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**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
TRENTON VICINAGE**

<p>BRISTOL MYERS SQUIBB COMPANY, Plaintiff,</p> <p>vs.</p> <p>XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, <i>et al.</i>, Defendants.</p>	<p><b>Civil Action No. 23-cv-03335-ZNQ</b></p>
<p>JANSSEN PHARMACEUTICALS, INC., Plaintiff,</p> <p>vs.</p> <p>XAVIER BECERRA, Secretary of the U.S. Department of Health and Human Services, <i>et al.</i>, Defendants.</p>	<p><b>Civil Action No. 23-cv-03818-ZNQ</b></p>

**[PROPOSED]  
BRIEF OF AMICUS CURIAE CONSTITUTIONAL ACCOUNTABILITY CENTER  
IN SUPPORT OF DEFENDANTS**

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## **INTEREST OF *AMICUS CURIAE*<sup>1</sup>**

*Amicus* Constitutional Accountability Center (CAC) is a think tank and public interest law firm dedicated to fulfilling the progressive promise of the Constitution’s text and history. CAC works in our courts, through our government, and with legal scholars to improve understanding of the Constitution and to preserve the rights and freedoms it guarantees. CAC has an interest in ensuring that the Takings Clause of the Fifth Amendment is interpreted in accordance with its text and history and accordingly has an interest in this case.

## **INTRODUCTION AND SUMMARY OF ARGUMENT**

In 2022, after years of prohibiting Medicare from engaging in drug price negotiation, Congress reversed course and established a new Drug Price Negotiation Program for Medicare Spending (“the Program”) in response to a growing prescription drug affordability crisis. Following careful deliberation and consideration of competing interests, Congress concluded that the prohibition on drug price negotiation had “shift[ed] . . . [the] financial burden to the Medicare program,” thereby “undermin[ing] the program’s premise of leveraging market competition to reduce prices for beneficiaries and taxpayers.” U.S. Br. 5. Under the Program, the Centers for Medicare and Medicaid Services (CMS) negotiates with drug manufacturers to set the price for certain high-expenditure drugs for which there are no competitors. If a drug manufacturer opts into the negotiation process, the manufacturer must provide CMS with certain information about the drug, and CMS and the manufacturer then engage in a negotiation process to determine the “maximum fair price” for the drug. *See* 42 U.S.C. § 1320f-3. If CMS and the manufacturer

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<sup>1</sup> *Amicus curiae* certifies that no party or party’s counsel authored this brief in whole or in part, or contributed money intended to fund its preparation or submission. *Amicus curiae* also certifies that only *amicus curiae* provided funds to prepare and submit this brief.

agree on a price, the manufacturer provides access to the drug for Medicare beneficiaries in exchange for the agreed-upon payment. *Id.* If the manufacturer refuses to participate in the negotiation process or cannot reach an agreement with the government on a price, it can continue selling its drugs to Medicare beneficiaries at non-negotiated prices and pay an excise tax, 26 U.S.C. § 5000D, or it can withdraw its portfolio of drugs from Medicare and Medicaid programs, *see* CMS, Medicare Drug Price Negotiation Program: Revised Guidance at 33-34, 120-21, 129-31 (June 30, 2023), <https://perma.cc/K6QB-C3MM> (“Revised Guidance”); 26 U.S.C. § 5000D(c)(1). It can also transfer its interest in the selected drug to another entity and continue selling the other drugs in its portfolio to Medicare. Revised Guidance, *supra*, at 131-32.

Plaintiff drug manufacturers argue that the Program violates the Takings Clause of the Fifth Amendment, which provides that private property shall not “be taken for public use, without just compensation.” U.S. Const. amend. V. According to Plaintiffs, the Program effects a taking of their products because, in their view, they have no choice but to participate in the Program and allow Medicare recipients access to their products at prices not of their choosing. Compl. 16-18. But the Program does not take a single pill from drug manufacturers. It simply allows the federal government—just like any other market participant—to negotiate the prices it will pay for a limited number of drugs. And Plaintiff drug manufacturers are free to participate in the Program or not. This is simply not the sort of governmental action the Takings Clause proscribes. Indeed, the Takings Clause has never been understood in a manner that would compel Congress to ensure Plaintiffs turn a profit to the detriment of Medicare beneficiaries and taxpayers.

