5536195, at *7, *8–9. Regardless, there is no misunderstanding on Merck's part. The IRA calculates the tax using a formula that turns on the "tax" and the "price for which" the drug is "sold." 26 U.S.C. § 5000D(a). Using that formula, the Congressional Research Service explained that the tax would reach "1,900% of the selected drug's price." Cong. Rsch. Serv., *Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376)* at 4, tbl. 2 (2022). The Government cites an IRS notice that it intends in the future to propose regulations treating the drug's "price" as *inclusive* of the "tax" even though the IRA refers to those inputs as *distinct*. *See* IRS, Notice No. 2023-52, at 3 (Aug. 4, 2023). On that approach—fictionally reducing the "price" of the drug to accommodate the tax—the penalty would appear to be smaller. Govt. Br. 7. Once again, the Government is trying to rewrite the statute to make it seem less draconian than what Congress enacted. But once again, its efforts are foreclosed by clear statutory text.

This does not work any better than the "option" of paying a monetary fine. If the Government announced an intent to seize your house in 30 days, your power to sell the house to a third party within that window obviously would not remedy the violation of the Fifth Amendment. The reason is simple: Transferring one's property "burdens ownership of property" no less than a fine. *Valancourt*, 2023 WL 5536195, at *9. Indeed, divesting the to-be-taken property strips the owner of all of the same property rights as the taking itself—the manufacturer would transfer "title" and "lose any right to control" the property. *Horne*, 576 U.S. at 364.

This argument is reminiscent of the Government's submission in *Horne* that there was no taking because the raisin growers could just "plant different crops" or "sell their raisin-variety grapes as table grapes or for use in juice or wine." 576 U.S. at 365. The Supreme Court rejected that theory "as a matter of law," because "basic and familiar uses of property"—like the right to sell goods—cannot be recharacterized as "special governmental benefit[s] that the Government may hold hostage, to be ransomed by the waiver of constitutional protection." *Id.* at 365–66. Likewise, in *Loretto v. Teleprompter Manhattan CATV Corp.*, the Court rejected an argument that no taking occurred because the "landlord could avoid the requirements of [the statute] by ceasing to rent the building to tenants." 458 U.S. 419, 439 n.17 (1982). Property rights "cannot so easily be manipulated," the Court warned. *Id.*

So too here. Merck can yield "access" to its products, pay an enormous penalty, or abandon its property interest in Januvia before the Government appropriates it. Just as in *Horne* and *Loretto*, that trilemma violates the Takings Clause.

D. The "Option" To Withdraw All Products from Medicare and Medicaid Is a Coercive and Disproportionate Penalty.

Finally, the last "option"—and the Government's principal theme—is that the manufacturer can suspend the IRA's tax penalty by withdrawing entirely from the Medicare and Medicaid programs for all of its products. The Government's defense hinges on the notion that this "choice" renders the Program entirely "voluntary," akin to any ordinary condition on a government benefit. *See* Govt. Br. 12–15. But that argument fails under multiple related lines of authority, all stemming from the same fundamental reality. The "option" to withdraw from Medicare and Medicaid is not a genuine offer that is reasonably tied to the Program's scope or objectives; it is a cudgel to coerce compliance by threatening exclusion from distinct and pre-existing funding streams that are known to be critical to the manufacturers' viability.

Despite its categorical statements, even the Government cannot seriously deny there are constitutional limits on the "conditions" it may attach to spending programs like Medicare. The Government could not limit coverage to the drugs of providers who endorse the President's reelection campaign, of course. Nor could it "condition" participation on agreement by manufacturers' CEOs to open their homes for charity events. Those may be extreme hypotheticals, but they illustrate that there are *legal standards* for the "conditions" that may be placed on government benefits—a mere tie-in to Medicare does not insulate the Program from scrutiny. Rather, the Court must consider whether ransoming all reimbursements from Medicare and Medicaid as a means to coerce a transfer of property is constitutionally permissible under the framework the Supreme Court has adopted. It is not.

1. The first "tell" that Congress was not genuinely offering Medicare and Medicaid coverage subject to the "condition" that manufacturers comply with the Program is that the statute does not work that way. The statute issues a simple command: provide access to selected drugs *or* pay a substantial penalty. *See* 42 U.S.C. § 1320f–6. It does not propose a *quid pro quo* whereby participation is rewarded by coverage or noncompliance is penalized by withholding it. Manufacturers are entitled by law to Medicare and Medicaid coverage for their products *either way*, and the IRA enforces the new Program rules through a distinct, independent penalty.

Valancourt is again instructive. The D.C. Circuit refused to recharacterize the Copyright Act's deposit obligation as a "condition" on copyright benefits. It observed that, under the statute, owners "receive no additional benefit for the works they forfeit," because depositing a book is not "required to continue retaining copyright." 2023 WL 5536195, at *7. "While copyright owners are subject to a series of fines for failure to deposit, they retain copyright regardless of whether they pay the fines." *Id.* That meant there was no "voluntary exchange for a benefit," as the benefit (copyright protection) was "illusory"—it was a right the owner "already enjoyed." *Id.* at *6 (citing *Horne*, 576 U.S. at 366). Since the obligation was "untethered" to the benefit, there was no "quid pro quo" and no "voluntary exchange." *Id.* at *8.

The IRA is structured exactly the same way, so it too cannot be characterized as offering a "voluntary exchange." If a manufacturer does not comply with its new Program obligations, the consequence is *not* that it loses coverage under Medicare or Medicaid, even for the selected product (let alone for all of its products). Rather, the

manufacturers "are subject to a series of fines" for failure to comply, but "retain" their coverage rights "regardless." *Valancourt*, 2023 WL 5536195, at *7. As in *Valancourt*, this structure signifies that Program compliance is not a "quid pro quo" exchange for coverage; the "benefit" to manufacturers is "illusory" because Medicare and Medicaid coverage are rights they already enjoy. *Id.* at *6, *8. The IRA is not—and was never intended to be—a genuine condition on, or exchange for, a governmental benefit.

2. The Government argues that, even though the Program is not *formally* structured as a condition on Medicare or Medicaid coverage, it is *functionally* similar because manufacturers can suspend the tax by opting out of Medicare and Medicaid. Govt. Br. 2, 15. The D.C. Circuit rejected the same maneuver in *Valancourt*.

There, the Government argued that because "a copyright owner can readily disavow copyright protection and thereby avoid the deposit requirement," the statute effectively functioned as "a voluntary exchange." 2023 WL 5536195, at *9. The D.C. Circuit disagreed. It granted only that, "perhaps," a forfeiture "might arguably be voluntary" if the owner had a "simple, seamless, and transparent" opt-out mechanism that was "known and costless." *Id.* Here, manufacturers' "choice" is none of those.

For starters, it is the opposite of "costless." In *Valancourt*, a $125 fee made the opt-out insufficient. Here, a manufacturer must surrender not only coverage of the selected drug, but also its coverage vis-à-vis *every product it sells*. Expecting Merck to disclaim half the U.S. market for *all its products* is akin to telling copyright owners they can avoid the deposit obligation for *one work* by abandoning copyright protection *for everything they publish*. That is not a voluntary exchange. It is a stick-up.

For another thing, this opt-out is neither "seamless" nor "transparent." As in *Valancourt*, the "statute itself gives no indication" that withdrawing from Medicare can be readily "effectuate[d]." *Id.* at *10. To the contrary, Congress expressly *blocked* manufacturers from withdrawing without providing up to 23 months' notice—by which point it *would already be too late* to avoid the Program. *See* 42 U.S.C. § 1395w–114a(b)(4)(B)(ii); Merck MSJ Br. 42–43. The Government responds that CMS has found a convoluted way to bypass that statutory limit: If manufacturers want to withdraw, the agency will exercise its own power to "terminate" the manufacturer earlier. Govt. Br. 16–17. The Government developed that workaround "only in the course of litigation," reflecting a "*post hoc*" tactic "by an agency seeking to defend past [congressional] action against attack." *Valancourt*, 2023 WL 5536195, at *11. It stands in evident conflict with the statute—which lays out two *distinct* paths for termination, an onerous one at the manufacturer's request, and a more flexible one when the agency invokes "good cause" to terminate the manufacturer against its will. If nothing else, CMS's reinterpretation—prepared in the shadow of litigation—cannot be deemed "simple, seamless, and transparent." *Id.* at *9.

