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Taking Your Medicine: Insulating the Drug Price Negotiation Program from Fifth Amendment Challenge

Thomas Feil

TAKING YOUR MEDICINE: INSULATING THE DRUG PRICE NEGOTIATION PROGRAM FROM FIFTH AMENDMENT CHALLENGE

Thomas Feil*

I. INTRODUCTION

Thirty-seven percent of U.S. adults responding to a 2023 survey reported that they had not filled a prescription due to the cost[1]—a significant increase from the twenty-nine percent found just four years earlier.[2] These surveys reveal the stark realities that many Americans face; as prices for their medicines grow increasingly out of reach they have to subvert their own medical needs to pay for rent, groceries, and other costs of living. This increase in the cost of prescription medicines is not a new phenomenon. Over the last twenty years, a plethora of media outlets have documented the precipitous increase in the price of lifesaving medicines—whether it be insulin,[3] cardiovascular drugs,[4] or EpiPens.[5] This is a worrisome trend and systemic problem. While there have been several attempts to correct this problem, failure to enact the proposed legislation often occurred.[6]

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* J.D. Candidate, 2024, Seton Hall University School of Law; B.A., *magnum cum* laude, 2020, Syracuse University.

[1] Gianna Melillo, *More Than One-Third of Americans Haven't Filled a Prescription Due to Cost: Survey*, THE HILL (Mar. 10, 2023), https://thehill.com/changing-america/respect/poverty/3893811-more-than-one-third-of-americans-havent-filled-a-prescription-due-to-cost-survey/.

[2] *Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, Including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age*, KFF (Mar. 1, 2019), https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/.

[3] *See* Steve Inskeep & Allison Aubrey, *Insulin Costs Increased 600% Over the Last 20 Years. States Aim to Curb the Price*, NPR (Sept. 12, 2022, 5:07 AM), https://www.npr.org/2022/09/12/1122311443/insulin-costs-increased-600-over-the-last-20-years-states-aim-to-curb-the-price.

[4] *Drug Prices Outpaced Inflation Since the 1990s*, USAFACTS (Sept. 29, 2022), https://usafacts.org/articles/drug-prices-outpaced-inflation-since-the-1990s/ ("A heart disease drug that cost $100 in 2000 would cost about $1,350 in 2021").

[5] *See* Lisa Rapaport, *Another Look at the Surge in EpiPen Costs*, REUTERS (Mar. 27, 2017, 6:03 PM), https://www.reuters.com/article/us-health-epipen-costs/another-look-at-the-surge-in-epipen-costs-idUSKBN16Y24O (describing how Mylan effectuated a 535% increase on their EpiPen by changing the products list price).

[6] *See* discussion *infra* Part II B.

The Drug Price Negotiation Program ("DPNP") was signed into law on August 16, 2022, as a part of the Inflation Reduction Act ("IRA"), and represents a potentially modest step towards fixing a drug pricing system plagued by exorbitant prices and impeded legislation. The DPNP permits for the first time in U.S. history the Department of Health and Human Services (HHS) to negotiate directly with manufacturers over Medicare products.[7] However, several pharmaceutical manufacturers allege that the law deprives them of their property rights under the Fifth Amendment Takings Clause, among other claims.[8]

The Takings Clause has historically protected real property, not intellectual property, and the extent to which the Takings Clause extends to drugs as personal property is unclear. Before the DPNP's enactment, the United States did not have any dependable process to control drug prices and instead relied on market forces, while other advanced nations permitted their governments to use their leverage and negotiate drug prices.[9] Finding the DPNP unconstitutional or limiting its scope due to claims that have no basis under the Fifth Amendment would force the United States to remain in a comparatively antiquated drug pricing system that continues to perpetuate harm to American consumers.

This Comment therefore proposes that neither these drugs nor their patents should qualify for the protections of the Takings Clause. Additionally, because of the dire need for government action, this Comment proposes the adoption of other price control mechanisms such as increased transparency, value-based pricing ("VBP"), and international reference pricing ("IRP") to

[7] Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-02, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f-1-1320f-7).
[8] *See* discussion *infra* Part III B.
[9] Jenna Miller, *Article*, *Adopting Collective Purchasing to Lower the Cost of Prescription Drugs*, 32 ANN. HEALTH L. ADVANCE DIRECTIVE 143, 158 (Dec. 21, 2022) (citing Katherine Igoe, *Putting the Drug Debate into Context: the State of Pharmaceutical Cost Reform in the U.S.*, HARVARD SCH. OF PUB. HEALTH (Jan. 8, 2020), https://www.hsph.harvard.edu/ecpe/state-of-pharmaceutical-cost-reform-in-the-us/).

supplement the DPNP. This would allow lawmakers to continue to address the drug pricing problem and avoid prolonged stagnation.

This Comment begins in Part II by describing the factors that influence drug pricing in the United States. Part II then provides a brief overview of past attempts at reformation, beginning with the Medicare Prescription Drug Price Negotiation Act of 2007. Finally, Part II discusses the basis for drug selection and negotiation under the DPNP. Part III highlights the types of property recognized as deserving of Fifth Amendment protections and current challenges brought by pharmaceutical manufacturers against the DPNP. Part IV argues that these challenges are illegitimate since participation in Medicare is voluntary and a patent is a federally granted benefit outside of what the Takings Clause protects. Part V analyzes alternative price control mechanisms used internationally. Part VI briefly concludes.

II. DRUG PRICING IN THE UNITED STATES

Outpatient drugs in the United States usually operate under a fee-for-service model where insurance companies provide reimbursement on a per-dose basis.[10] The history of drug pricing in the United States is crucial to understanding the potential downstream effects of the DPNP. This Part (1) provides an overview of the current drug pricing landscape focusing on the federal government's present level of involvement; (2) briefly outlines past legislative efforts to address rising drug prices; and (3) discusses both the eligibility criteria and implementation timeline for the DPNP.

[10] Ryan Knox, *Note*, *More Prices, More Problems: Challenging Indication-Specific Pricing As A Solution To Prescription Drug Spending In The United States*, 18 YALE J. HEALTH POL'Y L. & ETHICS 191, 197 (Apr. 1, 2019) (citing Gregory Daniel et al., *Advancing Gene Therapies and Curative Health Care Through Value-Based Payment Reform*, HEALTH AFF. BLOG (Oct. 30, 2017), https://www.healthaffairs.org/do/10.1377/hblog20171027.83602/full/).

A. *Current Pricing Landscape*

Private health insurance is more prevalent among consumers than public health insurance coverage in the United States with the former covering an estimated 65.6 percent of Americans in 2022.[11] The privatization of healthcare in the United States can be traced back to the early 20th Century when several mining and lumber employers felt compelled to provide physician services for their employees.[12] Coinciding with increasing insurance premiums due to the advent of new medical technology, more employers throughout the 1960s and 1970s began to offer private health plans to their employees.[13]

Predictably, vulnerable groups of Americans like the elderly could not afford the rising premiums that accompanied private insurance.[14] To remedy this, President Lyndon B. Johnson signed The Social Security Amendments Act of 1965, which created the federally run health programs known as Medicare and Medicaid.[15] The Medicare program went into effect in 1966 and provides coverage to those sixty-five years and older as well as younger people with certain disabilities.[16] Medicaid helps cover medical costs for those with limited income.[17] Both programs are overseen by the Centers for Medicare & Medicaid Services (CMS); however, Medicare is

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[11] Katherine Keisler-Starkey et al., *Health Insurance Coverage in the United States: 2022*, UNITED STATES CENSUS BUREAU (Sept. 13, 2023), https://www.census.gov/library/publications/2023/demo/p60-281.html#:~:text=In%202022%2C%20private%20health%20insurance,percent%20and%2036.1%20percent%2C%20respectively.

[12] *A Brief History of Private Insurance in the United States*, ACADEMIC HEALTHPLANS, https://www.ahpcare.com/a-brief-history-of-private-insurance-in-the-united-states/ (last visited Feb. 8, 2024).

[13] *Id*.; see Timothy Noah, *A Short History of Healthcare*, SLATE (Mar. 13, 2007 6:52 PM), http://www.slate.com/articles/news_and_politics/chatterbox/2007/03/a_short_history_of_health_care.html.

[14] Jordan A. Huffman, *Note: Cause and Effect: A Comparative Analysis on How Allowing Medicare Pharmaceutical Price Negotiations Could Impact Research and the Greater Pharmaceutical Industry*, 34 ARIZ. J. INT'L & COMP. LAW 227, 231 (2017).

[15] 89 P.L. 97, 79 Stat. 286.

[16] 92 P.L. 603, 86 Stat. 1329; *see* Steve Anderson, *A Brief History of Medicare in America*, MEDICARERESOURCES.ORG (Oct. 26, 2016), https://www.medicareresources.org/basic-medicare-information/brief-history-of-medicare/ (explaining the creation and expansion of the Medicare program).

[17] *What's The Difference Between Medicare and Medicaid?*, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://www.hhs.gov/answers/medicare-and-medicaid/what-is-the-difference-between-medicare-medicaid/index.html (last visited Feb. 5, 2024).

entirely federally operated whereas CMS only provides general rules for state Medicaid programs to follow.[18] This results in differences amongst state Medicaid programs which is beyond the scope of this Comment.