As originally understood, the Takings Clause applied only to the direct appropriation of private property. Similar clauses in colonial and state constitutions prohibited only the direct



appropriation of property, and the Framers of the Clause, including its drafter James Madison, understood that the new Clause in the federal Constitution would also be so limited. For decades, the Clause was applied consistently with this understanding. As Justice Scalia recognized, “early constitutional theorists did not believe the Takings Clause embraced regulations of property at all.” *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1028 n.15 (1992); see *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2071 (2021) (“Before the 20th century, the Takings Clause was understood to be limited to physical appropriations of property.”).

Over time, the Supreme Court has expanded somewhat the scope of the Takings Clause, including recognizing that some regulations can qualify as takings per se. But even in these cases, the Court has limited the Clause’s application to regulations that could reasonably be considered equivalent to direct expropriations that were within the scope of the Clause’s original meaning. *Lingle v. Chevron U.S.A. Inc.*, 544 U.S. 528, 539 (2005) (explaining that categories of takings per se “share a common touchstone,” as “[e]ach aims to identify regulatory actions that are functionally equivalent to the classic taking in which government directly appropriates private property or ousts the owner from his domain”).

The Medicare drug price negotiation program challenged here is plainly not a taking per se under the Supreme Court’s precedents, and expanding what is a taking per se beyond those precedents would run afoul of the original public meaning of the Takings Clause. The Program does not effect an actual physical expropriation of property, as Plaintiffs argue. It does not even effect the functional equivalent of a physical expropriation of property. All it does is provide that the federal government, like any other market participant, may determine how much it is willing

to spend and what it is willing to spend it on. Plaintiffs do not have a constitutionally protected property interest in retaining the government as a customer at a price of their choosing.

## ARGUMENT

### **I. As Originally Understood, the Takings Clause Applied Only to the Direct Appropriation of Property.**

The Takings Clause of the Fifth Amendment states that “private property [shall not] be taken for public use, without just compensation.” U.S. Const. amend. V. By its terms, the Clause’s scope is quite narrow: it applies only when the government takes private property, and it does not prevent such takings but rather requires the government to provide just compensation when those takings occur. *See First English Evangelical Lutheran Church of Glendale v. Cty. of Los Angeles*, 482 U.S. 304, 314 (1987). While the Constitution does not define the term, a “taking” most naturally means an expropriation of property, such as when the government exercises its eminent domain power to physically acquire private property to build a road, military base, or park. *See Douglas T. Kendall & Charles P. Lord, The Takings Project: A Critical Analysis and Assessment of the Progress So Far*, 25 B.C. Env’tl Aff. L. Rev. 509, 515 (1998).

This plain-language interpretation of the Clause is consistent with the Framers’ understanding that the Takings Clause would prohibit only actual appropriations of private property. *See William Michael Treanor, The Original Understanding of the Takings Clause and the Political Process*, 95 Colum. L. Rev. 782, 782 (1995) (“[T]he Takings Clause and its state counterparts originally protected property against physical seizures, but not against regulations affecting value.”). Indeed, “the limited scope of the [T]akings [C]lause[] reflected the fact that, for a variety of reasons, members of the framing generation believed that physical possession of

property was particularly vulnerable to process failure,” necessitating a compensation requirement specifically for the direct appropriation of private property. *Id.*

Historical circumstances preceding the adoption of the Takings Clause support this understanding of the Clause’s original meaning. Prior to the ratification of the Fifth Amendment, “there was no [federal] rule requiring compensation when the government physically took property or regulated it. The decision whether or not to provide compensation was left entirely to the political process.” *Id.* at 783; *see id.* (“[T]he framers did not favor absolute protection of property rights.”). Thus, during the Revolutionary War, the military regularly seized private goods without providing compensation. *See* 1 William Blackstone, *Commentaries with Notes of Reference to the Constitution and Laws, of the Federal Government of the United States; and of the Commonwealth of Virginia* 305-06 (St. George Tucker ed., 1803) (statement by Tucker); *Respublica v. Sparhawk*, 1 U.S. (1 Dall.) 357, 363 (Pa. 1788) (upholding uncompensated seizure of provisions from private citizens during the war).