3. The IRA's all-or-nothing "offer" also violates the anti-coercion principle articulated in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519 (2012) (*NFIB*). The Government there made exactly the same argument as here: Medicaid is "voluntary," so there is no constitutional barrier to "condition[ing]" that federal spending on the States' agreement to expand the program. *See* U.S. Medicaid Br. 22, *NFIB*, 567 U.S. 519 (No. 11-400). The Supreme Court saw it differently.

Spending Clause regulation is only permissible if it is *genuinely* voluntary, not coercive. *NFIB*, 567 U.S. at 578, 581 (choice must be "real," not just "theor[etical]"). The Medicaid expansion was the latter, because it leveraged massive, pre-existing funding streams on which the States had come to rely as a "means of pressuring" the States to accept federal terms that dramatically reshaped the program. *Id.* at 580. As Merck explained in its opening brief, it is hard to imagine a closer analogy to the Program. As in *NFIB*, manufacturers face the loss of *existing* funding streams—*all* Medicare and Medicaid coverage—if they do not bow to new demands. As in *NFIB*, those funding streams are crucial to the manufacturers' viability, leaving them with only the illusion of choice.[6] And as in *NFIB*, the new "conditions" work a fundamental revision to the original bargain.[7] *See* Merck MSJ Br. 39–42.

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[6] The Government's only evidence that a manufacturer could actually escape the IRA's demands is a single news article (hidden behind a paywall). *See* Govt. Br. 15 n.4. But the Government blatantly mischaracterizes the article's contents. It says nothing about whether any manufacturer would or could *withdraw* from Medicare and Medicaid. It simply notes that, because of the IRA, some drug companies may focus on developing medicines that do not prioritize the Medicare population.

[7] Indeed, as the Government's *amici* observe, one of the compromise elements of Medicare Part D was the provision preserving market forces by requiring price negotiations to occur between drug manufacturers and plan sponsors—without any threat of interference by government entities. *See, e.g.*, U.S. Senators Br. 11. In other words, Congress allowed Medicare to amass enormous, monopsonistic market power *only* on condition that it not use that power to disrupt market pricing. Medicare Part D's sponsors called this "noninterference" provision a "fundamental protection" against "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15624 (Nov. 23, 2003) (Sen. Grassley). Without it, the agency's newfound "market power" would enable it to "dictate a price" for "most pharmaceutical products." *Id.* at S15707 (Nov. 24, 2003) (Sen. Santorum). Congress recognized—then—that such "governmental price fixing" would "destroy" industry innovation. *Id.* at S15631 (Sen. Frist). The IRA breaks that fundamental promise—abandoning noninterference for unilateral price controls.

The Government's attempts to cast doubt on this analysis fall flat. It first tries to cabin *NFIB* as protecting only state sovereignty, not other constitutional rights. Govt. Br. 19–20. That is an analytical error. In *NFIB*, the Tenth Amendment and federalism were the reasons why Congress could not order the States *directly* to expand Medicaid; that would have violated the anti-commandeering principle. *See NFIB*, 567 U.S. at 577–78. The second, distinct question was whether Congress was improperly "using financial inducements" to reach that forbidden result—*i.e.*, to "*indirectly* coerce[] a State to adopt a federal regulatory system as its own." *Id.* (emphasis added). The Court's coercion analysis was directed toward that latter question—whether the Spending Clause path amounted to "economic dragooning" that left "no real option but to acquiesce." *Id.* at 578, 582.

In this case, the substantive right is conferred by the Fifth Amendment, not the Tenth; the Takings Clause, not federalism, disables Congress from ordering manufacturers to turn over their property. *Supra* Part II.A. But the next question—whether the Spending Clause lets the Government achieve indirectly what it cannot do directly—is the same. It asks whether "persuasion [has] give[n] way to coercion." *NFIB*, 567 U.S. at 585. That is precisely the inquiry the Supreme Court has applied for a century to evaluate unconstitutional conditions: asking whether constitutional rights have been impaired "by the indirect … process of requiring a surrender, which, though, in form voluntary, in fact lacks none of the elements of compulsion." *Frost & Frost Trucking Co. v. RR. Comm'n of Cal.*, 271 U.S. 583, 593 (1926); *see also Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 607 (2013) (citing *Frost*).

Indeed, these two lines of authority—one focused on spending inducements to cause States to forfeit sovereignty, and the other focused on spending inducements to cause private parties to forfeit constitutional rights—both ask whether "what cannot be done directly because of constitutional restriction cannot be done indirectly." *Pac. Co. v. Johnson*, 285 U.S. 480, 501 (1932). And in both contexts, the Supreme Court has long answered that question by trying to distinguish coercion from voluntary acceptance. *See* Kathleen Sullivan, *Unconstitutional Conditions*, 102 HARV. L. REV. 1413, 1428–34 (1989).[8] This overlap persists. *See, e.g.*, *Cummings v. Premier Rehab Keller, PLLC*, 142 S. Ct. 1562, 1570 (2022) (applying principle that Spending Clause legislation must be "voluntary" in context of private recipients); *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 286-87 (5th Cir. 2005) (en banc) ("the unconstitutional-conditions doctrine … is anchored at least in part in a theory of coercion" and is "part-and-parcel of the standard Spending Clause analysis"); *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002) ("The 'unconstitutional conditions' doctrine is based on the proposition that government incentives may be inherently coercive.").

In the end, the Government never actually defends its view that the *NFIB* coercion analysis depends on the source of the "constitutional restriction" at issue—*e.g.*, federalism or the Fifth Amendment. *Johnson*, 285 U.S. at 501. That *NFIB* dealt with one and not the other is an observation, not an argument.

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[8] *See Frost*, 271 U.S. at 593 ("compulsion"); *Steward Mach. Co. v. Davis*, 301 U.S. 548, 590 (1937) ("undue influence"); *Speiser v. Randall*, 357 U.S. 513, 518–19 (1958) ("coercing"); *United States v. Butler*, 297 U.S. 1, 71 (1936) ("coercion by economic pressure"); *Union Pac. R.R. Co. v. Pub. Serv. Comm'n*, 248 U.S. 67, 70–71 (1918) ("duress"); *Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) ("compulsion").

The Government next argues that *NFIB*'s coercion inquiry does not constrain its actions taken as a "market participant." Govt. Br. 20. Its cited authorities do not support that distinction, however. Most stand for the unremarkable point that States sometimes act as market participants rather than regulators—which matters for some *preemption* doctrines. *See Chamber of Com. of U.S. v. Brown*, 554 U.S. 60, 70 (2008) (NLRA preemption); *Associated Builders & Contractors Inc. v. City of Jersey City*, 836 F.3d 412, 417–18 (3d Cir. 2016) (ERISA preemption). The other cases hold only that States' market activities—as opposed to regulations—lie beyond the reach of the Commerce Clause. *Reeves, Inc. v. Stake*, 447 U.S. 429, 435–37 (1980); *Brooks v. Vassar*, 462 F.3d 341, 358 (4th Cir. 2006). Not one of the Government's cases evaluated a conditional spending program under anything like the *NFIB* coercion test—much less approved anything like the IRA's means of coercion.

In any event, the Government's premise is false; the Program is a patent abuse of sovereign power, not an everyday example of ordinary market participation. Only the Government can impose taxes on counterparties who decline its terms, as the IRA does. Only the Government can legislate its own market dominance, as Congress did by enacting Medicare Part D using its spending authority. And only the Government can punish intransigent counterparties by shutting them out of other markets, as the Program threatens to do. On the Government's own account, antitrust laws prohibit private entities from abusing market power that way. *See* Merck MSJ Br. 47–48. The Program thus represents a potent use of sovereign power. There is no excuse for shielding that use of power from constitutional constraints.

Finally, the Government insists the Program satisfies *NFIB*'s inquiry if that framework applies, because its conditions directly govern the use of the offered funds. Govt. Br. 22–23. Not so. The IRA leverages *all* Medicare and Medicaid spending on Merck's *other* products to extract below-market sales of *one* drug—Januvia. The condition (handing over Januvia at a large discount) has nothing to do with the funds being held hostage (reimbursement for other products sold to federal beneficiaries). Thus, while the Government may impose conditions that "place[] a direct restriction on how a [recipient] uses [the] federal funds," *Gruver v. La. Bd. of Supervisors*, 959 F.3d 178, 183 (5th Cir. 2020), that is not how the IRA operates. The Program does not limit how Merck "uses" the funds it receives for other products that Medicare and Medicaid purchase. It instead ransoms those independent funds to coerce a distinct transaction relating to different products. That is exactly what *NFIB* forbids.