The Medicare program is divided into four parts based on the different healthcare services offered.[19] Medicare Part A and Part B were each established with the Social Security Amendments Act of 1965.[20] Part A covers inpatient hospital visits while Part B primarily covers outpatient physician services, lab services, certain medical supplies, and prescription drugs administered by a physician.[21] Medicare Part C, also called Medicare Advantage Plans, includes the benefits found in Parts A and B as well as some additional benefits like dental, vision, and some prescription drug coverage.[22] Perhaps having the greatest impact on modern U.S. drug pricing, the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), instituted Medicare Part D, which allowed beneficiaries to purchase prescription drug plans ("PDPs") from private companies that contracted with the federal government.[23] Part D coverage began in 2006 and helped beneficiaries secure subsidized outpatient prescription drugs.[24] This added a new forum of drug coverage extending outside of the hospitals and physician offices covered by Parts A and B.[25]

While the federal government requires private companies to include certain drugs in their Part D plans, it was forbidden from performing one important function—negotiating. The MMA

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[18] *Id.*
[19] Knox, *supra* note 10, at 202 (citing *See What's Medicare*, Medicare.gov: The Official U.S. Government Site For Medicare, https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html).
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.*; *see* Jay-Donavin Ved, *The Inflation Reduction Act of 2022: Addressing Prescription Drug Coverage*, 32 ANN. HEALTH L. ADVANCE DIRECTIVE 131, 134 (June 21, 2023) ("38 years after Medicare was initially signed into law, this Act provided outpatient prescription drug coverage that was omitted in the initial package.").
[24] Knox, *supra* note 10, at 202.
[25] *Id.*

included a provision that forbids government involvement in Part D negotiations by stating: "the Secretary (1) may not interfere with the negotiations between drug manufacturers and pharmacies and prescription drug program sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."[26] This exclusion of CMS from negotiating represents a departure from the frameworks of other federal programs, as both the Department of Veterans Affairs (VA) and the Department of Defense are intimately involved in the pricing of formularies covered under their systems.[27] One rationale for the exclusion is that if the federal government was free to negotiate it would seek to cut costs and thus have the potential to negatively impact the quality of formularies offered.[28]

This rationale has some support as one study found the VA offered only fifty-nine percent of the top 200 drugs by national sales volume while Medicare plans included eighty-five percent[29] While the VA offering a smaller portion of the top 200 drugs may not directly impact quality, the fear is that the gradual restriction of consumer choice could eventually lead to that effect.[30] Another justification for the non-negotiation provision is that innovation will be stifled as manufacturers, due to decreased profits, will no longer be able to recoup high research and development costs.[31]

The same comparison study, however, revealed that the VA on average paid sixty percent of the prices paid by Medicare.[32] These savings achieved by the VA are significant and should not be undermined by concerns that can be mitigated through careful implementation of the DPNP.[33]

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[26] Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2195 (2003).
[27] See Eli Y. Adashi et al., *The Inflation Reduction Act: Recasting the Medicare Prescription Drug Plans*, 64 AM. J. OF PREVENTATIVE MED. 6, 936-38 (Jun. 1, 2023).
[28] Huffman, *supra* note 14, at 233.
[29] *Id.*
[30] *Id.*
[31] *Id.* at 234.
[32] *Id.* at 233.
[33] *See* Huffman, *supra* note 14, at 251 (noting how the United Kingdom used tax incentives to minimize the risk of declining investment in research brought on by negotiation).

This demonstrates that for over two decades, the government has forgone these savings,[34] and consumers have been deprived of lower drug prices in part due to the non-negotiation provision.

B. *Post-2003 Reform Efforts*

Since the MMA's enactment, there have been several legislative efforts spanning four different administrations to amend the non-negotiation provision or implement a different pricing scheme.[35] In 2007, just a year after the MMA went into effect, the Medicare Prescription Drug Price Negotiation Act was introduced, which would have allowed the government to negotiate the prices of covered drugs under Medicare Part D.[36] The bill was passed in the House of Representatives but was ultimately blocked in the Senate.[37] Throughout Congress's consideration of the Act, President Bush threatened to veto it with his Administration stating "[g]overnment interference impedes competition, limits access to lifesaving drugs, reduces convenience for beneficiaries and ultimately increases costs to taxpayers, beneficiaries and all American citizens alike."[38] Similar bills introduced in 2015 under the Obama Administration and in 2017 under the Trump Administration proposed a textual amendment to the non-negotiation provision but like the 2007 bill failed to be enacted.[39]

Political strife over drug pricing policy is further evidenced by two bills introduced during the Trump Administration. Like the earlier bills, the Elijah E. Cummings Lower Drug Costs Now

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[34] *Id* at 234 (estimating the government will save 14 billion dollars annually through negotiation).
[35] *See* Dan Diamond & Amy Goldstein, *A Bitter Pill: Biden Suffers Familiar Defeat on Prescription Drug Prices*, THE WASHINGTON POST (Oct. 29, 2021 11:02 AM), https://www.washingtonpost.com/health/2021/10/29/biden-medicare-drug-negotiation/ (last updated Oct. 29, 2021 12:43 PM).
[36] H.R. 4, 110th Cong. (2007).
[37] *Id.*; *see also* Drew Armstrong, *From the CQ Newsroom: Senate Republicans Reject Cloture to Proceed to Medicare Drug Price* Bill, THE COMMONWEALTH FUND (Apr. 18, 2007), https://www.commonwealthfund.org/publications/newsletter-article/cq-newsroom-senate-republicans-reject-cloture-proceed-medicare-drug.
[38] *House Passes Medicare Bill, President Bush Repeats Veto Threat*, CNBC (Jan. 12, 2007 2:42 PM), https://www.cnbc.com/2007/01/12/house-passes-medicare-bill-president-bush-repeats-veto-threat.html (last updated Sept. 13, 2013 4:33 PM).
[39] Medicare Prescription Drug Price Negotiation Act of 2015, S. 31, 114th Cong. (2015); Medicare Prescription Drug Price Negotiation Act of 2017, S. 41, 115th Cong. (2017).

Act would have repealed the non-negotiation provision, but it also defined specific parameters where at least twenty-five brand-name drugs among the top 125 in Medicare spending would be negotiated by the government.[40] Additionally, the bill would have capped the price of drugs selected at 120% of the average price paid in six other countries.[41] Echoing President Bush's position that "government interference impedes competition" Congressional Republicans countered with the Lower Costs, More Cures Act of 2019, which would have banned certain anticompetitive activities in an attempt to give more leverage to pharmacy benefit managers (PBMs) to negotiate lower prices.[42]

The Prescription Drug Price Relief Act of 2021 was introduced during the Biden Administration, which would have required the Secretary of HHS to implement a program based on IRP.[43] IRP involves creating an index based on the prices paid by higher-income countries as a benchmark to approximate how prices should be set domestically.[44] Canada, the United Kingdom, France, Germany, and Japan, were the five countries selected as "reference countries" under the Act, meaning that any drug whose price in the United States exceeded the median price of those five countries would have been deemed "excessively priced."[45] Like its predecessors, the Prescription Drug Price Relief Act was never enacted.[46]

This cycle was finally broken in 2022 when President Biden signed the IRA, which sought to promote the usage of clean energy, boost domestic manufacturing, reform areas of the tax code,

[40] H.R. 3, 116th Cong. 319 (2019).
[41] *Id.*
[42] H.R. 19, 116th Cong. 1 (2019).
[43] S. 909, 117th Cong (2021).
[44] *See* Sean D. Sullivan, et al., *International Reference Pricing of Pharmaceuticals in the United States: Implications for Potentially Curative Treatments*, 28 J. MANAG. CARE SPEC. PHARM. 566, 567 (May 2022).
[45] S. 909, 117th Cong (2021).
[46] *Id.*

and lower healthcare costs.[47] By introducing change in these various areas, the IRA is a transformative law in many ways.[48] Most relevant here, is how the IRA attempts to lower healthcare costs through the DPNP. The DPNP signaled a momentous change in the drug pricing landscape by receiving enough bipartisan support to finally allow HHS to negotiate drug prices.[49] Under the DPNP, the Secretary of the HHS is tasked with selecting certain single-source drugs and then negotiating with drug manufacturers a "maximum fair price."[50] Although it may not entirely solve the drug pricing problem, the DPNP can be viewed as the culmination of all the failed bills that came before it. Fifteen years after the Medicare Prescription Drug Negotiation Act first demanded government negotiation, the DPNP achieved that longstanding goal.