Indeed, only two foundational documents from the colonial era included even limited recognition of a right to compensation for the taking of private property, and both covered only physical appropriations of property. Treanor, *supra*, at 785. First, the Massachusetts Body of Liberties, adopted in 1641, imposed a compensation requirement that applied only to the seizure of personal property: “No mans Cattel or goods of what kinde soever shall be pressed or taken for any publique use or service, unlesse it be by warrant grounded upon some act of the generall Court, nor without such reasonable prices and hire as the ordinarie rates of the Countrie do afford.” Mass. Body of Liberties § 8 (1641), *reprinted in Sources of Our Liberties: Documentary Origins of Individual Liberties in the United States Constitution and Bill of Rights* 149 (Richard L. Perry & John C. Cooper eds., 1959) (hereinafter *Sources of Our Liberties*); *see*

Treanor, *supra*, at 785 n.12 (“This provision of the Body of Liberties appears to have been modelled on Article 28 of Magna Carta, which barred crown officials from ‘tak[ing] anyone’s grain or other chattels, without immediately paying for them in money.’” (quoting Magna Carta art. 28 (1215), *reprinted in Sources of Our Liberties* 16)).

Likewise, the 1669 Fundamental Constitutions of Carolina, which were drafted by John Locke and never fully implemented, would have mandated compensation for the direct seizure of real property. Treanor, *supra*, at 785-86. These documents sought to authorize public construction of buildings and highways, so long as “[t]he damage the owner of such lands (on or through which any such public things shall be made) shall receive thereby shall be valued, and satisfaction made by such ways as the grand council shall appoint.” *Id.* at 786 (quoting Fundamental Constitutions of Carolina art. 44 (1669), *reprinted in* 1 Bernard Schwartz, *The Bill of Rights: A Documentary History* 115 (1971)).

Although colonial governments commonly regulated land use and business operations, *see id.* at 789 (collecting examples), no colonial charter required compensation for property owners affected by those regulations—not even when the regulations affected a property’s value, *id.* at 788-89; *see* John F. Hart, *Land Use Law in the Early Republic and the Original Meaning of the Takings Clause*, 94 Nw. U.L. Rev. 1099, 1100 (2000) (“American legislatures extensively regulated land use between the time America won its independence and the adoption of the property-protecting measures of the Constitution and the Bill of Rights.”). After the American Revolution, most state constitutions echoed their colonial predecessors in this respect, as “[n]one of the state constitutions adopted in 1776 had just compensation requirements” for physical takings or for regulations that affected property rights. Treanor, *supra*, at 789.

As state constitutions later began to provide compensation for the taking of property, those protections applied only to physical appropriations of property. *See id.* at 791. The Vermont Constitution, for example, provided that “whenever any particular man’s property is taken for the use of the public, the owner ought to receive an equivalent in money.” Vt. Const. of 1777, ch. I, art. II, *reprinted in* 6 *The Federal and State Constitutions, Colonial Charters, and Other Organic Laws of the States, Territories, and Colonies Now or Heretofore Forming the United States of America* 3740 (Francis N. Thorpe ed., 1909) (hereinafter *The Federal and State Constitutions*). Similarly, the Massachusetts Constitution of 1780 stated that “whenever the public exigencies require that the property of any individual should be appropriated to public uses, he shall receive a reasonable compensation therefor.” Mass. Const. of 1780, part I, art. X, *reprinted in* 3 *The Federal and State Constitutions, supra*, at 1891. Further, the Northwest Ordinance of 1787 stated that “should the public exigencies make it necessary, for the common preservation, to take any person’s property, or to demand his particular services, full compensation shall be made for the same.” Northwest Ordinance of 1787, art. 2, *reprinted in Sources of Our Liberties, supra*, at 395. Significantly, “[i]n each case, a plain language reading of the text indicates that it protected property only against physical confiscation, and the early judicial decisions construed them in this way.” Treanor, *supra*, at 791.

Ultimately, when the Framers adopted the federal Takings Clause, “the right against physical seizure received special protection . . . because of the framers’ concern with failures in the political process.” *Id.* at 784. For various reasons, the Framers feared that the ordinary political process would not adequately protect physical possession of property. *Id.* at 827; *see, e.g., id.* at 829-30 (explaining how Vermont’s Takings Clause and other state analogues were

“designed to provide security against the type of process failure to which majoritarian decisionmaking processes were peculiarly prone”—namely “real property interests”).