4. Finally, this scheme also runs afoul of the traditional unconstitutional conditions doctrine. In the Takings Clause context, the Supreme Court applies a two-pronged test to evaluate the constitutionality of conditioning a government benefit on forfeiture of a property right: Such a condition can survive only if it has an "essential nexus" to the benefit and is "rough[ly] proportiona[l]" to it. *Dolan v. City of Tigard*, 512 U.S. 374, 391 (1994); *see also Nollan v. Cal. Coastal Comm'n*, 483 U.S. 825, 834–37 (1987). Neither holds true here. Almost by definition, forcing Merck to hand over discounted Januvia has no "essential nexus" to Medicare or Medicaid coverage for *other* products, and leveraging *all* of Medicare and Medicaid to induce a single distinct transaction is the opposite of "proportional."

The Government does not deny that the Program, viewed as a condition, fails the nexus-and-proportionality test. Instead, the Government correctly observes that this test only applies if "the government could not have constitutionally ordered the person asserting the claim to do what it attempted to pressure the person into doing." Govt. Br. 33 (quoting *Koontz*, 570 U.S. at 612). It then says that "predicate is absent here for all the reasons explained above." *Id.* That is sleight of hand. The "reasons explained above" reduce to the notion that the Program is voluntary *because of the option to withdraw from Medicare*. That is a *conditions* argument, so the Government must survive the *conditions* framework. Put another way, the "predicate" is satisfied because the Government could not order Merck to surrender its drugs or pay a fine. *See supra* Parts II.A–C. The only way out is to recast the Program as a condition on Medicare funding, and that implicates the *Nolan-Dollan* framework.

Next, the Government contends that the *Nolan-Dollan* standard governs only in the context of "land-use decisions." Govt. Br. 33. That is demonstrably wrong. In *Cedar Point*, which had nothing to do with zoning, the Government tried to recast a physical taking as a condition on government benefits, and the Court invoked *Nolan-Dollan* to reject that defense. 141 S. Ct. at 2079–80. The Court held that the "nexus and rough proportionality requirements" were the proper "framework" for analyzing whether "the government may require property owners to cede a right of access as a condition of receiving certain benefits, without causing a taking." *Id.* at 2079. That is precisely the question posed here. *Accord Horne*, 576 U.S. at 366 (citing *Nollan* in rejecting effort to characterize raisin appropriation as "voluntary exchange").

The earlier decision in *City of Monterey v. Del Monte Dunes at Monterey, Ltd.*, 526 U.S. 687 (1999), is not to the contrary. *Contra* Govt. Br. 33. Monterey held only that "it was unnecessary for the [Ninth Circuit] to discuss rough proportionality," because the jury instructions "did not mention" that standard, which was "not readily applicable" to a case challenging a "denial of development." 526 U.S. at 703. This case does not challenge denial of development; like *Cedar Point*, it challenges a law that conditions government benefits on the provision of access to property.

Ultimately, however the standard is articulated, the Government cannot deny that a standard exists—regulating by way of spending conditions is not a free pass. And however the standard is framed, the Program fails it. Ransoming distinct and pre-existing funding streams that are critical to an industry's viability to induce the abandonment of other property rights is a paradigmatic unconstitutional condition.

E. The Government's Cases Are Inapposite or Outdated.

The Government relies heavily on a series of out-of-circuit cases describing other Medicare provisions as "voluntary." Those cases cannot bear the weight the Government places on them. They do not immunize all spending conditions from constitutional review—as just explained, that obviously "proves too much." *Horne*, 576 U.S. at 365 (quoting *Loretto*, 458 U.S. at 439 n.17). Rather, these cases merely underscore that the critical question is whether the Program is actually "voluntary" from a constitutional perspective. And answering that question—evaluating whether *this particular government program* is voluntary or coerced—requires applying the frameworks set forth in cases like *NFIB*, *Horne*, and *Nollan-Dolan*.

The cases that the Government cites do not answer that question. Indeed, all but two of them predate the clarifications in *NFIB* and *Horne* of what "voluntary" participation means. *See NFIB*, 567 U.S. at 581 (recognizing that coercive conditions render participation involuntary); *Horne*, 576 U.S. at 365 (denying that ability to leave raisin market rendered participation in program voluntary). And none of the cases discussed *NFIB*'s conditions framework or applied the *Nollan-Dolan* test. *E.g.*, *Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Public Welfare*, 742 F.2d 442, 446-47 (8th Cir. 1984) (applying "substantive due process" test); *Burditt v. HHS*, 934 F.2d 1362, 1376 (5th Cir. 1991) (conducting no scrutiny). Unsurprisingly, some of these cases rest on reasoning that cannot be squared with more recent Supreme Court authority. *Compare*, *e.g.*, *Horne*, 576 U.S. at 365 (power to exit market did not ameliorate coercion), *with Franklin Mem. Hosp. v. Harvey*, 575 F.3d 121, 126 (1st Cir. 2009) (reasoning that hospital could avoid mandate to provide free service by "choos[ing] to stop using its property as a hospital").

In any event, the Government's cases are easily distinguished on their facts; they principally addressed schemes that bear no resemblance to the Program here. Most are plainly irrelevant because they dealt only with ordinary price regulation, not a command to provide property to others. *Bowles v. Willingham*, for example, sustained a price cap imposed on property rentals during World War II, emphasizing the deference accorded to wartime legislation. 321 U.S. 503, 509–10, 517, 519 (1944). But that statute had "no requirement that the apartments in question be used for the purposes which bring them under the Act." *Id.* at 517.

Similarly, a host of the cited cases featured objections to particular Medicare reimbursement rates—federal law did not mandate the provision of goods or services. *See Garelick*, 987 F.2d at 916–17; *Whitney v. Heckler*, 780 F.2d 963, 972 (11th Cir. 1986); *St. Francis Hosp. Ctr. v. Heckler*, 714 F.2d 872, 874–75 (7th Cir. 1983) (per curiam); *Se. Ark. Hosp., Inc. v. Burwell*, 815 F.3d 448, 449–50 (8th Cir. 2016); *see also Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1279–80 (11th Cir. 2014) (mandate imposed by Florida law, but plaintiff sued only federal defendants). Indeed, *Garelick* recognized that the Takings Clause requires compensation where companies "are compelled to employ their property to provide services to the public"; those just were not the facts in that case. 987 F.2d at 916. Here, by contrast, the IRA mandates that manufacturers turn over their property, under threat of either paying a tax penalty or being cut off from Medicare and Medicaid altogether.[9]

Even if these cases were legally on point and correctly decided, they still do not imply that the Program is constitutional. After all, *NFIB*'s coercion test and *Nollan-Dolan*'s proportionality test are fact-intensive. This case involves unprecedented, stark facts: (1) threatened exclusion from half a national market, (2) draconian penalties, (3) extreme demands that effectively constitute a new program, and (4) a dramatic change that upended reliance on earlier congressional promises.

[9] Even more irrelevant is *Baptist Hospital East v. HHS*, which involved a hospital's bid to obtain Medicare reimbursements for services it *voluntarily* provided *for free* to *non-Medicare* patients. 802 F.2d 860, 862, 869–70 (6th Cir. 1986) (denying "any obligation by the federal government to allay a part of [a hospital's] financial burden resulting from bad debts and acts of charity").

None of the Government's cases involved such extremes. The plaintiff in *Baker County*, for example, challenged a relatively modest condition—the obligation to treat federal prisoners at Medicare rates—that had been on the books for decades before the challenge. *Baker*, 763 F.3d at 1276; *see also Gruver*, 959 F.3d at 184 (suggesting voluntariness is more likely when condition has existed for decades). The outcry that the Program here has elicited from the affected manufacturers is a telling refutation of the supposed analogies to prior, routine Medicare terms and conditions.