C. *Parameters of the DPNP*

1. Selection

Selection for the DPNP involves three steps. First, the manufacturer's drug must be covered under Medicare Part D and be among the top fifty drugs with the highest total expenditures by Medicare in a 12-month period.[51] Second, the drug or biologic being selected must be deemed a "qualifying single source," meaning that it is not the reference product for a competitor's product that has also been approved by the FDA.[52] Lack of competition will still be found if there is an authorized generic and will not preclude a "qualifying single source" designation.[53] Third, the

[47] Press Release, U.S. Dep't of the Treasury, *Fact Sheet: How the Inflation Reduction Act's Tax Incentives Are Ensuring All Americans Benefit from the Growth of the Clean Energy Economy*, (Oct. 20, 2023), https://home.treasury.gov/news/press-releases/jy1830#:~:text=The%20Inflation%20Reduction%20Act%20modifies,proportion%20of%20qualified%20apprentices%20from.
[48] *Id.*
[49] *See* Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-02, 136 Stat. 1818 (codified at 42 U.S.C. §§ 1320f-1–1320f-7).
[50] *Id.*
[51] 42 U.S.C. § 1320f-1(d)(1).
[52] 42 U.S.C. § 1320f-1(e)(1)(A)(iii) (citing 42 U.S.C. § 705(j)); 42 U.S.C. § 1320f-1(e)(1)(B)(iii) (citing 42 U.S.C. § 262(k)).
[53] 42 U.S.C. § 1320f-1(e)(2); *see FDA List of Authorized Generic Drugs,* FDA, https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs (last updated

DPNP contains some selection exceptions designed to protect innovation in specific areas.[54] Certain orphan drugs, low-spend Medicare drugs, plasma-derived products, and small biotech drugs are exempt from selection.[55]

2. Calculating "Maximum Fair Price"

When developing its initial offers, CMS evaluates existing therapeutic alternatives to the selected drug.[56] CMS then adjusts its offer for the selected drug based on any clinical benefit that sets the drug apart from the therapeutic alternative.[57] If no therapeutic alternative exists, then CMS uses either the Federal Supply Schedule (FSS)—the price available to direct federal purchasers—or the "Big Four Agency" price, which is prices paid by the VA, the Department of Defense, the Public Health Service, and the Coast Guard [58] The rationale behind using FSS or "Big Four Agency" prices to craft the initial offer is that because those prices have already been subject to negotiation it will therefore be akin to the fair price the DPNP is trying to achieve.[59]

CMS also considers research and development costs, current unit costs of production and distribution, patent status, relevant FDA exclusivities, market revenue, and sales data.[60] After CMS considers all of these factors, CMS will send its initial offer for the maximum fair price.[61] Notably,

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Jan. 4, 2024) (defining an authorized generic as "an approved brand name drug that is marketed without the brand name on its label."); *see also* 42 U.S.C. § 1320f-1(e)(1)(A)–(B) (making drugs eligible for selection seven years after FDA approval and biologics eleven years following FDA approval).

[54] *See generally* Jim Han et al., *The Pros and Cons of Allowing the Federal Government to Negotiate Prescription Drug Prices*, LIBRARY OF CONGRESS: CONGRESSIONAL RESEARCH SERVICE (Feb. 18, 2005).

[55] 42 U.S.C. § 1320f-1(d)(2); *see* 21 C.F.R. 316.3 (defining an orphan drug as one that is approved to treat rare diseases that either affect less than 200,000 people in the United States or affect more but there is "no reasonable expectation that the cost of developing and marketing the drug will be recovered from sales in the United States.").

[56] 42 U.S.C. § 1320f-3(e)(2).

[57] *Id.*

[58] *See* Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs*, (Feb. 2021) (naming the Big Four agencies and how they usually pay lower than other federal direct purchasers).

[59] Kate Meyer, *Determining the Right Offer Price in Medicare Drug Negotiations,* COMMONWEALTH FUND (Sept. 22, 2023), https://www.commonwealthfund.org/blog/2023/determining-right-offer-price-medicare-drug-negotiations.

[60] 42 U.S.C. § 1320f-3(e)(1).

[61] *Id.*

the DPNP specifically states the HHS Secretary "shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, non-disabled, or not terminally ill."[62] This precludes one use of the quality-adjusted life years (QALYs) unit of measurement, which is used in other countries,[63] but raises ethical concerns.[64]

Finally, a ceiling price is set, which CMS' offer may not exceed. The price is based on a set percentage of the product's non-FAMP[65] as increased by the consumer price index among urban consumers.[66] The percentage applied to the non-FAMP depends on how long the drug has been on the market.[67] The "maximum fair price" agreed upon during the negotiation does not exist in perpetuity and can be reevaluated by HHS based on the originally considered criteria.[68]

3. Implementation

The DPNP is to be implemented gradually, with ten drugs selected in 2023 for negotiation and the negotiated price to take effect starting in 2026.[69] After being selected on September 1, 2023, manufacturers have one year to reach an agreement with Medicare. Negotiations are currently ongoing with the first ten selected drugs,[70] and if they persist CMS will render a final

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[62] 42 U.S.C. § 1320f-3(e)(2).
[63] *See* discussion *infra* Part V B.
[64] *See* Carl Coleman, *Cost-Effectiveness Comes to America: The Promise and Perils of Cost-Effectiveness Analysis in Medication Coverage Decisions*, 38 GA. ST. U. L. REV. 811, 856-59 (2022) (noting how QALYs can prove discriminative against those with underlying disabilities).
[65] *See* Congressional Budget Office, *supra* note 58 ("[n]onfederal average manufacturer price is the average price wholesalers pay manufacturers for drugs distributed to nonfederal purchasers, reflecting discounts but excluding any prices found by the Secretary of the VA to be merely nominal.").
[66] 42 U.S.C. § 1320f-3(c)(6).
[67] CTRS. FOR MEDICARE & MEDICAID SERVS., *Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*, (June 30, 2023), https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.
[68] 42 U.S.C. § 1320f-2(b).
[69] 42 U.S.C. § 1320f-1(a).
[70] *See HHS Selects the First Drugs for Medicare Drug Price Negotiation*, DEPARTMENT OF HEALTH AND HUMAN SERVICES (Aug. 29, 2023), https://www.hhs.gov/about/news/2023/08/29/hhs-selects-the-first-drugs-for-medicare-drug-price-negotiation.html.

offer by July 15, 2024, which must be accepted by August 1, 2024.[71] Starting in September 2024, fifteen drugs will be chosen each of the next two years, with their negotiated prices taking effect in 2027 and 2028.[72] In 2026 and every year thereafter, twenty drugs will be selected, and the negotiated prices will start in 2029 and each subsequent year.[73]

If manufacturers refuse to negotiate, significant monetary penalties will result in the form of an excise tax.[74] These penalties depend on the daily sales of the product selected and increase based on the duration of noncompliance.[75] This escalating tax can prove quite burdensome as it begins at sixty-five percent of daily sales but can reach as high as ninety-five percent.[76]

III. TAKINGS CLAUSE JURISPRUDENCE AND MANUFACTURER CHALLENGES

This Part discusses historically cognizable Taking Clause claims under the Fifth Amendment and the substance of the ten complaints filed against the DPNP. The manufacturers have claimed that their patent-protected drugs have been appropriated through government negotiation and because they cannot set desired prices, an unconstitutional taking has occurred.

A. *Takings Clause*

The Takings Clause simply states, "nor shall private property be taken for public use without just compensation."[77] While the Takings Clause aims to reassure citizens that if their private property is taken by the federal government they are due compensation, the lack of

[71] *Id.*
[72] *Id.*
[73] *Id.*
[74] 26 U.S.C. § 500D.
[75] *Id.*
[76] *Id.*
[77] U.S. Const. amend. V.

consistent principles and application of the Clause somewhat hampers that reassurance.[78] Adding more uncertainty is whether intellectual property falls within the ambit of the Takings Clause.[79]

As manufacturers attempt to use this uncertainty to strengthen their claims, an analysis of the common law rights envisioned to be protected by the Fifth Amendment shows that whatever slight tension or uncertainty exists cannot offer validation. Scholars at the time of the Constitution's drafting had a theory of property that centered on physical control—recognizing land, chattel, and items that individuals had dominion over as private property worthy of protection.[80] These theories were later expanded in the 20th century by the "bundle of sticks" theory, which views property as a bundle of limited rights and added rights of access, use, exclusion, and disposal.[81] Separately, the Copyright and Patent Clause provides that Congress shall have power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[82] The Patent Clause differs in that it was less focused on the protection of individual property and more focused on the advancement of public welfare that authors and inventors could bring to the developing United States if properly incentivized.[83]

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[78] *See* Jessica L. Asbirdge, *Article: Redefining the Boundary Between Appropriation and Regulation*, 47 B.Y.U. L. REV. 809, 812 (2021) (arguing government appropriations and government regulation require a stronger distinction based on history); Eduardo Moisés Peñalver, Regulatory Takings, 104 COLUM. L. REV 2182, 2186 (2004) ("[t]akings Clause jurisprudence is characterized by nothing if not the confusion and intense disagreement it generates.").

[79] *Compare* Zoltek Corp. v. United States, 442 F.3d 1345, 1353 (Fed. Cir. 2006) (per curiam), cert. denied, 127 S. Ct. 2936 (2007) (holding that the patents infringed by the government did not constitute property protected by the Takings Clause) *with* James v. Campbell, 104 U.S. 356, 358 (2007) ("a new invention or discovery in the arts, confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land . . . . ").

[80] William Blackstone, *II Commentaries on the Laws of England*, Ch. 1 (Wilfrid Prest, ed. 2016); John Locke, *II Two Treatises on Government*, ch. 5. (Peter Laslett, ed. 1988).

[81] *See* Cass R. Sunstein, *On Property and Constitutionalism*, 14 CARDOZO L. REV. 907, 911 (1993).

[82] U.S. Const. art. I, § 8, cl. 8.

[83] *See* Mazer v. Stein, 347 U.S. 201, 219 (1954) (recognizing how the Patent Clause encouraging inventors benefits the economy); *see generally* John M. Gooden *et al.,* PRINCIPLES OF PATENT LAW: CASES AND MATERIALS, 16-40 (7th ed. 2018) (describing several theories of patent law including those based on incentivization and public good).