The statements of James Madison, who drafted the Takings Clause, “uniformly indicate that the clause only mandated compensation when the government physically took property.” Treanor, *supra*, at 791; *see Lucas*, 505 U.S. at 1057 n.23 (Blackmun, J., dissenting) (“James Madison, author of the Takings Clause, apparently intended it to apply only to direct, physical takings of property by the Federal Government.”); *accord* Bernard Schwartz, *Takings Clause—“Poor Relation” No More?*, 47 Okla. L. Rev. 417, 420 (1994). Madison believed that physical property needed special protection in the form of a compensation requirement “because its owners were peculiarly vulnerable to majoritarian decisionmaking.” Treanor, *supra*, at 847. Madison wrote, for instance, of the need for a means to protect physical property ownership separate from the political process because, “[a]s the holders of property have at stake all the other rights common to those without property, they may be the more restrained from infringing, as well as the less tempted to infringe the rights of the latter.” James Madison, *Note to His Speech on the Right to Suffrage* (1821), in 3 *The Records of the Federal Convention of 1787*, at 450-51 (Max Farrand ed., 1911). He described “[t]he necessity of . . . guarding the rights of property,” a matter that he observed “was for obvious reasons unattended to in the commencement of the Revolution.” James Madison, *Observations on the “Draught of a Constitution for Virginia”* (ca. Oct. 15, 1788), in 11 *The Papers of James Madison* 287 (Robert A. Rutland et al. eds., 1977). Thus, Madison was concerned that the political process would be insufficient to preserve physical property rights, and he drafted the Takings Clause to protect against political-process failures. *See* Treanor, *supra*, at 854.

The drafting history of the Takings Clause is also consistent with its limited scope. As originally drafted, the Clause read, “No person shall be . . . obliged to relinquish his property, where it may be necessary for public use, without a just compensation.” *Lucas*, 505 U.S. at 1028 n.15 (quoting Speech Proposing Bill of Rights (June 8, 1789), in 12 J. Madison, *The Papers of James Madison* 201 (C. Hobson et al. eds., 1979)). Although no legislative history exists that explains why a select committee, of which Madison was a member, altered the wording before the Amendment’s adoption, “[i]t is . . . most unlikely that the change in language was intended to change the meaning of Madison’s draft Takings Clause.” Schwartz, *supra*, at 420.

As one scholar has argued, “[t]he substitution of ‘taken’ for Madison’s original ‘relinquish’ did not mean that something less than acquisition of property would bring the clause into play,” *id.*, because Samuel Johnson’s *Dictionary*—a prominent Founding-era dictionary—defined “to take” in 1789 as, among other things, “[t]o seize what is not given”; “[t]o snatch; to seize”; “[t]o get; to have; to appropriate”; [t]o get; to procure”; and “[t]o fasten on; to seize,” *id.* at 420-21 (quoting 1-2 Samuel Johnson, *A Dictionary of the English Language (1755-56)*). Moreover, because no one besides Madison advocated for the inclusion of a Takings Clause in the Bill of Rights, and there is no record of anyone advocating to expand the scope of Madison’s original draft, there is no reason to think the final draft was meant to be more robust than the original. *See* Treanor, *supra*, at 834 (“Aside from Madison, there was remarkably little desire for any kind of substantive protection of property rights against the national government.” (footnote omitted)).

Accounts from shortly after the adoption of the Clause confirm that it was understood to apply only to physical appropriations. “[A]lthough ‘contemporaneous commentary upon the meaning of the compensation clause is in very short supply,’” *Lucas*, 505 U.S. at 1057 n.23

(Blackmun, J., dissenting) (quoting Joseph L. Sax, *Takings and the Police Power*, 74 Yale L.J. 36, 58 (1964)), an 1803 treatise recognized that the Clause “was probably intended to restrain the arbitrary and oppressive mode of obtaining supplies for the army, and other public uses, by impressment, as was too frequently practiced during the revolutionary war.” 1 William Blackstone, *Commentaries, supra*, at 305-06. Another treatise writer observed in 1857 that “[i]t seems to be settled that, to entitle the owner to protection under [the Takings] [C]ause, the property must be actually taken in the physical sense of the word.” Theodore Sedgwick, *A Treatise on the Rules Which Govern the Interpretation and Application of Statutory and Constitutional Law* 519 (1857).

