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Subject: **Legal Analysis of Title I of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act**

From: [redacted]

This memorandum was prepared to enable distribution to more than one congressional office.

This memorandum examines various constitutional and other legal considerations raised by Title I of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.[1] Title I of H.R. 3 would authorize the Secretary of Health and Human Services (HHS Secretary or Secretary) to negotiate the prices of certain selected drugs with drug manufacturers in an effort to lower drug prices.[2]

This memorandum begins by describing relevant provisions of Title I. It then examines selected legal issues related to the Fifth Amendment's Takings Clause; Congress's Taxing Power; the Eighth Amendment's Excessive Fines Clause; issues related to preclusion of judicial review; and certain statutory interpretation issues.

Overview of Title I of H.R. 3

Title I of H.R. 3 would establish a Fair Price Negotiation Program (Program). The Program would generally require the Secretary to negotiate, on behalf of Medicare[3] and commercial health plans[4] that do

[1] H.R. 3, 117th Cong. §§ 101–102 (2021).

[2] *See id.*

[3] Medicare is a health program for persons age 65 and older, as well as certain other qualified beneficiaries. 42 U.S.C. §§ 1395–1395*lll*. The program largely consists of four main parts: A, B, C, and D. Medicare Part A primarily covers inpatient hospital and post-acute care services, and Medicare Part B mainly covers physician and other outpatient items and services. *See id*. §§ 1395c–1395i-5 (Medicare Part A); *id*. §§ 1395j–1395w-6 (Medicare Part B). Part C (Medicare Advantage or MA) establishes a private plan option for providing Part A and B benefits (except hospice), and Medicare Part D provides federally subsidized outpatient prescription drug coverage to Medicare beneficiaries who choose to enroll in this benefit. *See id.* §§ 1395w-21–1395w-29 (Medicare Part C); *id.* §§ 1395w-101–1395w-154 (Medicare Part D). All parts of the Medicare statute are codified within the Social Security Act (SSA).

[4] Commercial (i.e., private-sector) health coverage is largely regulated under three main statutes: the Public Health Service Act (PHSA), the Employee Retirement Income Security Act (ERISA), and the Internal Revenue Code (IRC). Each statute generally applies similar requirements to different types of private health coverage (such as employment-based group health plans and the individual insurance market). *See* 42 U.S.C. §§ 300gg–300gg-92 (PHSA); 29 U.S.C. §§ 1001–1191c (ERISA); 26 U.S.C. §§ 9801–9812 (IRC).

not affirmatively opt out of the Program (herein described as participating commercial plans), the maximum prices (referred to as the "maximum fair price" or MFP) of certain selected single source drugs[5] with their manufacturers.[6] A selected drug's MFP would be the published price a manufacturer and the Secretary, following negotiation, agree to for an applicable price year or period.[7] The Program would cap the maximum negotiated prices based on the relevant drugs' prices in certain international markets.[8]

The Bill would task the Secretary with three central functions related to the Program: (1) selecting negotiation-eligible drugs; (2) entering into agreements with manufacturers concerning the process and requirements for negotiating, renegotiating, and administering the MFP for selected drugs; and (3) participating in the negotiation process in accordance with certain specified factors.[9] These three functions, as well as other provisions of Title I that are relevant to this memorandum, are discussed below.

(1) Selected Drug Identification and Publication

Under the Program, the Secretary would need to publish annually a list of selected drugs that would be subject to price negotiation or renegotiation.[10] The list would include (1) *chosen* non-insulin, qualifying single source drugs; (2) *all* "new-entrant" qualifying single source drugs;[11] and (3) *all* qualifying insulin products.[12] With respect to the first category, the Secretary would need to choose drugs from a larger pool of negotiation-eligible drugs that are either among the 125 qualifying single source covered Medicare Part D drugs with the greatest estimated net spending in Medicare Parts C and D, or the 125 qualifying single source drugs in the United States with the greatest estimated net spending.[13] In choosing selected drugs from this larger pool, the Secretary would have to select drugs that, based on the Secretary's projections, result in the greatest savings during a price applicability period to the federal government or fair price eligible individuals.[14]

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[5] The Program would apply to qualifying single source drugs, defined to include a Food and Drug Administration (FDA)-approved drug product that continues to be marketed pursuant to FDA approval and for which no generic drug has been approved. A qualifying single source drug could also be a biological product that is licensed and continues to be marketed pursuant to the license and is not the reference product for any biosimilar. In determining whether a particular drug or biological product is a qualifying single source drug, products marketed by the same sponsor or manufacturer as a listed drug or reference product would not be considered. An insulin product would be considered a qualifying single source drug if it is FDA-approved or licensed and continues to be marketed under the approval or license. *See* H.R. 3, § 101(a) (creating SSA § 1192(e)). For background on federal prescription drug approval and biologic licensing processes, see CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, by Agata Bodie, and CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*, by Agata Bodie.