The Supreme Court's Takings Clause jurisprudence can be separated into two recognizable categories: *per se* takings and regulatory takings.[84] *Per se* takings involve physical invasion of a citizen's private property and can occur in two ways. First, when the government physically occupies an area of an individual's property—irrespective of how small that area is—a taking can be found.[85] Reiterating the bundle of sticks theory, the Supreme Court recently held in *Cedar Point Nursery v. Hassid* that a California regulation allowing union organizers access to a farmer's property was a *per se* taking because the farmer's right to exclude was "one of the most treasured" rights of property ownership.[86] Addressing concerns that many important access regulations would be impacted by the holding,[87] the Court emphasized that the government can still obtain the right of access to an owner's property by conditioning certain benefits—specifying that "government health and safety inspection regimes will generally not constitute takings."[88] Second, even when there is no physical intrusion onto the property by the government, a *per se* taking can be found when the owner is deprived of "all economically beneficial or productive use of [their] property.[89]

Regulatory takings occur when a loss in property value arises as a result of a changed law or regulation. These are often more difficult to analyze due to a reliance on ad hoc factual

[84] Zachary Baron & Andrew Twinamatsiko, *A Deep Dive Into Takings Clause Challenges To The Medicare Drug Price Negotiation Program*, HEALTH AFFAIRS (July 6, 2023), https://www.healthaffairs.org/content/forefront/deep-dive-into-takings-clause-challenges-medicare-drug-price-negotiation-program.
[85] *See* Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 435 (1982) (finding that requiring cable companies to run cable lines into an apartment building was a taking).
[86] Cedar Point Nursery v. Hassid, 141 S. Ct. 2063, 2072 (2021) (quoting Loretto, 458 U.S. at 435); *see also* Carolyn Liziewski, *The Supreme Court's All-or-Nothing Approach to the Right to Exclude in Cedar Point Nursery v. Hassid*, COLUM. BUS. L. REV. (Nov. 21, 2012), https://journals.library.columbia.edu/index.php/CBLR/announcement/view/455.
[87] *See* Cedar Point Nursery, 141 S. Ct. at 2081 (Breyer, S., dissenting) ("virtually every government-authorized invasion is an 'appropriation.'").
[88] Cedar Point Nursery, 141 S. Ct. at 2079.
[89] *See* Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1016 (1992) (finding the government forbidding a landowner from performing any construction on their plot of beachfront property to be a categorical taking).

inquiries.[90] Not all diminutions in property value can be considered regulatory takings, as "[g]overnment hardly could go on if to some extent values incident to property could not be diminished without paying for every such change in the general law."[91] Regulatory takings are analyzed using the tripartite balancing test adopted by the Court in *Penn Central Transp. Co. v. New York City*.[92] Under this test, courts consider the economic impact of the regulation on the owner, the extent to which the regulation has interfered with the owner's reasonable investment-backed expectations, and the character of the government action involved in the regulation.[93] Applying the balancing test for the first time, the Court in *Penn Central* found that a law forbidding the appellants from building atop Grand Central terminal did not amount to a regulatory taking.[94] The Court reasoned that the appellants could still get a reasonable return on their investment and the regulation was substantially related to general welfare by preserving historic landmarks.[95]

B. *Takings Clause Challenges to the DPNP*

Among the ten lawsuits filed by manufacturers and trade organizations against the DPNP, six of the complaints contained *per se* Takings Clause claims.[96] The other four complaints alleged due process claims but remain relevant due to their broad description of patent rights.[97] Though

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[90] *See* David H. Isaacs, *Article: Not All Property is Created Equal: Why Modern Courts Resist Applying the Takings Clause to Patents, and Why They Are Right To Do So*, 15 Geo. Mason L. Rev. 1, 4 (Oct. 1, 2007) ("the Supreme Court's regulatory takings precedent is a hodge-podge of unanswered questions and inconsistent statements.").
[91] Penn. Coal Co. v. Mahon, 260 U.S. 393, 413 (1922).
[92] Penn Central Transp. Co. v. New York City, 438 U.S. 104, 124 (1978).
[93] *Id.* at 124-26.
[94] *Id.* at 107.
[95] *Id.* at 133.
[96] Complaint, Merck & Co. v. Becerra, No. 23-1615 (D.D.C. June 6, 2023), ECF No. 1 [hereinafter Merck Compl.]; Complaint, Bristol Myers Squibb Company v. Becerra, No. 23-3335 (D.N.J. June 16, 2023), ECF No. 1 [hereinafter Bristol Myers Compl.]; Complaint, Astellas Pharma U.S., Inc. v. Becerra, No. 23-4578 (N.D. Ill. July 14, 2023), ECF No. 1 (voluntarily dismissed by Plaintiff) [hereinafter Astellas Compl.]; Complaint, Janssen Pharmaceuticals Inc. v. Becerra, No. 23-3818 (D.N.J. July 18, 2023), ECF No. 1 [hereinafter Janssen Compl.]; Complaint, Boehringer Ingelheim Pharmaceuticals, Inc., v. Becerra, No. 23-1103 (D. Conn. Aug. 18, 2023), ECF No. 1 [hereinafter Boehringer Compl.]; Novartis Pharmaceuticals Corp. v. Becerra, No. 23-4221 (D.N.J. Sept 1, 2023), ECF No. 1.
[97] Complaint, U.S. Chamber of Commerce v. Becerra, No. 23-0156 (S.D. Ohio, June 9, 2023), ECF No. 1 [hereinafter Chamber of Com. Compl]; Complaint, Pharmaceutical Research and Manufacturers of America v. Becerra, No. 23-0707 (W.D. Tex. June 21, 2023), ECF No. 1 [hereinafter PhRMA Compl.]; Complaint, AstraZeneca

three complaints have been dismissed,[98] seven active challenges remain in four different jurisdictions. With a single decision unlikely to be final,[99] and the possibility of more challenges being brought as more drugs are selected for negotiation each year,[100] understanding the takings claims remains imperative.

Each of the manufacturers' takings claims relies on two recent Supreme Court cases to support their position. First, is *Horne v. Department of Agriculture*, where raisin growers challenged a program that required them to set aside a portion of their crops during certain years for government use without payment so the government could "maintain an orderly market".[101] The Court held that the program violated the Takings Clause because raisins "are private property––the fruits of the growers' labor—not public things subject to the absolute control of the state."[102] The Court found that the Takings Clause protects not just traditional private property such as land but also movable personal property like the set-aside raisins.[103] Moreover, the Court rejected the Department of Agriculture's argument that the order was part of a voluntary exchange where farmers received the benefit of being able to sell their remaining raisins that were not set aside.[104]

Pharmaceuticals LP v. Becerra, No. 23-0931 (D. Del. Aug. 25, 2023), ECF No. 1 [hereinafter AstraZeneca Compl.]; Novo Nordisk v. Becerra, No. 23-0814 (D.N.J. Sept. 29, 2023), ECF No. 1 [hereinafter Novo. Compl.].

[98] *See* Notice of Voluntary Dismissal, Astellas Pharma U.S., Inc. v. Becerra, No. 23-4578 (N.D. Ill. Sept. 6, 2023), ECF No. 16; Order Granting Defendants' Motion to Dismiss, Pharmaceutical Research and Manufacturers of America v. Becerra, No. 23-0707 (W.D. Tex. June 21, 2023), ECF No. 53; Order Granting Defendants' Cross Motion for Summary Judgment, AstraZeneca Pharmaceuticals LP v. Becerra, No. 23-0931 (D. Del. Mar. 1, 2024), ECF No. 19.

[99] *See* Xin Tao & Lois Liu, *Key Legal Trends For Healthcare And Life Sciences In 2024*, LAW360 (Jan. 8, 2024), https://www.law360.com/articles/1783030/key-legal-trends-for-healthcare-and-life-sciences-in-2024 (speculating that the DPNP challenges could reach the Supreme Court).

[100] *See* Gabrielle Wanneh & Maaisha Osman, *New Anti-IRA Lawsuits Could Give Rise To Stronger Claims Against CMS*, INSIDE HEALTH POLICY (Oct. 25, 2023), https://insidehealthpolicy.com/daily-news/new-anti-ira-lawsuits-could-give-rise-stronger-claims-against-cms (predicting a second wave of lawsuits against the IRA is forthcoming).

[101] Horne, 576 U.S. 351, 367 (2015).

[102] *Id.*

[103] *Id.* at 358 ([t]he government has a categorical duty to pay just compensation when it takes your car, just as when it takes your home.").

[104] *Id.* at 366 ("[s]elling produce in interstate commerce, although certainly subject to reasonable government regulation, is similarly not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection.").