Moreover, the few Supreme Court decisions prior to 1870 interpreting the Takings Clause held that “acts done in the proper exercise of governmental powers, and not directly encroaching upon private property, though their consequences may impair its use, are universally held *not* to be a taking within the meaning of the constitutional provision.” *Northern Transp. Co. v. City of Chicago*, 99 U.S. 635, 642 (1878) (emphasis added). In fact, until the last few decades of the nineteenth century, the Supreme Court steadfastly refused to extend the Clause beyond actual appropriations. In 1870, the Court affirmed that the Takings Clause “has always been understood as referring only to a direct appropriation, and not to consequential injuries resulting from the exercise of lawful power.” *Legal Tender Cases*, 79 U.S. (12 Wall.) 457, 551 (1870); *see Tahoe-Sierra Pres. Council, Inc. v. Tahoe Regional Plan. Agency*, 535 U.S. 302, 321 (2002) (“The text of the Fifth Amendment itself provides a basis for drawing a distinction between physical takings and regulatory takings. Its plain language requires the payment of compensation whenever the government acquires private property for a public purpose, whether the acquisition is the result



of a condemnation proceeding or a physical appropriation. But the Constitution contains no comparable reference to regulations . . .”).

In subsequent years, the Supreme Court somewhat expanded the scope of the Clause, but even in those cases, continued to limit it to the functional equivalent of the involuntary physical appropriations of property, as the next Section discusses.

## **II. Even as Expanded by the Supreme Court, the Takings Clause Only Applies to the Functional Equivalent of a Physical Appropriation of Property.**

The notion that the Takings Clause may apply to government actions beyond the physical expropriation of property emerged gradually over the next century as the Supreme Court considered cases in which government action very closely resembled expropriations of property. The first of these cases, *Pumpelly v. Green Bay & Mississippi Canal Co.*, involved a state-authorized dam that flooded the petitioner’s property. 80 U.S. 166 (1871). The Court noted that “[i]t would be a very curious and unsatisfactory result, if . . . it shall be held that if the government refrains from the absolute conversion of real property to the uses of the public it . . . can inflict irreparable and permanent injury to any extent,” or “in effect, subject it to total destruction without making any compensation, because, in the narrowest sense of that word, it is not *taken* for the public use.” *Id.* at 177-78. To avoid such a result, the Court held that, “where real estate is *actually invaded* by superinduced additions of water, earth, sand, or other material, . . . so as to *effectually destroy or impair its usefulness*, it is a taking, within the meaning of the Constitution.” *Id.* at 181 (emphases added). The Court made clear, however, that “[b]eyond this we do not go, and this case calls us to go no further.” *Id.*

Nearly fifty years later, in *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393 (1922), the Court again narrowly expanded the reach of the Takings Clause. This time the Clause was expanded to encompass regulations that the Court viewed as particularly oppressive. Yet even in

expanding the scope of the Clause to reach government regulations, the Court was once again careful to limit its reach to instances in which the effect of a regulation is tantamount to the direct appropriation of property contemplated in the text of the Fifth Amendment. *See Lingle*, 544 U.S. at 539 (noting that to bring a successful regulatory takings claim, a plaintiff must “identify regulatory actions that are functionally equivalent to the classic taking in which government directly appropriates private property or ousts the owner from his domain”).

*Mahon* involved a challenge to the Kohler Act, a Pennsylvania law that prevented coal companies from mining coal that formed the support for surface-level land. 260 U.S. at 416-17. Pennsylvania law recognized this support property as a distinct property interest, and the Supreme Court stated that the Act “purports to abolish what is recognized in Pennsylvania as an estate in land—a very valuable estate.” *Id.* at 414. The Court declared that the Pennsylvania law had “very nearly the same effect for constitutional purposes as appropriating or destroying [the estate],” *id.*, and, again relying on this analogy to an expropriation of property, declared that a regulation can be considered a taking when it “goes too far,” *id.* at 415; *see Lucas*, 505 U.S. at 1014 (reiterating the “oft-cited maxim” from *Mahon* that, “while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking” (quoting *Mahon*, 260 U.S. at 415)); *accord Tahoe-Sierra Pres. Council*, 535 U.S. at 325 n.21. In that case, the Court concluded that “[b]ecause the statute made it commercially impracticable to mine the coal, and thus had nearly the same effect as the *complete destruction of rights* claimant had reserved from the owners of the surface land, . . . the statute was invalid as effecting a ‘taking’ without just compensation.” *Penn Central Transp. Co. v. City of New York*, 438 U.S. 104, 127-28 (1978) (emphasis added) (discussing *Mahon*).