[6] H.R. 3, § 101(a) (creating SSA § 1191). Negotiated MFPs would also be used as the purchase price for drugs under the Federal Employees Health Benefits Program and the Department of Veterans Affairs' health care system (at the option of the Veterans Affairs' Secretary). Additionally, MFPs would be included in calculating drug prices under the Medicaid program. *Id.* § 101(b).

[7] *Id.* (creating SSA § 1191(c)(2)).

[8] *Id.* (creating SSA § 1194(c)).

[9] *Id.* (creating SSA § 1191(a)).

[10] *Id.* (creating SSA § 1192). Should the Department of Health and Human Services' Inspector General determine that the Secretary has a conflict of interest regarding a negotiation-eligible drug, selection duties would be carried out by another presidentially nominated, Senate-confirmed department official. *Id.* (creating SSA § 1192(h)).

[11] In general, "new entrant" drugs would include products first approved or licensed by FDA during the year before the drug is selected for price negotiation. *Id.* (creating SSA § 1192(g)).

[12] Qualifying insulin products include all insulin products approved under Sections 505(c) and 505(j) of the Federal Food, Drug, and Cosmetic Act or licensed under Sections 351(a) and 351(k) of the Public Health Service Act (PHSA). *See id.* (creating SSA § 1192(d)(1)(C)).

[13] *Id.* (creating SSA § 1192(d)).

[14] *Id.* (creating SSA § 1192(b)). With respect to selected drugs, "fair price eligible individuals" generally would include specified Medicare beneficiaries and individuals enrolled in participating commercial plans with which there was in effect an agreement

(2) Agreements Between the Secretary and Manufacturers

Following the publication of the list of selected drugs, the Bill would instruct the Secretary to enter into agreements with manufacturers of selected drugs.[15] A central component of these agreements would be that participating manufacturers of selected drugs would be required to offer these drugs at the negotiated MFP to (1) certain Medicare beneficiaries and enrollees of participating commercial plans; and (2) specified health care providers that administer selected drugs to beneficiaries and enrollees.[16] Additionally, pursuant to these agreements, the Secretary and manufacturers would need to renegotiate the MFP for a selected drug if the Secretary determines there is a "material change" in any item on a list of specified factors considered in price negotiation.[17]

(3) Price Negotiation and Renegotiation Process

Title I would expressly direct manufacturers of selected drugs and the Secretary to negotiate (or, if applicable, renegotiate) an MFP.[18] The Bill would instruct the Secretary to develop a consistent methodology for MFP negotiations, subject to certain specified factors, to be included in the agreements.[19] As part of this process, Title I would generally establish a cap on a selected drug's annual MFP.[20] More specifically, any MFP negotiated or renegotiated for a selected drug for each plan year during a price applicability period could not exceed 120% of the drug's average international market (AIM) price for that year.[21] The Bill would generally define the AIM price as an average unit price for the drug in applicable countries (Australia, Canada, France, Germany, Japan, and the United Kingdom) if an average price is available for any unit of the drug sold in that country.[22] If no AIM price exists for an applicable year, the MFP or renegotiated MFP would not exceed 85% of the drug's average manufacturer price for the year.[23] In such a case, manufacturers and the Secretary would be restricted from negotiating a selected drug's MFP above this price threshold.

Pursuant to Title I, the Secretary would be required to publish the negotiated MFP for a selected drug in the *Federal Register*.[24] In years subsequent to the initial year of a pricing agreement with respect to the selected drug, the Secretary would have to publish prices for these drugs that generally reflect an increase based on the consumer price index.[25] If a selected drug had an MFP that was renegotiated, the renegotiated price would be published as the drug's MFP for the first year that price was renegotiated.[26]

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with the Secretary for a selected drug. *Id.* (creating SSA § 1191(c)).

[15] *Id.* (creating SSA § 1193).

[16] *Id.* (creating SSA § 1193(a)).

[17] *Id.* (creating SSA § 1193(a)(2)).

[18] *Id.* (creating SSA § 1194).

[19] *Id.* (creating SSA § 1194(b), (d)).

[20] *Id.* (creating SSA § 1194(c)).

[21] *Id.*

[22] *Id.* (creating SSA § 1191(c)(3)).

[23] *Id.* (creating SSA § 1194(c)). While Title I would not define average manufacturer price (AMP), the AMP for a Medicaid-covered outpatient drug during a calendar quarter is the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies that purchase drugs directly from drug manufacturers. *See* 42 U.S.C. § 1396r-8(k)(1).

[24] H.R. 3, § 101 (creating SSA § 1195).

[25] *Id.* (creating SSA § 1195(b)(1)).

[26] *Id.* (creating SSA § 1195(b)(2)).