* * *

In the end, Merck's Takings Clause claim is simple. The IRA demands that Merck "provide access" to its drugs for less than fair market value. The Government tries to distract with the claim that manufacturers have other "options." But both the Supreme Court and D.C. Circuit have rejected similar illusory "options" before. Without judicial relief, Merck has only one real choice: submit to the Government's demand to turn over its property for less than it is worth. And that is precisely what the IRA was designed to accomplish—a reality only highlighted by the campaign of Government-boosting *amici* who praise the Program's supposed policy merits (while ignoring its innovation-killing impacts). There are many ways to advance the policy goal of reducing drug prices, but the Constitution imposes constraints. The Program crosses the constitutional line, as Merck has demonstrated, the Government fails to rebut, and its *amici* ignore. This Court should see past the Government's revisionism and recognize the Program for what it is: a classic *per se* taking without just compensation.

III. THE PROGRAM COMPELS MERCK TO SPEAK IN SERVICE OF AN IDEOLOGICAL AGENDA.

Had Congress merely wanted to compel discounted drug sales to Medicare, it could have authorized CMS to set prices and ordered manufacturers to provide access to their drugs at those prices. That would have been *economically* equivalent to the Program. But not *politically* equivalent. Instead, Congress routed those obligations through "agreements" the manufacturers are compelled to sign, characterizing CMS's prices as "maximum fair prices" reached through "negotiation." None of that is true, and Merck agrees with none of it, but is compelled to sign on pain of economic ruin. That charade lets the Government pretend the Program is a politically popular negotiation rather than a politically toxic socialization of prescription drugs.

The IRA's unprecedented mandate to sign these "agreements" or face penalties compels speech in violation of the First Amendment. The Government does not argue that this scheme passes muster under any form of heightened scrutiny; indeed, it articulates no interest that could possibly justify the IRA's compulsion of speech. Instead, the Government denies that signing the "agreement" involves speech at all. But by forcing manufacturers to sign on the dotted line, the Program compels expression *directly*—there is nothing "incidental" about it.

The Government next falls back to its refrain that the Program is voluntary because manufacturers can withdraw from Medicare and Medicaid. But beyond all the points discussed above, the Supreme Court has made clear that federal spending can *never* be conditioned on compelled speech. Requiring Merck to peddle a contested political narrative is unconstitutional—full stop.

A. The Government Cannot Conscript Manufacturers To Conceal the Program's Nature.

1. The Government first argues that the Program impacts speech only in an "incidental" way. Govt. Br. 29. It analogizes to "run-of-the-mill price regulation," which forbids certain transactions and thus incidentally limits speech proposing or facilitating those transactions. *Id.* There is no comparison. Congress did not impose price caps, with indirect implications for manufacturers' speech. It *directly mandated* that manufacturers express assent to purported "agreements" *about* the Program's prices, their "fairness," and the process by which they were reached. Whereas price regulations regulate *prices* (conduct), the IRA compels *agreements* (speech).

Thus, while it is certainly true that "the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech," *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 567 (2011), that principle has no application here. It applies only where the law regulates conduct but affects speech downstream. In the classic examples, anti-discrimination laws incidentally prohibit "White Applicants Only" signs, and bans on "outdoor fires" incidentally forbid flag-burning. *Id.* Likewise, "typical price regulation" regulates the "seller's conduct" by placing certain prices off-limits—affecting speech "indirectly" by barring the offering or advertising of those prices. *Expressions Hair Design v. Schneiderman*, 581 U.S. 37, 47 (2017). In all these cases, it is the non-speech conduct that is regulated (racial discrimination; starting fires; charging illicit prices); speech is burdened incidentally, only insofar as it effectuates the forbidden conduct. Such laws do not directly "dictate the content of the speech *at all*." *FAIR*, 547 U.S. at 62 (emphasis added).

The IRA does. It requires a manufacturer to represent "agree[ment]" with the "maximum fair price" set by HHS. 42 U.S.C. § 1320f–2(a). Indeed, the Government admits that the "agreement" itself is "the core mechanism" of the Program and the "source of the enforceable obligation for manufacturers to ultimately provide their drugs at the negotiated prices." Govt. Br. 34. This is therefore the *inverse* of the classic "incidental" cases, where conduct is regulated and speech is only indirectly affected. Here, the Program directly compels speech (the agreement), and that speech incidentally affects conduct (by accepting the obligation to provide the drugs). Again, Congress did not merely cap drug prices and thereby effectively limit Merck's speech or contracts as a practical consequence. Rather than simply place certain prices off-limits, Congress ordered manufacturers to speak *about* the prices HHS imposes—to express "agree[ment]" to those prices, admit they are "fair," and describe them as the product of "negotiation." Unlike routine price caps, laws so directly "regulating the *communication* of prices" have speech as their *object*, and thus merit heightened First Amendment scrutiny. *Expressions Hair*, 581 U.S. at 48 (emphasis added).

Notwithstanding the Government's fearmongering, Merck's position thus does not imply that "*any* price control" prohibits sellers "from expressing the idea that its products are worth more." Govt. Br. 31. Again, that would be a price regulation with incidental speech effects. The Program is instead a direct speech compulsion with incidental price effects. And there is nothing "run-of-the-mill" about it—indeed, the Government fails to identify *any other scheme* that works like this. It appears to be completely unprecedented in this regard.

For the same reasons, the cases the Government cites are inapposite. It rests heavily on *Nicopure Labs, LLC v. FDA*, 944 F.3d 267 (D.C. Cir. 2019), but the statute there banned distribution of free samples of certain tobacco products. *Id.* at 290. That is conduct, not speech; at most, the statute incidentally prohibited offering the product for the price of $0 (*i.e.*, proposing an illicit transaction). *See id.* at 291; *see also Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, 731 F.3d 71, 78 (1st Cir. 2013) (reasoning similarly that First Amendment does not protect "offers to engage in banned activity"). As explained, the IRA is fundamentally different. Merck claims no open-ended right to advertise prices or propose transactions; it only seeks relief from Congress's demand that it sign an "agreement" that conveys a string of deceptive messages *about* the agency-mandated prices. *Nicopure* did not consider—much less endorse—anything like that. Meanwhile, when HHS tried to force tobacco companies to disseminate controversial government messages, the D.C. Circuit promptly held that its regime flouted the First Amendment. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1211-12 (D.C. Cir. 2012).

Nor do the Government's other cases help it. In *FAIR*, the Supreme Court held that providing military recruiters with equal access to campus did not compel speech. 547 U.S. at 62. Again, that was *conduct*. But suppose the Solomon Amendment had forced schools to post fliers on the quad declaring the military to be a "qualified employer" who would visit pursuant to an "agreement" with the Pentagon. Because that law would have "dictate[d] the content of the speech"—and done so intentionally to give credence to the military—the Court would have struck it down. *Id.*

2. Pivoting slightly, the Government suggests that even if the IRA directly compels manufacturers to sign "agreements," those documents are not "expressive" and thus do not implicate the First Amendment. *See* Govt. Br. 29, 32. That is not a credible position. The agreements plainly convey a message: Manufacturers literally sign on the dotted line, expressing assent to a "fair price" they supposedly "agree" to following "negotiation." That clearly qualifies as speech under the First Amendment. Indeed, the agreement's expressive force—and its political value to the Government—is the only conceivable reason for structuring the Program this unusual way.

To state the obvious, the "creation and dissemination of information are speech within the meaning of the First Amendment." *Sorrell*, 564 U.S. at 570. Indeed, "if the acts of 'disclosing' and 'publishing' information do not constitute speech, it is hard to imagine what does fall within that category." *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001). Thus, while First Amendment "protection does not *end* at the spoken or written word," it certainly *starts* there. *Texas v. Johnson*, 491 U.S. 397, 404 (1989) (emphasis added). Consistent with that, the Supreme Court has deemed all manner of written information "speech"—regardless of its form or function. *E.g.*, *Sorrell*, 546 U.S. at 570 ("sales, transfer, and use of prescriber-identifying information"); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 481 (1995) ("information on beer labels"); *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 759 (1985) (plurality op.) (credit reports). Of particular note, the Court has recognized that "an individual's signature will express" the messages conveyed, expressly or implicitly, by what he signs. *John Doe No. 1 v. Reed*, 561 U.S. 186, 194–95 (2010).