As the Supreme Court has clarified its regulatory takings doctrine in recent years, it has continued to recognize that there are limits on applying the Takings Clause beyond direct appropriations of physical property. In *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987), the Court held that a “permanent physical occupation” amounting to an unconstitutional taking occurs “where individuals are given a *permanent and continuous* right to pass to and fro, so that the real property may continuously be traversed, even though no particular individual is permitted to station himself permanently upon the premises.” *Id.* at 832 (emphasis added). In *Nollan*, California had conditioned a couple’s purchase of a beachfront lot and the grant of a coastal development permit on the couple providing a “classic right-of-way easement,” *id.* at 832 n.1, across their property so that members of the public could access the beach at all times, *see id.* at 827-29. The Court determined that requiring such a “permanent and continuous” easement without compensation violated the Takings Clause.

Even as the Court held that some regulatory programs can run afoul of the Clause, it has made clear that regulatory programs can only constitute a taking if they compel participation. In other words, a taking must be involuntary. In *Yee v. City of Escondido*, 503 U.S. 519 (1992), the Court rejected a physical takings challenge to an ordinance regulating the landlord-tenant relationship. Under the ordinance, mobile “[p]ark owners [could] no longer set rents or decide who their tenants will be”; instead, the ordinance set rents in mobile-home parks at a certain rate and required a council to review requests for rent increases. *Id.* at 526, 524. The Supreme Court rejected the argument that the ordinance effected a physical taking, explaining that “[t]he government effects a physical taking only where it *requires* the landowner to submit to the physical occupation of his land. . . . Thus whether the government floods a landowner’s property, or does no more than require the landowner to suffer the installation of a cable, the Takings

Clause requires compensation if the government authorizes a compelled physical invasion of property.” *Id.* at 527 (citing *Pumpelly*, 80 U.S. at 166, and *Loretto v. Teleprompter Manhattan CATV Corp.*, 458 U.S. 419). But, the Court reasoned, the challenged rent-control ordinance “authorize[d] no such thing.” *Id.*

The Court emphasized that the owners challenging the ordinance had “voluntarily rented their land to mobile home owners” and that, “[a]t least on the face of the regulatory scheme, neither the city nor the State compels petitioners, once they have rented their property to tenants, to continue doing so.” *Id.* at 527-28. Thus, “no government has required any physical invasion of petitioners’ property.” *Id.* at 528. It is a well-established principle that “[w]hen a person voluntarily surrenders liberty or property, the State has not *deprived* the person of a constitutionally-protected interest.” *L.L. Nelson Enters., Inc. v. Cnty. of St. Louis*, 673 F.3d 799, 806 (8th Cir. 2012) (citing *Zinermon v. Burch*, 494 U.S. 113, 117 n.3 (1990)); *see also Yee*, 503 U.S. at 527; *F.C.C. v. Fla. Power Corp.*, 480 U.S. 245, 252 (1987).

Finally, in its most recent Takings Clause decisions, the Supreme Court has continued to emphasize the Takings Clause’s particular concern with direct physical appropriations, holding that “clear physical takings” violate the Clause even when a regulation that had essentially the same effect would not. In *Horne v. Department of Agriculture*, the Court heard a challenge to a marketing order that required “a percentage of a grower’s crop [to] be *physically set aside* in certain years for the account of the Government, free of charge.” 576 U.S. 350, 354 (2015) (emphasis added). Under the scheme, a government entity “acquires title to the reserve raisins” and subsequently “sells, allocates, or otherwise disposes” of them as it determines is appropriate to protect the market. *Id.* at 354-55. While noting that *Lucas* suggested that “different treatment of real and personal property” was appropriate for regulatory takings, the Court explained that

“direct appropriations of real and personal property” should be treated alike because individuals “do not expect their property, real or personal, to be actually occupied or taken away.” *Id.* at 361. Thus, because the scheme was a “clear physical taking,” with “[a]ctual raisins . . . transferred from the growers to the Government,” it was a *per se* physical taking requiring just compensation, *id.* at 361-62, even though the petitioners conceded that “the government may prohibit the sale of raisins without effecting a *per se* taking,” *id.* at 362. The Court explained that even though a physical taking and a regulatory limit “may have the same economic impact,” “[t]he Constitution . . . is concerned with means as well as ends.” *Id.*

The Supreme Court further articulated its understanding of the Takings Clause in *Cedar Point Nursery v. Hassid*, holding that a California regulation which allowed union organizers to enter a farm’s property was a *per se* taking because it granted the organizers an easement to physically invade the land. 141 S. Ct. 2063 (2021). The Court explained that the distinction between a *per se* taking and a potential regulatory taking is “whether the government has physically taken property for itself or someone else—by whatever means—or has instead restricted a property owner’s ability to use his own property.” *Id.* at 2072. According to the Court, “the access regulation appropriates a right to invade the growers’ property and therefore constitutes a *per se* physical taking.” *Id.* In reaching its decision, the Court drew upon *Horne*, explaining that “[t]he physical appropriation by the government of the raisins in that case was a *per se* taking, even if a regulatory limit with the same economic impact would not have been.” *Id.* at 2074.