Second, is *Cedar Point Nursery*, which reiterated the bundle of sticks theory of property by recognizing an owner's right to access and right to exclude others from using their property.[105]

The complaints combine the holdings of *Cedar Point* and *Horne* to allege that both their rights to exclude beneficiaries and rights in their drugs as personal property are violated by the DPNP.[106] The plaintiffs also argue that their rights are bolstered through patent protection which, confers an additional "right to exclude others from making, using or vending the invention."[107]

IV. *HORNE AND CEDAR POINT* ARE INAPPLICABLE AND PATENTS ARE FEDERALLY GRANTED BENEFITS WHICH SHOULD PRECLUDE THEM FROM TAKING CLAUSE PROTECTIONS

The DPNP as a program and the manufacturers' drugs as personal property are factually distinct from *Horne* and *Cedar Point*. Additionally, a patent is granted in exchange for the disclosure of key aspects of the underlying invention—rewarding the inventor with limited exclusivity while encouraging innovation and follow-on developments through public disclosure. The public benefit inherently intertwined with a patent grant makes it difficult to adopt the broad scope of patent rights asserted by manufacturers. As a result, this Comment argues not for the erosion of Fifth Amendment rights, but for the Takings Clause to not be overextended in an attempt to insulate businesses from economic regulations like the DPNP. Section A rebuts the manufacturers' use of *Horne* and explains why their drugs cannot qualify as personal property. Section B argues that the manufacturers' right to exclude argument is flawed because of the public health exception stated in *Cedar Point*. Section C argues that patent rights are limited due to both the discretion involved in a patent grant and their classification as federally granted benefits.

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[105] Cedar Point Nursery, 141 S. Ct. at 141; *see* discussion *supra* Part III A.
[106] *See* Merc. Compl. at 16 (analogizing the DPNP to Horne by stating manufacturers are being compelled to surrender their drugs to third parties); BMS Compl. at 17 (stating BMS is deprived of its "rights to possess, use and dispose of its property"); Astellas Compl. at 20 (emphasizing that the penalty for noncompliance coupled with the loss of Medicare and Medicaid revenues forces Astellas to give unlimited access of their patented drugs to beneficiaries); Boehringer Compl. at 35 (alleging government appropriations that compelled physical surrender and impinged the right to exclude third parties).
[107] Janssen Compl. at 28 (quoting Talbot v. Quaker-State Oil Refin. Co., 104 F.2d 967, 968 (3d Cir. 1939)).

A. *Distinguishing Horne by Personal Property Classification and Voluntariness of the DPNP*.

With the Court in *Horne* extending the Takings Clause to include personal property, on the surface the holding might appear to support a viable takings claim against the DPNP. But even a surface-level reading of *Horne* cannot overcome the factual differences presented by the manufacturers' complaints. First, the claim that the manufacturers' drugs are personal property is more attenuated than in *Horne.* In *Horne*, the Court cited language in the Magna Carta and property unfairly appropriated during the Revolutionary War as evidence that agricultural products were meant to be protected from uncompensated takings.[108] Though the Court did not supply a bright-line test for what constituted "personal property," the fact that it clearly grounded its analysis in history suggests not all property will qualify. The complaints against the DPNP, unlike *Horne*, are devoid of such a connection to history that could prove their drugs represent personal property meant to be protected by the Takings Clause. Manufacturers, however, are not completely foreclosed from compensation as the Due Process Clause and certain statutes may support more legitimate claims.[109]

Further, with *Horne* only recently extending protections to personal property, careful policing of what constitutes "personal property" is necessary to prevent over-exhaustion of the Takings Clause. The proper inquiry recognizes that the Takings Clause traditionally protected real property before then considering whether a personal property designation applies to the underlying factual circumstances. *Horne* involved a family that carefully raised and handled their raisins each season,[110] whereas manufacturers being selected for the DPNP develop multiple drugs at a time

[108] Horne, 576 U.S. at 358.
[109] *See* 28 U.S.C. § 1498; Bowen v. Gilliard, 483 U.S. 587, 603-06 (1987) (recognizing certain rights with Due Process Clause protection may not be entitled to Takings Clause protection).
[110] Horne, 576 U.S. at 356.

and amass billions of dollars in profit each year.[111] No precedent states the size or profitability of a company is determinative, but ignoring these factual differences and allowing manufacturers to simply use *Horne* to attain the label of "personal property" presents a dangerous proposition.

Even if the drugs are considered "personal property," the manufacturers' claims are weaker because the DPNP is a voluntary program. Unlike *Horne*, where the raisin growers were required to set aside half of their raisins for free to be able to sell the other half in interstate commerce,[112] here the manufacturers are required to sell their drugs at a lower price if they wish to participate in the Medicare program. There is an apparent disparity in the level of coerciveness as manufacturers are not giving their drugs away for free and are not faced with a total exclusion from interstate commerce—only the Medicare program. Manufacturers cite a myriad of reasons why participation in the DPNP is mandatory, such as the large noncompliance tax and how it is not feasible for them to pull their drugs from Medicare when it represents about forty percent of the healthcare market.[113] Others argue that since no limitation had been imposed for nearly sixty years of Medicare's existence, the quick change in conditions renders the DPNP mandatory.[114]

The voluntariness of the DPNP however is best demonstrated in the dismissal of the U.S. Chamber of Commerce's request for a preliminary injunction, where Judge Newman stated "there is no constitutional right (or requirement) to engage in business with the government, the consequences of that participation cannot be considered a constitutional violation."[115] Judge

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[111] *See* Alicia Kaylor, *Senate Report Exposes Big Pharma's Profiteering at Americans' Expense*, PHARMA NEWS INTELLIGENCE (Feb. 14, 2024), https://pharmanewsintel.com/features/senate-report-exposes-big-pharmas-profiteering-at-americans-expense.
[112] Horne, 576 U.S. at 356.
[113] Janssen Compl. at 21.
[114] PhRMA Compl. at 46; *see* Plaintiff's Motion for Summary Judgment, Boehringer Ingelheim Pharmaceuticals, Inc., v. Becerra, No. 23-1103 (D. Conn. Sept. 27, 2023) ECF No. 28 at 11 (claiming Boehringer is "faced with a Hobson's choice between paying confiscatory penalties or engaging in a performative 'negotiation' in which an agency with a financial state will dictate a price for BI's drug . . .").
[115] Order, U.S. Chamber of Commerce v. Becerra, No. 23-0156 (S.D. Ohio Sept. 29, 2023), ECF No. 55 at 23.

Newman emphasized that "participation in Medicare, no matter how vital it may be to a business model, is a completely voluntary choice."[116] Recent guidance from CMS has strengthened this point by clarifying that there is no waiting period to withdraw from Medicare if a manufacturer truly wants to avoid negotiation.[117]

The rejection of Takings Clause claims against past acts that impacted Medicare conditions by numerous circuit courts further demonstrates that the DPNP can only be viewed as voluntary. The Eleventh Circuit rejected a claim that a taking occurred when the Deficit Reduction Act placed a temporary freeze on fees that non-participating physicians could charge Medicare Part B patients.[118] Just as the DPNP imposed a deadline for manufacturers to withdraw from Medicare if they wished to forego negotiation, the Deficit Reduction Act required physicians to indicate whether they would participate in the price freeze to be eligible for various incentives.[119] Non-participating physicians were subject to removal from the Medicare program along with civil penalties if they charged a Medicare beneficiary above the non-participating patient's customary fee.[120] Still, the non-participating physicians claimed that the possibility of incurring civil penalties, price restrictions, monitoring by the HHS, and the exclusion from the incentives violated their Fifth Amendment rights.[121] In rejecting the takings claim, the court reasoned that it is "well established that government price regulation does not constitute a taking of property where the regulated group is not required to participate in the regulated industry."[122]

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[116] *Id.* (citing Baptist Hosp. East v. Sec'y of HHS, 802 F.2d 860, 869 (6th Cir. 1986)).
[117] *See Fact Sheet: Key Information on the Process for the First Round of Negotiations for the Medicare Drug Price Negotiation Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 2023), https://www.cms.gov/files/document/fact-sheet-negotiation-process-flow.pdf.
[118] Whitney v. Heckler, 780 F.2d 963, 965 (11th Cir. 1986).
[119] *Id.*
[120] *Id.* at 967; 42 U.S.C. § 1395u (j)(2).
[121] Whitney, 780 F.2d at 967.
[122] *Id.* at 972 (referencing Bowles v. Willingham, 321 U.S. 503, 417-18 (1944) (stating "rent controls do not constitute prohibited takings because the statute does not require landlords to offer their apartments for rent").