Under those standards, the IRA's signed "agreements" are clearly expressive. They consist of "written word[s]" attributed to Merck (*Johnson*, 491 U.S. at 404), and "publish[] information" about Merck's participation in the Program (*Vopper*, 532 U.S. at 527), to "disseminat[e]" it to the public (*Sorrell*, 564 U.S. at 570). Moreover, the agreements are plainly "inten[ded] to convey a particularized message." *Spence v. Washington*, 418 U.S. 405, 410–11 (1974) (per curiam). The 12-page Template Agreement authored by CMS calls itself an "Agreement" nearly 50 times, and states over 20 times that Merck and the Government have or will "agree" on various matters. *See* ECF 23–6 (Template Agreement). The document's communicative intent could not be clearer: to (mis)inform the public that Merck and CMS "agreed" on a negotiated "maximum fair price" through a voluntary process of "negotiations."

That the IRA's agreements are legally binding does not make them less than expressive. *See Reed*, 561 U.S. at 195 ("[W]e do not see how adding … legal effect to an expressive activity somehow deprives that activity of its expressive component, taking it outside the scope of the First Amendment."). Nor does it matter that the agreements also include some *factual* information about Merck's legal obligations. *See Riley v. Nat'l Fed'n of the Blind*, 487 U.S. 781, 797–98 (1988); *Sorrell*, 564 U.S. at 570. The IRA's compelled agreements are not purely "factual," anyway, because they do not merely require a manufacturer to acknowledge that the Program's rules *exist*. Instead, the IRA forces manufacturers to represent *agreement* to those mandates—including the "maximum fair prices" dictated by HHS. Merck's statutory obligation is, regrettably, a fact. But its "agreement" is pure fiction.

The Government trumpets Merck's observation that "most ordinary contracts do not express views or convey beliefs." Govt. Br. 29. But as Merck explained, *some* commercial agreements *do* carry expressive weight. *See* Merck MSJ Br. 29–30 (citing *New Hope Family Servs., Inc. v. Poole*, 966 F.3d 145, 177–78 (2d Cir. 2020)). The Government offers no rebuttal, instead blithely depicting the Program's agreements as "ordinary" contracts. Govt. Br. 29. Hardly. Typical contracts simply memorialize the terms of arm's-length transactions—not "agree" to disputed political value judgments. The IRA's "agreements" are unique, indeed unprecedented, in purporting to conceal government mandates as voluntarily assumed commitments.

And that is exactly their purpose. The Government protests that Merck has not proven as much. Govt. Br. 31. But the proof is in the pudding: The IRA's backers continue to rely on this deceit to cast the Program as one of voluntary negotiations between consenting parties. Indeed, immediately after the first ten manufacturers signed the IRA's "agreements"—their only viable choice—the Government used those coerced signatures to promote its political narrative. In an Oval Office video, the President crowed that manufacturers "are coming to the negotiating table," and the White House announced that all ten had "signed agreements to participate."[10] Media outlets dutifully parroted the same deceptive message: "The manufacturers of 10 expensive medications have *agreed to negotiate* with the federal government for lower

[10] President Biden, X (Oct. 3, 2023, 8:05 AM), https://twitter.com/POTUS/status/1709177956285759844?s=20; The White House, *Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program* (Oct. 3, 2023) (emphasis added).

prices." Michael D. Shear, *Drug Makers Agree to Negotiate With Medicare on Prices of 10 Medications*, N.Y. TIMES, Oct. 3, 2023 (emphasis added). Transparently, Congress and the Executive compelled speech to score political points.

The Government fails to offer *any other explanation* for the Program's sham "agreements." It would have been easy for Congress to provide that manufacturers "shall not" charge certain prices. Instead, it imposed an unprecedented obligation to feign "agree[ment] with the Government's policy." *Agency for Int'l Dev. v. All. For Open Soc'y Int'l, Inc.*, 570 U.S. 205, 213 (2013). The Government's *amici* unwittingly explain why, trotting out polls showing broad support for "Medicare negotiating with drug companies to lower prescription drug prices." AARP Br. 11. The IRA's façade facilitates that framing. But enlisting regulated entities in a PR campaign on behalf of their regulators strikes at the heart of the First Amendment.

3. Once again, the agency has tried to mitigate the statute's constitutional defect, in this instance by tucking a "disclaimer" into the Template Agreement. Govt. Br. 30. Once again, the effort is futile. The IRA itself is the source of the compelled speech here. Congress designed the Program to hinge on "agree[ments]" to negotiate, identify, and offer "maximum fair price[s]." 42 U.S.C. § 1320f–2(a). That is the "core mechanism" of the Program (Govt. Br. 34), and that original sin inevitably permeates its implementation—regardless of inconsistent bureaucratic argle-bargle.

In all events, the law is clear that compelled speech cannot be cured by ordering the speaker to incant *additional* language disclaiming the message he has been forced to transmit. Merck MSJ Br. 28–29; *see also Telescope Media Grp. v. Lucero*, 936 F.3d

740, 757 (8th Cir. 2019); *Frudden v. Pilling*, 742 F.3d 1199, 1205 (9th Cir. 2014); *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). The Government ignores all of this law and simply insists that the disclaimer merely "emphasize[s] an already obvious point." Govt. Br. 31 n.12. Of course, if that were true, CMS would have saved its breath. Regardless, the parties appear to agree that the disclaimer should play no role in the Court's First Amendment analysis—either it does not solve the problem (Merck's view) or there is no problem to solve (the Government's view).

In a similar vein, the Government argues that the Program does not impair the marketplace of ideas because Merck can share its own perspective with the public. Govt. Br. 32–33. The Government cites no precedent for its assertion that counter-speech would cure a speech compulsion—and for good reason. That would be true in *every* compelled speech case. The Supreme Court's foundational compelled speech cases would then make no sense. After all, as the dissent in *Wooley v. Maynard* noted, New Hampshirites were free to "disavow" the State's motto using "a conspicuous bumper sticker." 430 U.S. 705, 722 (1977) (Rehnquist, J., dissenting). Likewise, an employee could erect a sign explaining that his dues should not be understood as endorsements of union viewpoints. *But see Knox*, 567 U.S. at 309. Even still, the Supreme Court has long held that the First Amendment protects each American's right to "decide for himself or herself the ideas and beliefs deserving of expression," *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994), and to "present their message[s] undiluted by views they d[o] not share," *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023). The Program's staged "agreements" thus violate the First

Amendment's compelled speech doctrine even if Merck remains free to issue a self-serving press release explaining away its signature on the dotted line.

In short, the Government's solutions are part of the problem—Congress cannot "require speakers to affirm in one breath that which they deny in the next." *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 (1986) (plurality op.).

B. Federal Funds Cannot Be Conditioned on Compelled Speech.

In the end, the Government retreats again to its all-purpose defense of the IRA: voluntary participation. Govt. Br. 34–35, 39. As Merck has explained, compliance with the Program is coerced, not voluntary. *Supra* Part II. The Government cannot evade First Amendment scrutiny of the IRA's speech compulsion, just as it cannot evade Fifth Amendment scrutiny of the IRA's forced sale requirements.

Even if the Program could be deemed "voluntary" for Takings Clause purposes, however, the First Amendment is more demanding. Merck MSJ Br. 44. The Supreme Court has "broadly rejected the validity of limitations on First Amendment rights as a condition to the receipt of a governmental benefit." *Elrod v. Burns*, 427 U.S. 347, 359 (1976) (plurality op.). In particular, Congress may *never* use funding conditions to "requir[e] recipients to profess a specific belief" or express "the Government's view on an issue of public concern." *All. for Open Soc'y*, 570 U.S. at 218. Such conditions are unconstitutional even where the funding offer is not "actually coercive, in the sense … that [it] cannot be refused." *Id.* at 214. Accordingly, even if Merck *did* have a realistic path to escape the Program, the IRA's regime of compelled agreements would remain unconstitutional and must be enjoined.

The Government responds by citing the line of authority holding that Congress does not violate the First Amendment by declining to subsidize private speech. Govt. Br. 34; *Regan v. Tax'n With Representation*, 461 U.S. 540, 545 (1983). That principle lets Congress "define the limits of [a] ... spending program" by attaching conditions that "specify the activities Congress wants to subsidize." *All. for Open Soc'y*, 570 U.S. at 214–15. So, for example, Congress may support "family planning projects" without equally funding projects that encourage abortion. *Rust v. Sullivan*, 500 U.S. 173, 178, 196–99 (1991). And Congress can grant tax-exempt status to charitable non-profits without also offering that implicit subsidy to lobby groups. *Regan*, 461 U.S. at 544. Simply put, Congress's choices about which activities to *support* do not burden the speech rights of those whose activities it *leaves out*.