Thus, the throughline of the Supreme Court’s precedents in this area has been that the Takings Clause prevents uncompensated expropriations of physical property and the functional equivalent of such physical appropriations, but does not require compensation for the economic

consequences of voluntary participation in federal programs. Under those precedents, the price-negotiation program at issue in this case is plainly not a per se taking, as the next Section discusses.

### **III. The IRA Drug Negotiation Program Is Not a Direct Appropriation of Property or the Functional Equivalent Thereof and Is Therefore Not a Per Se Taking.**

The IRA drug negotiation program establishes parameters for a federal agency's behavior as a market participant, setting guidelines CMS must use to negotiate prices for a list of ten of the costliest and most widely used pharmaceutical products. In allowing CMS to negotiate drug prices, Congress simply authorized it to do what private consumers and even other federal agencies like the Department of Defense and Department of Veterans Affairs routinely do. *See Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payers and Federal Programs*, U.S. Government Accountability Office, Jan. 11, 2007, <https://www.gao.gov/products/gao-07-358t> (describing other federal programs that negotiate drug prices). In other words, this Program is nothing more than an exercise of the federal government's prerogative to determine what it is willing to purchase, and on what terms, and is not an impermissible taking.

To start, the Program is not a physical taking because it does not authorize the physical taking of a single pill. Unlike the government's physical acquisition of raisins that was found to be a per se taking in *Horne*, the Program does not take "the rights to possess, use and dispose of" the "bundle of property rights" in the pharmaceutical products. 576 U.S. at 361 (internal citations omitted). Nor does it deprive plaintiffs of any other right that has traditionally defined ownership of physical property. *See Cedar Point*, 141 S. Ct. at 2072 ("The right to exclude is 'one of the most treasured' rights of property ownership." (quoting *Loretto*, 458 U.S. at 435)); *id.* at 2073 ("Given the central importance to property ownership of the right to exclude, it comes as

little surprise that the Court has long treated government-authorized physical invasions as takings requiring just compensation.”). While plaintiffs who do not participate in the Program cannot sell their products to the government for distribution through Medicare or Medicaid without either paying the excise tax on sales of the selected drug to Medicare or transferring their interest in the selected drug (in which case they can continue to sell other drugs in their portfolio to Medicare), they retain full legal rights over all pharmaceutical products in their custody, and they remain free to sell any of their products within the commercial insurance market to any other buyers in the world, at any price, in any quantity. *See, e.g.*, 42 U.S.C. § 1320f-1(b), (d).

Plaintiffs argue that they are like the plaintiffs in *Horne* who were forced to pay a penalty if they did not sell a share of their crop to the government. But in *Horne*, the plaintiffs could not sell their raisins at all without providing a share of their crop to the government or paying a penalty. *Horne*, 576 U.S. at 366 (rejecting the notion that the government may “hold hostage” the raisin growers’ ability to “[s]ell[] produce in interstate commerce”). Indeed, the government argued that there was no Takings Clause violation because if the raisin growers did not want to participate in the program, “they can ‘plant different crops,’ or ‘sell their raisin-variety grapes as table grapes or for use in juice or wine,’” *id.* at 365—an argument the Supreme Court decisively rejected, *id.* (“‘Let them sell wine’ is probably not much more comforting to the raisin growers than similar retorts have been to others throughout history.”). Here, by contrast, Plaintiffs remain free to sell their products to any willing buyer and will not be subject to the excise tax if they choose not to negotiate with the government so long as they sell their drugs to buyers other than Medicare or transfer their interest in the selected drug to another entity (in which case they can continue to sell their other drugs to Medicare). In other words, Plaintiffs will be subject to the excise tax only if they refuse to negotiate but still choose to retain their interest in the selected

drug and reap the benefits of participating in Medicare and Medicaid. And even then, the excise tax will be only on the Medicare sales of the selected drug. *See* Section 5000D Excise Tax on Sales of Designated Drugs; Reporting and Payment of the Tax, Internal Revenue Service, <https://www.irs.gov/pub/irs-drop/n-23-52.pdf>. Thus, the Program simply prevents Plaintiffs from foisting their product on Medicare without complying with Medicare's requirements for vendors of certain drugs. If Plaintiffs choose to opt out of negotiations or cannot reach an agreement with the government, the only "penalty" they face is a lost customer.