Similarly, the Second Circuit rejected a Takings Clause challenge against the Omnibus Budget Reconciliation Act of 1989 (OBRA), which imposed a "limiting charge" on non-participating physicians in an attempt to protect Medicare Part B beneficiaries from excessive billing.[123] The Court reasoned that participation was voluntary since physicians were not compelled to treat Part B beneficiaries and remained free of price restrictions when treating those with private insurance.[124] Despite the physicians arguing that it was not economically viable for them to avoid treating Part B beneficiaries, the Court found that "economic hardship is not equivalent to a legal compulsion for purposes of takings analysis."[125] Just as the Second Circuit found there was no legal duty for non-participating physicians to treat Part B beneficiaries, the DPNP does not require manufacturers to make their drugs available to those enrolled in Medicare and thus dispels arguments made by several manufacturers.[126]

More recently, the Ninth Circuit rejected a Takings Clause challenge premised on reduced reimbursement rates.[127] The Court reasoned that not only was participation in Medicaid voluntary, but it was illogical to "expect that reimbursement rates will never change."[128] The Court emphasized that the government never made a promise that reimbursements would be distributed at a fixed rate.[129] The government has taken the same position in claims against the DPNP, stating "Congress has made clear that the terms of Medicare and Medicaid can change over time and that new conditions may be added."[130] Further support is found at the federal district court level where

[123] Garelick v. Sullivan, 987 F.2d 913, 915 (2d. Cir. 1993).
[124] *Id.* at 916.
[125] *Id.* at 917.
[126] *See, e.g.*, Boehringer Compl. at 16; Novo Compl. at 45; AstraZeneca Compl. at 37; Janssen Compl. at 12; PhRMA Compl. at 22; BMS Compl. at 15; Chamber of Com. Compl. at 33; Merck Compl. at 10.
[127] Managed Pharm. Care v. Sebelius, 716 F.3d 1235, 1252 (9th Cir. 2013).
[128] *Id.*
[129] *Id.*
[130] Reply Brief in Support of Defendants' Cross-Motion for Summary Judgment, Merck & Co. v. Becerra, No. 23-1615 (D.D.C. June 6, 2023), ECF No. 63 at 13 (citing 42 U.S.C. § 1304).

takings claims brought against the Affordable Care Act,[131] No Surprises Act,[132] and 340B Drug Discount Program[133] were all rejected. All of this history demonstrates that participation in Medicare is a voluntary choice different from the regulation in *Horne*, because here "[m]anufacturers cannot claim that having to decide whether to continue participating in light of that new condition renders the program involuntary."[134]

Both future amendments to the DPNP and laws that later address drug pricing should be careful not to go too far as to be deemed involuntary. For example, the government of the United Kingdom operates as a single buyer under the National Health Service (NHS).[135] With a single buyer system, the NHS has considerable leverage and if a manufacturer refuses to negotiate it has no market share outside of the NHS.[136] If a single buyer system was adopted in the United States it may be viewed as compulsive and not the voluntary scheme that the DPNP currently benefits from—thus potentially prompting more credible takings claims.

B. *Defining A Regulation and Applying Cedar Point's Public Health and Safety Exception*

A regulatory takings analysis should be applied because the DPNP is a regulation not an appropriation.[137] Many commentators believe *Cedar Point* disrupts a clear distinction in property law,[138] and the uncertainty that follows is problematic. The prospect of a legal regime being deemed an appropriation and automatically requiring just compensation even when there is no

[131] Ass'n of Am. Physicians & Surgs. v. Sebelius, 901 F. Supp. 2d 19, 38 (D.D.C. 2012).
[132] Haller v. United States HHS, 621 F. Supp. 3d 343, 361 (E.D.N.Y. 2022).
[133] Eli Lilly & Co. v. United States HHS, No. 1:21-cv-00081-SEB-MJD, 2021 U.S. Dist. LEXIS 209257 at *68 (S.D. Ind. 2021).
[134] *Id.*
[135] Miller, *supra* note 9, at 150.
[136] *Id.* at 151.
[137] *See* Cedar Point Nursery, 141 S. Ct. at 2083 (Breyer, S., dissenting) (arguing the majority confuses a regulation with an appropriation).
[138] *See, e.g.*, Aziz Z. Huq, *Property Against Legality: Takings After Cedar Point*, 109 VA. L. REV. 233, 238 (Apr. 1, 2023) (noting how *Cedar Point* blurs the distinction between regulations and appropriations and adds uncertainty into takings jurisprudence).

physical invasion is troubling as evident here. However, one notable distinction between the taking in *Cedar Point* and the DPNP is that *Cedar Point* still involved a third-party invasion of land while the DPNP does not. This lack of temporary physical occupation of land should aid in the DPNP being viewed more as a regulation rather than an appropriation like the taking in *Cedar Point* was.

Notably, none of the complaints against the DPNP contained regulatory takings claims. Whether this was done to avoid an unfavorable application of the *Penn Central* test, which would likely recognize the DPNP as substantially related to the promotion of general welfare while allowing manufacturers to recoup a reasonable return on investment, is unclear.[139] What is clear is that manufacturers try to broaden the holding of *Cedar Point* enough to use a constitutional doctrine against a fair economic regulation.

Even if the DPNP is found to be an appropriation, *Cedar Point* delineated an exception for government health and safety that applies here. The regulation in *Cedar Point* was not "germane to any benefit provided to agricultural employers or any risk posed to the public" and as a result, the owner's right of access and right to exclude others were violated.[140] In contrast, by negotiating lower prices for drugs that have become too expensive for a significant number of American citizens,[141] the primary motive of the DPNP is public health. Though the Court in *Cedar Point* cited pesticide and pharmaceutical inspections as examples of the public health and safety exception,[142] the availability of prescription drugs is inherently related to public health. Extending the public health and safety exception to the DPNP becomes even more rational after considering that inspections require government agents to visit a company's facilities and view their drugs,

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[139] *Id.* at 238-239. (describing how the *Penn Central* balancing test tends to favor the government).
[140] Cedar Point, 141 S. Ct. at 2080.
[141] *See* Sherri Gordon, *CDC Report: 9 Million Americans Not Taking Medications as Prescribed Due to Cost*, HEALTH.COM (June 12, 2023), https://www.health.com/drug-costs-united-states-cdc-7509659#:~:text=Researchers%20found%20that%20three%20in,three%20or%20fewer%20prescription%20medications.
[142] Cedar Point Nursery, 141 S. Ct. at 2079.

whereas the DPNP requires no such visit with the negotiations occurring offsite. This makes the DPNP far less intrusive while advancing the same goal of protecting public health.

C. *The Limitation of Patent Rights as Federally Granted Benefits*

Manufacturers argue their patent rights bolster their takings claims but fail to consider the limited scope of those rights. While patents provide a right to exclude,[143] patents do not convey a right to insist on prices that contravene the conditions for participation in Medicare. Adopting the manufacturers' broad interpretation of patent rights as a basis for supporting a takings claim would be unjustified for four reasons.

The first reason is found textually. Patent rights can be immensely valuable, sometimes the most valuable asset a company possesses,[144] but these rights remain limited by the clause that creates their existence. Article 1 Section 8 of the Constitution starts with "Congress shall have power" before listing various abilities such as taxing, borrowing money, and promoting science and the arts.[145] The use of "shall have power" rather than "shall issue" demonstrates that the grant of a patent is discretionary. Congress is conferred the power but not compelled to do anything specific in regards to the promotion of "the Progress of Science and useful Arts . . . ."[146] Instead, the Patent Clause merely recognizes that the award of a limited-time exclusive right to authors and inventors may be beneficial in furthering that goal.[147] Further support for this textual interpretation

[143] 35 U.S.C. § 154(a)(1).
[144] *See* Kary Oberbrunner, *Intellectual Property: Your Company's Most Valuable Asset*, Forbes (Jan. 11, 2024 8:30 AM), https://www.forbes.com/sites/forbesbusinesscouncil/2024/01/11/intellectual-property-your-companys-most-valuable-asset/?sh=62fa48803824.
[145] U.S. Const. art. I, § 8; Robin Feldman, *Patents as Property for the Takings*, 12 N.Y.U. J. OF INTELL. PROP. & ENT. LAW 198, 232-33 (June 21, 2023).
[146] U.S. Const. art. I, § 8.
[147] *Id*; Feldman, *supra* note 145, at 233 (stating just as art. I § 8 does not require Congress to levy taxes or borrow money, awarding patent rights for a limited duration is not required).

of the Patent Clause is found by comparing the other sections of the Constitution where the Framers also use "shall have power" to give Congress discretionary authority.[148]

Second, embracing the manufacturers' understanding of the scope of patent rights would be functionally incompatible with historical developments in U.S. patent law. To support their arguments, most of the manufacturers cite *James v. Campbell*, which involved the United States postmaster being accused of infringing a reissue patent for a device that postmarked letters and canceled postage stamps.[149] This 19th Century case is largely predicated on the natural rights theory which posits that patent rights exist prior to and independent of a patent grant by the government.[150] This theory ignores the bargain between the inventor and the government that underlies the United States patent system and does not consider 20th-century developments.[151]

One such development is the Patent Act of 1952, which states "patents shall have the attributes of personal property."[152] The use of "attributes of personal property" in the Patent Act reveals a key distinction—Congress was not giving patents the label of "personal property" but instead was acknowledging that patents had some of the characteristics of personal property.[153] Congress had the opportunity to clarify the protections given to patents but instead failed to even classify patents as "personal property" outright—thus rendering patents as a diluted form of personal property with less constitutional guarantees.[154]

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[148] *See, e.g.*, U.S. const. art. I, § 8 ("The Congress shall have Power to lay and collect Taxes, Duties, Imposts and Excises, to pay the Debts and provide for the common Defence and general Welfare of the United States . . . .").
[149] James v. Campbell, 104 U.S. 356, 358-60 (1882).
[150] *See* Daniel Webster, 41 ANNALS OF CONG. 934 (1824) ("the right of the inventor is a high property; it is the fruit of his mind—it belongs to him more than any other property—he does not inherit it—he takes it by no man's gift—it peculiarly belongs to him, and he ought to be protected in the enjoyment of it.").
[151] *See* Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC, 584 U.S. 325, 335 (2018) (defining patents as "public franchises" given to inventor for new and useful improvements); Feldman, *supra* note 145, at 256.
[152] 35 U.S.C. § 261
[153] Feldman, *supra* note 145, at 241.
[154] *Id.*; *see also* Teva Pharms. USA, Inc. v. Sandoz, Inc., 574 U.S. 318, 344 (2015) (Thomas, C., dissenting) (arguing not to "blithely extend the rules governing the construction of deeds to their even more distant cousins, invention patents").