That principle does not permit *compelled* speech, and has never been deployed to do so. *See Evergreen Ass'n, Inc. v. City of New York*, 740 F.3d 233, 250–51 (2d Cir. 2014). Nor does it apply on its own terms. The IRA is not a tailored subsidy of *speech*. It amends Medicare—a program that subsidizes *prescription drugs*—to require that funding recipients express "the Government's view[s]" on new pricing mandates. *All. for Open Soc'y*, 570 U.S. at 218. "[B]y its very nature," that kind of condition "goes beyond defining the limits of [a] federally funded program." *Id.* Indeed, an IRA that imposed price caps and compelled sales without a sham "agreement" requirement would result in the exact same level of federal spending—proving that this regime has no logical connection to delimiting the Government's spending choices. It instead is a mechanism to defuse political opposition to those spending choices.

The Government tries to water down the First Amendment test by asserting that "conditions on speech" are valid if they "pertain to the nature of the government program." Govt. Br. 34. But that is an overbroad articulation of the rule: "Congress cannot recast a condition on funding as a mere definition of its program in every case, lest the First Amendment be reduced to a simple semantic exercise." *Legal Servs. Corp. v. Velazquez,* 531 U.S. 533, 547 (2001). After all, "the definition of a particular program can always be manipulated to subsume the challenged condition." *All. for Open Soc'y*, 570 U.S. at 215. If Congress limited Affordable Care Act subsidies to individuals who agreed to put "I love Obamacare" bumper stickers on their cars, the condition would similarly "pertain to the nature of the government program," but that would obviously constitute an impermissible effort to leverage federal funding to coerce political speech.

The Government tries a similar (and similarly ineffective) manipulation here, pointing out that the compelled "agreements" are central to operation of the Program. Govt. Br. 34–35. They are, but that does not change the reality that the agreements do not function to constrain how federal funds are spent; they function to secure the appearance of consent to an agency-dictated process and price. Simply embedding a speech compulsion in a spending scheme does not immunize it from First Amendment scrutiny. And, viewed as a "condition," the Program's "agreement" mandate fails that scrutiny. This Court should therefore enjoin it.

CONCLUSION

The Court should deny the Government's motion for summary judgment and instead enter judgment for Merck and grant its requested relief.[11]

Dated: October 19, 2023

Respectfully submitted,

/s/ Jacob ("Yaakov") M. Roth
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[11] In a footnote, the Government purports to reserve its right to file additional briefing on "the appropriate scope of remedy" if the Court rules in Merck's favor. Opp. 35 n.14. That is improper. Merck sought summary judgment and explained why it was entitled to declaratory and injunctive relief. The Government had ample space in its opposition to make any arguments about the scope of remedy. By failing to do so, the Government has waived any such arguments.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC., and MERCK SHARP & DOHME LLC, Plaintiffs, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services, *et al.* Defendants.	Civ. No. 1:23-01615 (CKK)

SUPPLEMENTAL DECLARATION OF PATRICK T. DAVISH

I, Patrick T. Davish, declare as follows pursuant to 28 U.S.C. § 1746:

1. Merck Sharp & Dohme LLC ("MSD") is a wholly owned subsidiary of Merck & Co., Inc. Merck & Co., Inc. is the parent, holding company for the Merck group of legal entities, which includes MSD. MSD is the primary U.S. operating company for Merck & Co., Inc. I am an employee of MSD; my title is Associate Vice President, Global Market Access.

2. On June 27, 2023, I executed a declaration in support of the Motion for Summary Judgment filed by Merck & Co., Inc. in its constitutional challenge to the Inflation Reduction Act ("IRA"). In that declaration, I explained how the regulatory burdens of the IRA's Drug Price Negotiation Program (the "Program") will affect Merck's operations and ability to research, develop, and market innovative new products.

3. On June 30, 2023, the Centers for Medicare & Medicaid Services ("CMS") issued new guidance on the Program's implementation (the "Revised Guidance"). *See* ECF 23-5. The Revised Guidance announced a new definition of the statutory term "manufacturer" for purposes of the Program's "negotiation" and "agreement"

requirements. In relevant part, CMS defined "manufacturer" as "the entity that holds the [New Drug Application ('NDA')] for the selected drug." Revised Guidance at 118.

4. CMS and Merck & Co., Inc. are parties to a Medicaid National Drug Rebate Agreement, a true and correct copy of which is attached to this declaration as Exhibit A. That agreement is "[b]etween the Secretary of Health and Human Services ... and the Manufacturer." Exh. A. at 1. The agreement names Merck & Co., Inc. as the "manufacturer," and Merck & Co., Inc. signed the agreement. *See id.* at 1, 9.

5. On August 29, 2023, CMS published the list of drugs selected for the Program's initial round of "negotiations." *See* Dep't of Health & Human Servs., *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023). Januvia is among the selected drugs. MSD holds the NDA for Januvia.

6. My initial declaration expressed (and was intended to express) my personal knowledge of how the Program will affect both Merck & Co, Inc. and its wholly-owned operating subsidiary, MSD. All representations in my initial declaration about the Program's operation and effects on Merck & Co., Inc. likewise describe (and were intended to describe) its operation and effects on MSD. Moreover, all representations in my initial declaration about Merck & Co., Inc.'s views regarding the Program, its operation, and its prices likewise describe (and were intended to describe) MSD's views. I provide this supplemental declaration to clarify the scope of my initial declaration in this regard.

I declare under penalty of perjury that the foregoing is true and correct.

Executed: 10/17/23

Patrick T. Davish

EXHIBIT A

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

National Drug Rebate Agreement
Between the Secretary of Health and Human Services
(Hereinafter referred to as "the Secretary") and the Manufacturer

The Secretary, on behalf of the U.S. Department of Health and Human Services and all states which have a Medicaid State Plan approved under 42 U.S.C. 1396a, and the manufacturer, on its own behalf, for purposes of section 1927 of the Social Security Act ("the Act"), 42 U.S.C. 1396r-8, hereby agree to the following:

I. Definitions

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act and implementing Federal regulations, as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" will have the meaning set forth in section 1927(k)(1) of the Act as implemented by 42 CFR 447.504.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by the Food and Drug Administration (FDA) after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" will have the meaning set forth in sections 1927(c)(2)(A)(ii)(II) and 1927(c)(2)(B) of the Act.

(d) "Best Price" will have the meaning set forth in section 1927(c)(1)(C) of the Act as implemented by 42 CFR 447.505.

(e) "Bundled Sale" will have the meaning set forth in 42 CFR 447.502.

(f) "Centers for Medicare & Medicaid Services (CMS)" means the agency of the U.S. Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) "Consumer Price Index-Urban (CPI-U)" will have the meaning set forth in 42 CFR 447.502.

(h) "Covered Outpatient Drug" will have the meaning set forth in sections 1927(k)(2), (k)(3) and (k)(4) of the Act as implemented by 42 CFR 447.502.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(ii) of the Act as implemented by 42 CFR 447.502.

(k) "Manufacturer" will have the meaning as set forth in section 1927(k)(5) of the Act as implemented by 42 CFR 447.502.

(l) "Marketed" means that a covered outpatient drug is available for sale by a manufacturer in the states.

(m) "Monthly AMP" will have the meaning as set forth in 42 CFR 447.510.

(n) "Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(i) of the Act as implemented by 42 CFR 447.502.

(o) "National Drug Code (NDC)" will have the meaning as set forth in 42 CFR 447.502.

(p) "Non-innovator Multiple Source Drug" will have the meaning as set forth in section 1927(k)(7)(A)(iii) of the Act as implemented by 42 CFR 447.502.

(q) "Quarterly AMP" will have the meaning as set forth in 42 CFR 447.504.

(r) "Rebate period" will have the meaning as set forth in section 1927(k)(8) of the Act as implemented by 42 CFR 447.502.

(s) "Secretary" means the Secretary of the U.S. Department of Health and Human Services, or any successor thereto, or any officer or employee of the U.S. Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated. In this agreement, references to CMS indicate such successor authority.

(t) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(u) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(v) "Single Source Drug" will have the meaning set forth in section 1927(k)(7)(A)(iv) of the Act as implemented by 42 CFR 447.502.