Plaintiffs argue that they cannot really opt out of the Program and that it is "[a] forced transfer dressed up as a 'sale,'" BMS Compl. 13, "akin to the Government taking your car on terms that you would never voluntarily accept and threatening to also take your house if you do not 'agree' that the taking was 'fair.'" Janssen Compl. 6. They argue that withdrawing from the Program would subject them to an excise tax, BMS Compl. 24; Janssen Compl. 30, but as just noted, manufacturers can withdraw from the negotiation process without being subject to any excise tax. All manufacturers have to do is indicate their intent to withdraw at least 30 days in advance of when the tax would otherwise begin to accrue. And notably the tax will not begin to accrue until 2026. Revised Guidance, *supra*, at 33-34, 120-21, 129-31; 26 U.S.C. § 5000D(c)(1). Second, they argue that because Medicare and Medicaid cover a large share of their potential customer base, any choice about whether to participate in the Program is illusory. BMS Compl. 26; Janssen Compl. 4. But the fact that Plaintiffs may not like the choice does not make it any less a choice. "[E]conomic hardship is not equivalent to legal compulsion for purposes of takings analysis." *Garelick v. Sullivan*, 987 F.2d 913, 918 (2d Cir. 1993); *see id.* at 917 (observing that "[a]ll court decisions of which we are aware that have considered takings challenges by physicians to Medicare price regulations have rejected them in the recognition that



participation in Medicare is voluntary”); *Whitney v. Heckler*, 780 F.2d 963, 972, 972 n.12 (11th Cir. 1986) (holding that because “appellants are not required to treat Medicare patients . . . the temporary freeze [of physician reimbursement rates for Medicare beneficiaries] is therefore not a taking within the meaning of the Fifth Amendment,” and “the fact that Medicare patients comprise a substantial percentage of their practices does not ender their participation ‘involuntary’” (quoting *Bowles v. Willingham*, 321 U.S. 503, 517 (1944))).

And because Plaintiffs’ participation in the Program is entirely voluntary, there is no unconstitutional taking. See *Franklin Mem’l Hosp. v. Harvey*, 575 F.3d 121, 129 (1st Cir. 2009) (“Of course, where a property owner voluntarily participates in a regulated program, there can be no unconstitutional taking.”); *Baker Cnty. Med. Servs., Inc. v. U.S. Atty. Gen.*, 763 F.3d 1274, 1276 (11th Cir. 2014) (“a long line of cases instructs that no taking occurs where a person or entity voluntarily participates in a regulated program or activity”); *Managed Pharmacy Care v. Sebelius*, 716 F.3d 1235, 1252 (9th Cir. 2013) (“providers do not have a property interest in a particular reimbursement rate” from Medicare or Medicaid); *Virginia Hosp. & Healthcare Ass’n v. Roberts*, No. 3:20-CV-587-HEH, 2023 WL 3132005 (E.D. Va. Apr. 27, 2023) (“[T]he federal government action giving rise to a Takings Clause claim must ‘legally compel[ ]’ an obligation affecting property for it ‘to give rise to a taking.’ That is true even if ‘business realities’ effectively dictate participation.” (first quoting *Garelick*, 987 F.2d at 913, 916, and then quoting *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446) (internal citations omitted)). Quite simply, the Constitution does not entitle Plaintiffs to maintain their bottom line by dictating the prices Medicare must pay.

\* \* \*

In short, the text and history of the Takings Clause demonstrate that it was designed to apply only to actual physical appropriations of private property. Although the Supreme Court has expanded somewhat the scope of the Clause, it has never applied it to anything remotely like the Program here. Plaintiffs' argument that the challenged Program violates the Takings Clause is at odds with both Supreme Court precedent and the text and history of the Clause. This Court should reject it.

### CONCLUSION

For the foregoing reasons, this Court should hold that the Program does not violate the Fifth Amendment's Takings Clause.

Dated: October 23, 2023

Respectfully submitted,

/s/ Daniel R. Leathers

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 23, 2023, the foregoing document was filed with the Clerk of the Court, using the CM/ECF system, causing it to be served on all counsel of record.

Dated: October 23, 2023

/s/ Daniel R. Leathers  
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