Another development is the cause of action given to patentees under 28 U.S.C. § 1498, which allows them to sue the government for unlicensed use of their patents and requires "reasonable and entire compensation for such use and manufacture."[155] Recognizing the utility of this alternate cause of action, the Federal Circuit rejected arguments that patents were property by foreclosing patentees from using the Takings Clause and confining their recourse for alleged patent infringement to § 1498.[156] The Federal Circuit's holding emphasizes another reason why the manufacturers should not be able to use the Takings Clause; overextending a constitutional doctrine would be illogical when compensation might be possible through § 1498.[157]

Third, lingering government intervention even after a patent has been issued detracts from the notion that patent rights are violated by the DPNP. For example, the Federal Circuit has held that the retroactive application of inter partes review proceedings to pre-Leahy-Smith America Invents Act patents is not an unconstitutional taking.[158] The Federal Circuit reasoned that "patent owners have always had the expectation that the validity of patents could be challenged in district court" and that "[f]or forty years, patent owners have also had the expectation that the PTO could reconsider the validity of issued patents on particular grounds."[159] Similarly, manufacturers should expect that the Medicare conditions are subject to changes that may impact patent valuation.

Relatedly, the manufacturers' assertion that patents convey such a broad right to exclude is diminished in instances where the government provides grant funding to companies and in turn

[155] Pub. L. No. 61-305, ch. 423, 36 Stat. 851 (1910) (later codified as amended at 28 U.S.C. § 1498).
[156] Zoltek Corp. v. United States, 442 F.3d 1345, 1349 (Fed. Cir. 2006) (per curiam), cert. denied, 127 S. Ct. 2936 (2007) (mem.); *cf.* Isaacs, *supra* note 90, at 9-12 (describing how Zoltek's reasoning might be flawed but the outcome is correct).
[157] Feldman, *supra* note 145, at 258.
[158] Celgene Corp. v. Peter, 931 F.3d 1342, 1362 (Fed. Cir. 2019); *see also* Christy, Inc. v. United States, 141 Fed. Cl. 641 (2019) ("patent rights are not cognizable property interests for Takings Clause purposes.").
[159] Celgene, 931 F.3d at 1362-63.

receives march-in rights under the Bayh-Doyle Act.[160] The federal government is only supposed to utilize these rights in certain circumstances, like if there is a pressing public health need or if the licensee does not make their invention available to the public.[161] Though march-in rights have never been used by the federal government, the mere threat of use has resulted in manufacturers making concessions on the price and availability of their products.[162] The Biden Administration has considered a framework for using these march-in rights against the patents for certain drugs, though it remains a question whether these rights were supposed to be exercised as price controls.[163] Still, the retention of march-in rights by the federal government weakens the argument that patent rights are violated through mere negotiation.

Fourth, patents are federally created benefits, and affording them the expansive rights that manufacturers request would be detrimental to numerous federal programs. Unlike other forms of real and personal property that have rights based on common law, the existence of patent rights relies on federal creation.[164] Exemplifying this is the fact that "an inventor needs to apply for a patent before acquiring any legal rights . . . ."[165] Being the first to conceive of an invention does not by itself reserve any property rights—only adherence to the proper procedures for obtaining a patent does.[166] Notably, the Supreme Court has found that some federal benefits are entitled to the full panoply of constitutional protections while others are not.[167] Patents should not be entitled to

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[160] 35 U.S.C.S. § 201.
[161] Aaron S. Kesselheim et al., *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement*, 30 STAN. L. & POL'Y REV 421, 455 (Jan. 1, 2019).
[162] *Id.* at 455-56; *see* Anna Gordon, *The White House's Latest Move to Rein in Drug Prices*, TIME (Dec. 8, 2023), https://time.com/6344274/the-white-house-plan-lower-drug-prices/ (describing how in 2001 the government leveraged their march-in rights to successfully secure a discount from Bayer for anthrax antibiotics).
[163] Ian Lopez, *Biden Drug Patent Seizures Would Test Scope of Government Power*, BLOOMBERG LAW (Dec. 8, 2023), https://news.bloomberglaw.com/health-law-and-business/biden-drug-patent-seizures-would-test-scope-of-government-power.
[164] Isaacs, *supra* note 90, at 3.
[165] Feldman, *supra* note 145, at 233; *see* David Isaacs, *Shifting Constitutional Sands: Can and Should Patentholders Rely on the Due Process Clause to Thwart Government Action?*, 35 FLA. ST. U.L. REV. 627, 639 (Apr. 1, 2008).
[166] Feldman, *supra* note 145, at 236.
[167] Bowen v. Gilliard, 483 U.S. 587, 605, 607-08 (1978).

the full panoply of constitutional protections due to their reliance on federal creation and societal benefits being a major justification for their creation.[168]

Observing the treatment of other federally granted benefits with property-like rights serves as a helpful comparison.[169] For instance, the Supreme Court has held that the change in the value of a grazing permit did not violate the Takings Clause because to hold otherwise would "create private claims in the public domain."[170] Similarly, the Federal Circuit refused to recognize a property interest in fishing permits and cited in dicta an "absence of crucial indicia of a property right,"[171] such as exclusive use, irrevocability, and transferability.[172] While patents can be transferred,[173] exclusive use and irrevocability are not present as evident in the government's reservation of march-in rights and the ability to challenge a patent's validity in district court. As a result, patents should similarly be undeserving of the full panoply of constitutional protections.

Moreover, given the wide array of benefits granted by the federal government, finding patents are entitled to full constitutional protections would have far-reaching ramifications. For example, an aggrieved federal licensee could bring a takings claim if subsequent government action economically impacts the value of their license. Not only could this inundate courts with a plethora of challenges, but it could inhibit the federal government from making necessary socially valuable changes.[174] A chilling effect could also result if Congress and the PTO fear that they cannot address future abuses and therefore grant fewer patents—thus hindering the future innovation that a patent grant is supposed to promote.[175]

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[168] Isaacs, *supra* note 90, at 3-4.
[169] Feldman, *supra* note 145, at 239.
[170] United States v. Fuller, 409 U.S. 488, 493 (1973) (quoting United States v. Twin City Power Co., 350 U.S. 222, 228 (1956)).
[171] Conti v. United States, 291 F.3d 1334, 1342 (Fed. Cir. 2002).
[172] *See* Feldman, *supra* note 145, at 248.
[173] 35 U.S.C § 261.
[174] Isaacs, *supra* note 90, at 3.
[175] *See* Feldman, *supra* note 145, at 270.

V. ALTERNATIVE PRICING SCHEMES

In addition to recognizing the Takings Clause should not apply to the DPNP, commentators have noted potential alternative drug pricing mechanisms that could be implemented in the United States. This Part discusses three potential alternative mechanisms: increased transparency, VBP, and IRP. These mechanisms help tether drug prices to carefully collected data and should be considered irrespective of the DPNP's constitutionality.

A. *Increased Transparency*

Promoting transparency would serve a dual purpose by allowing manufacturers to get a return on their investments[176] while giving consumers the ability to make more informed purchases and have greater agency in controlling their health. Currently, drug price negotiations between PBMs and manufacturers require no public disclosure, with most of the conversations being confined to back-room discussions.[177] While some manufacturers deemed the determination of a "maximum fair price" under the DPNP arbitrary,[178] increased transparency would allow consumers to assess the manufacturers' arguments and determine whether they are comfortable paying the set price for a drug. Providing consumers with more data about how prices are determined should also lessen the general distrust that many consumers have toward manufacturers. An analogous example is the government's negotiation of utilities such as electricity rates that take place in plain view to ensure both a reliable and fair price is provided for the public.[179] American citizens being able to trace the history of their electricity rates negotiated on their behalf, but not the negotiations for their lifesaving drugs seems unreasonable.

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[176] *Id.*
[177] Clovia Hamilton & Gerald Stokes, *Patented Brand Drugs Are Essential Facilities And Regulatory Compacts*, 21 NW. J. TECH. & INTELL. PROP. 76, 126 (Nov. 1, 2023).
[178] AstraZeneca Compl. at 42; PhRMA Compl. at 7.
[179] Hamilton, *supra* note 177, at 126.