(w) "State Drug Utilization Data" means the total number of both fee-for-service (FFS) and managed care organization (MCO) units of each dosage form and strength of the manufacturer's covered outpatient drugs dispensed and/or paid for, as applicable during a rebate period under a Medicaid State Plan, other than units dispensed to Medicaid beneficiaries that were purchased by covered entities through the drug discount program under section 340B of the Public Health Service Act; state utilization data is supplied on the CMS-R-144 form (OMB control number: 0938-0582) (that is, the state rebate invoice).

(x) "States" will have the meaning as set forth in 42 CFR 447.502.

(y) "State Medicaid Agency" means the agency designated by a state under sections 1902(a)(5) and 1927(k)(9) of the Act to administer or supervise the administration of the Medicaid program.

(z) "Unit" means drug unit in the lowest dispensable amount. The manufacturer will specify the unit information associated with each covered outpatient drug per the instructions provided in CMS-367c (OMB control number 0938-0578).

(aa) "Unit Rebate Amount (URA)" means the computed amount to which the state drug utilization data is applied by states in invoicing the manufacturer for the rebate payment due.

(bb) "United States" will have the meaning as set forth in 42 CFR 447.502.

(cc) "Wholesaler" will have the meaning as set forth in section 1927(k)(11) of the Act as implemented by 42 CFR 447.502.

II. Manufacturer's Responsibilities

In order for the Secretary to authorize that a state receive payment for the manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the manufacturer agrees to the requirements as implemented by 42 CFR 447.510 and the following:

(a) The manufacturer shall identify an individual point of contact for the Legal, Invoice, and Technical contacts at a United States address to facilitate the necessary communications with states with respect to rebate invoice issues.

(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by 42 CFR 447.510. Furthermore, except as provided under section V.(b). of this agreement, manufacturers are required to calculate a URA and make a rebate payment in accordance with each calculated URA to each State Medicaid Agency for the manufacturer's covered outpatient drug(s) by NDC paid for by the state during a rebate period. CMS may calculate a URA based on manufacturer-submitted product and pricing data and provide the URA to states in order to facilitate rebate billing. However, CMS's URA calculation does not relieve the manufacturer of its responsibility to calculate the URA.

(c) In accordance with the specifications pursuant to Office of Management and Budget (OMB)-approved CMS-367c form, report all covered outpatient drugs and corresponding drug product, pricing, and related data to the Secretary, upon entering into this agreement. This information is to be updated as necessary to include new NDCs and updates to existing NDCs. CMS uses drug information listed with FDA, such as Marketing Category and Drug Type, to be able to verify that an NDC meets the definition of a covered outpatient drug, therefore, manufacturers should ensure that their NDCs are electronically listed with FDA. Reports to CMS should include all applicable NDCs identifying the drug product which may be dispensed to a beneficiary, including package NDCs (outer package NDCs and inner package NDCs).

(d) Beginning with the effective date quarter and in accordance with the specifications pursuant to OMB-approved CMS-367a form (OMB control number 0938-0578), report quarterly pricing data to the Secretary for all covered outpatient drugs in accordance with 42 CFR 447.510. This includes reporting for any package size which may be dispensed to the beneficiary. The manufacturer agrees to provide such information not later than 30 days after the end of each rebate period beginning with the effective date quarter. Adjustments to all prior quarterly pricing data must be reported for a period not to exceed 12 quarters from when the pricing data were originally due as required under 42 CFR 447.510(b).

(e) In accordance with the OMB-approved CMS-367b form (OMB control number 0938-0578), report information including monthly AMPs and monthly AMP units for all covered outpatient drugs in accordance with 42 CFR 447.510. The manufacturer agrees to provide such information not later than 30 days after the end of the month of the effective date, and not later than 30 days after the end of each month thereafter.

(f) Except as provided under V.(b)., to make rebate payments not later than 30 days after receiving the state rebate invoice. The manufacturer is responsible for timely payment of the rebate within 30 days so long as the state invoice contains, at a minimum, the number of units paid by NDC in accordance with 1927(b)(1) of the Act. To the extent that changes in product, pricing, or related data cause increases to previously-submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice. To the extent that changes in product, pricing, or related data cause decreases to previously-submitted total rebate amounts, the manufacturer should communicate with the states regarding where to apply the line-item (NDC-level) credit.

(g) To comply with the conditions of 42 U.S.C. section 1396r-8, changes thereto, implementing regulations, agency guidance and this Agreement.

(h) In accordance with 1927(a)(1) of the Act, rebate agreements between the Secretary and the manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall have a mandatory effective date equal to the first day of the rebate period that begins more than 60 days after the date the agreement is entered into. Rebate agreements entered into on or after November 29, 1999 will also have an effective date equal to the date the rebate agreement is entered into that will permit optional state coverage of the manufacturer's NDCs as of that date.

(i) To obtain and maintain access to the system used by the Medicaid Drug Rebate program, use that system to report required data to CMS, and ensure that their contact information is kept updated as required in the OMB-approved CMS-367d form (OMB control number 0938-0578).

(j) To continue to make a rebate payment on all of its covered outpatient drugs for as long as an agreement with the Secretary is in force and state utilization data reports that payment was made for that drug, regardless of whether the manufacturer continues to market that drug. If there are no sales by the manufacturer during a rebate period, the AMP and best price reported in the prior rebate period should be used in calculating rebates.

(k) To keep records (written or electronic) of the data and any other material from which the

calculations of AMP and best price were derived in accordance with 42 CFR 447.510, and make such records available to the Secretary upon request. In the absence of specific guidance in section 1927 of the Act, federal regulations and the terms of this agreement, the manufacturer may make reasonable assumptions in its calculations of AMP and best price, consistent with the purpose of section 1927 of the Act, federal regulations and the terms of this agreement. A record (written or electronic) explaining these assumptions must also be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR 447.510, and such records must be made available to the Secretary upon request.

(l) To notify CMS of any filing of bankruptcy, and to transmit such filing to CMS within seven days of the date of filing.

III. Secretary's Responsibilities

(a) The Secretary will employ best efforts to ensure the State Medicaid Agency shall report to the manufacturer, not later than 60 days after the last day of each rebate period, the rebate invoice (CMS-R-144) or the minimum utilization information as described in section II.(f). of this agreement, that is, information about Medicaid utilization of covered outpatient drugs that were dispensed and/or paid for, as applicable, during the rebate period. Additionally, the Secretary will expect any changes to prior quarterly state drug utilization data to be reported at the same time.

(b) The Secretary may survey those wholesalers and manufacturers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as set forth in section 1927(b)(3)(B) of the Act and section IV of this agreement.

(c) The Secretary may audit manufacturer information reported under section 1927(b)(3)(A) of the Act.

IV. Penalty Provisions

(a) The Secretary may impose a civil monetary penalty under section III.(b)., as set forth in 1927(b)(3)(B) of the Act and applicable regulations, on a wholesaler, manufacturer, or direct seller of a covered outpatient drug, if a wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request by the Secretary, or the Secretary's designee, for information about covered outpatient drug charges or prices in connection with a survey or knowingly provides false information, including in any of its quarterly reports to the Secretary. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B) of the Act and applicable regulations.

(b) The Secretary may impose a civil monetary penalty, for each item of false information as set forth in 1927(b)(3)(C)(ii) of the Act and applicable regulations.

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, best price or base date AMP. The amount of the penalty shall be determined as set forth in 1927(b)(3)(C)(i) of the Act and applicable regulations.

(d) Nothing in this Agreement shall be construed to limit the remedies available to the United States government or the states for a violation of this Agreement or any other provision of law.

V. Dispute Resolution

(a) In the event a manufacturer discovers a potential discrepancy with state drug utilization data on the rebate invoice, which the manufacturer and state in good faith are unable to resolve prior to the payment due date, the manufacturer will submit a Reconciliation of State Invoice (ROSI) form, the CMS-304 (OMB control number: 0938-0676), to the state. If such a discrepancy is discovered for a prior rebate period's invoice, the manufacturer will submit a Prior Quarter Adjustment Statement (PQAS) form, CMS-304a (OMB control number: 0938-0676), to the state.