This desire for increased transparency has been the subject of several bills,[180] as well as a recent Senate committee hearing.[181] Insurers, manufacturers, and PBMs negotiating in secret makes it unclear whether increased prices can be attributed to improved patient care or greed.[182] The American Medical Association (AMA) suggests that manufacturers should have to provide public notice and a justification whenever the price of their drug is increased by ten percent or greater.[183] The AMA also recommends the public dissemination of rebate and discount information, financial incentives, formulary information, and the methodologies used to calculate prices.[184] Internationally, several World Health Organization member countries have demanded greater transparency by requiring manufacturers to disclose the cost of producing certain drugs and governments to reveal how much they pay.[185] Another action to further transparency is moving away from the PBM model entirely and is demonstrated on a smaller scale by the Mark Cuban Cost Plus Drug Company, which excludes costs incurred by PBMs and instead sets drug prices "based on the acquisition cost plus transparent mark-ups and fees." [186]

In sum, an increase in transparency might not save the government fourteen billion dollars like the DPNP is estimated to do,[187] but it could put greater accountability on manufacturers to set reasonable prices and allow consumers to make informed decisions. Transparency is worth

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[180] *See, e.g.*, Prescription Pricing for the People Act of 2023, S. 113, 118th Cong. (2023); Pharmacy Benefit Manager Transparency Act of 2023, S. 127, 118th Cong. (2023); HELP Copays Act, S. 1375, 118th Cong. (Feb. 16, 2023).
[181] *See* Bringing Transparency and Accountability to Pharmacy Benefit Managers: Hearing Before the Committee on Commerce, Science, and Transportation, 118 Cong. (2024).
[182] *See Tell Congress to Increase Drug Price Transparency*, TRUTH IN RX, https://truthinrx.org/take-action (last visited Mar. 11, 2024).
[183] *Improving Prescription Drug Price and Cost*, AMERICAN MEDICAL ASSOCIATION (2023), https://www.ama-assn.org/system/files/issue-brief-improving-drug-price-cost-transparency.pdf.
[184] *Id.*
[185] Tom Miles, *WHO Agrees Watered-Down Resolution on Transparency in Drug Costs*, REUTERS (May 28, 2019), https://www.reuters.com/article/idUSKCN1SY0XF/.
[186] Josh Wingrove, *Mark Cuban Backs Biden in 2024, Urging More Action on Drug Costs*, BLOOMBERG NEWS (Mar. 4, 2024), https://ampvideo.bnnbloomberg.ca/mark-cuban-backs-biden-in-2024-urging-more-action-on-drug-costs-1.2042514.
[187] Huffman, *supra* note 14, at 234.

promoting even if manufacturers would likely claim that the data they use to set drug prices is proprietary information. Whether it be a public disclosure requirement, forcing manufacturers to provide a justification statement for price increases, or moving away from PBM involvement, all should be considered for the current U.S. healthcare system where transparency is lacking.

B. *Value-Based Pricing*

VBP sets drug prices based on the value that is provided to patients and is guided by the principle that drug costs should correspond with the health benefits being delivered.[188] Several countries have adopted variations of VBP, including Canada, Australia, France, Germany, and the United Kingdom.[189] Despite using different valuation methods, Germany and Australia are two countries that have been successful at lowering drug prices without impeding patient access through VBP.[190] VBP is already used in the United States by nonprofits like the Institute for Clinical and Economic Review (ICER), which analyzes the cost-effectiveness of drugs and reports findings that sometimes can influence U.S. policy.[191]

Comparative clinical effectiveness and cost-effectiveness are often the starting point for VBP, but further economic models have been developed to quantify these values such as a drug's value based on QALYs.[192] ICER measures the social value of a drug by using "the cost per unit of health benefit gained of one treatment over another."[193] To measure cost-effectiveness, however, ICER uses QALYs, which value extension of life and improvement in well-being in the calculation

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[188] Afschin Gandjour, *Reference Pricing and Price Negotiations for Innovative New Drugs: Viable Policies in the Long Term?*, 31 PHARMACOECONOMICS 11, 12 (Nov. 6, 2012).
[189] Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 525 (Mar. 1, 2023).
[190] Alana Sheppard, *Value-Pricing Prescription Drugs*, THE REGUL. REV. (Nov. 24, 2021), https://www.theregreview.org/2021/11/24/sheppard-value-pricing-prescription-drugs/.
[191] Hemel, *supra* note 189, at 526.
[192] Murray Joseph Casey, *Value-Based Costing of Anti-Cancer Drugs: An Ethical Perspective Grounded in Catholic Teachings on Human Dignity and the Common Good*, 36 ISSUES L. & MED. 44, 53 (June 21, 2021).
[193] *See* INST. FOR CLINICAL & ECON. REV., *2020-2023 Value Assessment Framework* 19 (2022), https://perma.cc/TB39-H7EZ.

of a coefficient.[194] The use of QALYs has been criticized as a discriminatory metric because groups such as the elderly and disabled are valued less because an improvement in well-being is not always realistic.[195] Though ICER has developed another metric that guards against discrimination to use alongside QALYs,[196] the DPNP along with past legislation has forbidden using QALYs to quantify how a drug extends the length of life.[197]

Anchoring a drug's price to the value it adds to patient care would help combat the notion that prices are arbitrarily set because manufacturers would receive compensation that is commensurate with the level of innovation its drug provides. With CMS listing all of the factors it will and will not consider when sending out initial offers to manufacturers, it is implied that VBP will influence the DPNP.[198] Emphasizing this point is revised guidance from CMS that states cost-effectiveness along with other patient-centered impacts will be considered in calculating initial offers.[199]

Although manufacturers may argue that prices should be set based on traditional market exclusivities,[200] the implementation of VBP does not alter their voluntary participation in the Medicare program. For example, one of the government's arguments for the DPNP is that conditions for participation in Medicare were always subject to change.[201] Therefore, a shift from

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[194] *Id.*
[195] *See* Steven D. Pearson, Commentary, *Why the Coming Debate over the QALY and Disability Will Be Different*, 47 J.L. MED. & ETHICS 304, 304 (2019).
[196] *See* INST. FOR CLINICAL & ECON. REV., *supra* note 193, at 22-23 (equal value life years gained (evLYG) removes the improvement in wellbeing from the measurement of extension of life.)
[197] 42 U.S.C. § 1320f-3(e)(2); *see Casey*, *supra* note 192, at 54.
[198] Sean D. Sullivan et al., *Has the Centers for Medicare & Medicaid Services Implicitly Adopted a Value Framework for Medicare Drug Price Negotiations*, 26 VALUE IN HEALTH 1686, 1687 (Dec. 1, 2023).
[199] CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 67, at 4.
[200] Astellas Compl. at 2; Janssen Compl. at 28.
[201] Reply Brief in Support of Defendants' Cross-Motion for Summary Judgment, Merck & Co. v. Becerra, No. 23-1615 (D.D.C. June 6, 2023), ECF No. 63 at 13 (citing 42 U.S.C. § 1304).

a pricing scheme based on market exclusivities to one that more heavily favors VBP is another viable change that merits consideration.

C. *International Reference Pricing*

IRP involves comparing the drug prices paid in a set index of several other developed countries to inform approximately what the domestic price of the drug should be.[202] The use of IRP is commonplace, with a reported twenty-five out of twenty-eight European countries using some variation of IRP.[203] Using IRP might help because the determined reference price can also serve as an anchor and demonstrate that a reasonable return is still being awarded to manufacturers. IRP becomes even more reasonable when it that accounts for the historically elevated prices in the United States and allows drugs to be a given percentage above the international reference price.[204]

Although IRP may help achieve lower drug prices, it presents several challenges. First, it may be hard to implement given that it is unclear how willing countries would be to provide pricing data.[205] Even if such collaboration occurs, there is no exact model for the United States to follow since each country has its own set of values used to determine price.[206] Additionally, there is no standard for how frequently price revisions occur, with some countries implementing IRP at a product's launch and others revising prices periodically.[207] With this level of uncertainty, if IRP is not carefully implemented it may be ineffective despite all of the data collected.

Second, if global prices were to dip, there could be less investment in research and development and as a result fewer innovative discoveries.[208] Similar to arguments made by manufacturers against the DPNP, some scholars have argued IRP price controls would be

[202] Sullivan, *supra* note 44, at 566.
[203] *Id.* at 568.
[204] *See* H.R. 3, 116th Cong. 319 (2019) (proposing a ceiling price of 120% of the IRP from six listed countries).
[205] Sullivan, *supra* note 44, at 567.
[206] Gandjour, *supra* note 188, at 11.
[207] Sullivan, *supra* note 44, at 568.
[208] *Id.*

particularly problematic in the United States, which is a worldwide leader in innovative treatments, as shown by the "1,3000 unique gene and cell-based therapies in development as of 2020."[209] Mitigating against a decline in innovation is possible, however, through the inclusion of other reimbursements. For example, countries that utilize IRP, like Australia,[210] and countries that do not utilize IRP, like the United Kingdom,[211] offer tax incentives as a means to maintain research investment in their respective countries. A similar strategy is feasible for the United States to help surmount the detriment to innovation concerns.

Third, manufacturers can circumvent IRP by strategically launching their drugs in countries known to have higher prices first.[212] This launch strategy is advantageous if the higher-priced country serves as a reference to other countries awaiting the drug's launch.[213] Still, IRP presents an albeit imperfect solution that if implemented correctly can assist in lowering drug prices while avoiding a reduction in innovation.

VI. CONCLUSION

The DPNP represents the latest effort to correct excessive drug pricing in the United States. Understandably, manufacturers are concerned about recouping their research and development investments, but the voluntariness of the DPNP, the personal property at issue, and the classification of patents as federally granted benefits highlight that the Takings Clause is not the proper avenue for doing so. As a result, the DPNP's constitutionality under the Fifth Amendment should be upheld due to both the dire public health need and the aforementioned innate distinctions in property law. Moreover, excessive drug pricing represents an ongoing problem that is going to

[209] *Id.* at 567.
[210] Huffman, *supra* note 14, at 249.
[211] Leah Z. Rand & Aaron S. Kesselheim, *International Reference Pricing for Prescription Drugs: A Landscape Analysis*, 27 J. MANAG. CARE SPEC. PHARM. 1309, 1312 (Sept. 2021).
[212] Sullivan, *supra* note 44, at 568.
[213] *Id.*

necessitate further government action; implementing greater transparency, VBP, and IRP should be considered viable options and remain at the forefront of the discussion.