(b) If the manufacturer disputes in good faith any part of the state drug utilization data on the rebate invoice, the manufacturer shall pay the state for the rebate units not in dispute within the required due date in II.(f). Upon resolution of the dispute, the manufacturer will either pay the balance due, if any, plus interest as set forth in section 1903(d)(5) of the Act, or be issued a credit by the state by the due date of the next quarterly payment in II.(f).

(c) The state and the manufacturer will use their best efforts to resolve a dispute arising under (a) or (b) above within a reasonable time frame after the state's receipt of the manufacturer's ROSI/PQAS. In the event that the state and manufacturer are not able to resolve the dispute within a reasonable time frame, CMS will employ best efforts to ensure the state makes available to the manufacturer the same state hearing mechanism available to providers for Medicaid payment disputes (42 CFR 447.253(e)).

(d) Nothing in this section shall preclude the right of the manufacturer to audit the state drug utilization data reported (or required to be reported) by the state. The Secretary encourages the manufacturer and the state to develop mutually beneficial audit procedures.

(e) The state hearing mechanism is not binding on the Secretary for purposes of the Secretary's authority to implement the civil money penalty provisions of the statute or this agreement.

VI. Confidentiality Provisions

(a) Pursuant to section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the manufacturer in connection with this agreement is confidential and, notwithstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the manufacturer, or prices charged by the manufacturer, except as authorized under section 1927(b)(3)(D).

(b) The manufacturer will hold state drug utilization data confidential. If the manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the manufacturer will observe confidentiality statutes, regulations, and other properly promulgated policy concerning such data.

(c) Notwithstanding the nonrenewal or termination of this agreement for any reason, these confidentiality provisions will remain in full force and effect.

VII. Nonrenewal and Termination

(a) Unless otherwise terminated by either party pursuant to the terms of this agreement, the agreement shall be effective beginning on the date specified in section II.(h). of this agreement and shall be automatically renewed for additional successive terms of one year from the date specified in section II.(h)., unless the manufacturer gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) In accordance with section VII.(a). of this agreement and section 1927(b)(4)(B)(ii) of the Act, the manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer.

The Secretary may terminate the agreement for failure of a manufacturer to make rebate payments to the state(s), failure to report required data, for other violations of this agreement, or other good causes upon 60 days prior written notice to the manufacturer of the existence of such violation or other good causes. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(c) Manufacturers on the Office of Inspector General's (OIG's) List of Excluded Individuals/Entities (Exclusion List) will be subject to immediate termination from the Medicaid drug rebate program unless and until the manufacturer is reinstated by the OIG. Appeals of exclusion and any reinstatement will be handled in accordance with section 1128 of the Act and applicable regulations. Manufacturers that are on the OIG Exclusion List and are reinstated by the OIG under certain circumstances may be evaluated for reinstatement to the Medicaid drug rebate program by CMS. Reinstatement to the Medicaid drug rebate program would be for the next rebate period that begins more than 60 days from the date of the OIG's reinstatement of the manufacturer after exclusion.

(d) If this rebate agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement as set forth in section 1927(b)(4)(C) of the Act for at least one rebate period from the effective date of the termination. The manufacturer must also address to the satisfaction of CMS any outstanding violations from any previous rebate agreement(s), including, but not limited to, payment of any outstanding rebates and also make good faith efforts to appeal or resolve matters pending with the OIG relating to the MDRP or exclusion as referenced in subsection (c) of this section, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

VIII. General Provisions

(a) This agreement is authorized by the applicable provisions of sections 1902, 1903, 1905, and 1927 of the Act, and the implementing regulations at 42 CFR Part 447. This agreement is subject to any changes in the Medicaid statute or regulations that affect the rebate program.

(b) Any notice required to be given pursuant to the terms and provisions of this agreement will be permitted in writing or electronically.

Notice to the Secretary will be sent to:

Centers for Medicaid and CHIP Services
Disabled & Elderly Health Programs Group
Division of Pharmacy
Mail Stop S2-14-26
7500 Security Blvd
Baltimore, MD 21244

The CMS address may be updated upon notice to the manufacturer.

Notice to the manufacturer will be sent to the email and/or physical mailing address as provided under section X of this agreement and updated upon manufacturer notification to CMS at the email and/or address in this agreement.

(c) In the event of a transfer in ownership of the manufacturer, this agreement and any outstanding rebate liability are automatically assigned to the new owner subject to the conditions as set forth in section 1927 of the Act.

(d) Nothing in this agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this agreement is found to be invalid by a court of law, this agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(e) Nothing in this agreement shall be construed as a waiver or relinquishment of any legal rights of the manufacturer or the Secretary under the Constitution, the Act, other federal laws, or state laws.

(f) The rebate agreement shall be construed in accordance with Federal law and ambiguities shall be interpreted in the manner which best effectuates the statutory construct.

(g) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless such contractors are specifically excluded in the rebate agreement or such exclusion is specifically agreed to by an appropriate CMS official.

(h) Except for the conditions specified in II.(g). and VIII.(a)., as well as applicable OMB-approved forms, this agreement will not be altered.

(i) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

IX. CMS-367

CMS-367 attached hereto is part of this agreement.

X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: _____
(signature)

Michael Nardone, Director
Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ Christopher J. Haney
(signature) (please print name)

Title: Vice President, Integrated Accounts Management
Name of Manufacturer: Merck & Co., Inc.
Manufacturer Address 351 North Sumneytown Pike
North Wales, PA 19454

Manufacturer Labeler Code: 00006
Date: August 8, 2018

IX. CMS-367

CMS-367 attached hereto is part of this agreement.

X. Signatures

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ Date: 09/06/2018
(signature)

Acting Director
Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By: _____ _____
(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address _____

_____

Manufacturer Labeler Code: 00006

Date: _____

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 1 OF 2)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA) 00006

MERCK & CO., INC.

LABELER NAME (Corporate name associated with labeler code)

LEGAL CONTACT – Person to contact for legal issues concerning the rebate agreement

NAME OF CONTACT
Kathryn Glaser

267 305-2815
AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS: kathryn.glaser@merck.com

Merck & Co., Inc.

NAME OF CORPORATION

UG 4A - 38

351 N SUMNEYTOWN PIKE

STREET ADDRESS

NORTH WALES PA 19454
CITY STATE ZIP CODE

INVOICE CONTACT – Person responsible for processing invoice utilization data

MARK SERIS

NAME OF CONTACT

215 652-1269
AREA PHONE NUMBER EXTENSION

EMAIL ADDRESS: mark.seris@merck.com

Merck & Co., Inc.

NAME OF CORPORATION

WP39 - 407

770 SUMNEYTOWN PIKE

STREET ADDRESS

WEST POINT PA 19486
CITY STATE ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

MEDICAID DRUG REBATE AGREEMENT

ENCLOSURE B (PAGE 2 OF 2)
SUPPLEMENTAL DATA SHEET

LABELER CODE (as assigned by FDA) 00006

MERCK & CO., INC.

LABELER NAME (Corporate name associated with labeler code)

TECHNICAL CONTACT – Person responsible for sending and receiving data

Michael Quinn

NAME OF CONTACT

215-652-5665

AREA PHONE NUMBER EXTENSION

FAX # 215-652-5632

EMAIL ADDRESS: michael.quinn@merck.com

Merck & Co., Inc.

NAME OF CORPORATION

WP39 - 407

770 SUMNEYTOWN PIKE

STREET ADDRESS

WEST POINT	PA	19486
CITY	STATE	ZIP CODE

Note: This sheet is to be returned with the signed rebate agreement. If more than one labeler code, attach one sheet for each code.

CMS-367d (Exp. 03/31/2019), OMB No. 0938-0578 According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0578. The time required to complete this information collection is estimated to average 1 hour per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MERCK & CO., INC. MERCK SHARP & DOHME LLC, Plaintiffs, v. XAVIER BECERRA, U.S. Secretary of Health & Human Services; *et al.*, Defendants.	Civ. No. 1:23-1615 (CKK)

[PROPOSED] ORDER

Upon consideration of Defendants' Cross-Motion for Summary Judgment, the briefing in support of and in opposition to that Motion, and the entire record in this case, the Court concludes that Defendants are not entitled to judgment as a matter of law. Accordingly, it is hereby ORDERED that Defendants' Cross-Motion for Summary Judgment is denied.

_____

HONORABLE COLLEEN KOLLAR-KOTELLY
UNITED STATES DISTRICT JUDGE