Other Relevant Provisions

To promote participation in the Program, Title I would include certain enforcement mechanisms. Relevant here is an excise tax on a manufacturer, producer, or importer of drugs that the Secretary determines are selected drugs under the Program.[27] Companies that decline to negotiate or fail to reach an agreement on a negotiated price with the Secretary, or fail to submit certain required information in connection with this process, would be subject to an escalating excise tax based on the drug's sales price and the length of time the manufacturer was in a period of non-negotiation.[28] The excise tax would be imposed on the sale of selected drugs by a manufacturer, producer, or importer during certain "noncompliance periods."[29] That excise tax would be calculated as a percentage of the sum of the sales price plus the tax imposed, with the percentage escalating from 65% to 95% as the noncompliance period continues.[30]

To further promote compliance by participating manufacturers, Title I would also create two civil penalties. The first is "a civil monetary penalty" that would be applicable to manufacturers that enter into agreements with the Secretary, but generally fail to provide certain price access for drugs in relation to the MFP.[31] This penalty is "equal to ten times the amount equal to the difference between the price for such drug . . . and the [MFP] for such drug[.]"[32] The second civil penalty is imposed on a drug manufacturer in violation of certain requirements related to Program administration.[33] This penalty would not exceed $1 million per violation.[34]

Additionally, Title I would include a provision that precludes various aspects of the Program from judicial review, including the determination of whether a drug is on the list of selected drugs, whether a drug is a negotiation-eligible drug, and the determination of MFP.[35]

Analysis

With respect to Title I, the following analysis addresses four legal issues: (1) whether, in establishing a price-setting process for certain single source drugs, the Program may constitute a taking under the Fifth Amendment's Takings Clause; (2) whether the Program's enforcement mechanisms—the excise tax and civil monetary penalties—raise questions relating to the scope of Congress's taxing power and the Eight Amendment's Excessive Fines Clause; (3) whether the Program's limitation on judicial review may prompt questions regarding Congress's powers to limit the subject-matter jurisdiction of Article III courts; and (4) how issues of statutory interpretation may arise with respect to the legislation.

The Fifth Amendment's Takings Clause

The Fifth Amendment's Takings Clause prohibits private property from being "taken for public use, without just compensation."[36] The Takings Clause "does not prohibit the taking of private property, but

[27] *Id.* § 102 (creating 26 U.S.C. § 4192).

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.* § 101(a) (creating SSA § 1198).

[32] *Id.* (creating SSA § 1198(a)).

[33] *Id.* (creating SSA § 1198(b)).

[34] *Id.*

[35] *Id.* (creating SSA § 1199(d)).

[36] U.S. CONST. amend. V.

instead places a condition on the exercise of that power" by requiring the government to provide just compensation for an otherwise proper governmental interference with property rights.[37] While the "paradigmatic" instance of a taking is a direct government appropriation or physical invasion of private *real* property, a government regulation of private property—including real, personal, and intangible property—that is "so onerous that its effect is tantamount to a direct appropriation or ouster" may be a compensable "regulatory taking."[38] In general, if legislation causes a claimant's property to suffer a significant diminution in value or a deprivation of economically beneficial use, the legislation may result in a regulatory taking.[39]

Here, because the Program under Title I of H.R.3 would limit the prices manufacturers can charge for certain selected drugs, including certain single source (i.e., brand-name) drugs or biological products that would otherwise be entitled to a temporary monopoly resulting from applicable patent protection and regulatory exclusivities,[40] the Program's operation could result in certain economic losses to the manufacturers, possibly implicating a regulatory taking.[41]

For the Takings Clause to apply, however, a constitutionally protected property interest—i.e., one defined by a source independent from the Constitution such as a state law, ordinances, or express or implied contracts—must be at issue.[42] A number of potential property interests may be at issue under the Program. First, the selected drugs themselves, as a form of personal property, likely fall within the Takings Clause's ambit.[43] Second, for selected drugs that are single source drugs or biological products, there may be

[37] Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 536 (2005).

[38] *Id*. at 537; *see also* Horne v. Dep't of Agric., 576 U.S. 350, 359 (2015); Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001 (1983).

[39] *See* A&D Auto Sales, Inc. v. United States, 748 F.3d 1142, 1157 (Fed. Cir. 2014) ("In order to establish a regulatory taking, a plaintiff must show that his property suffered a diminution in value or a deprivation of economically beneficial use.").

[40] *See* H.R. 3, § 101(a) (creating SSA § 1192(e)) (defining "qualifying single source drug" to include drugs approved by FDA under a new drug application (NDA) and biological products licensed by FDA under a biologics license application (BLA)). In general, to encourage innovation, the temporary monopoly granted to a patent and/or regulatory exclusivity rights holder may, by design, allow the rights holder to set higher prices for the goods protected by these rights than they would otherwise be able to charge without the monopoly. For more information on how intellectual property rights like patents and regulatory exclusivities affect drug prices, see CRS Report R45666, *Drug Pricing and Intellectual Property Law: A Legal Overview for the 116th Congress*, coordinated by Kevin J. Hickey.

[41] In general, regulations that impose price controls—that is, certain ceiling prices that a property owner may charge for the use or transfer of its properties—may raise Takings Clause issues if the extent of the regulation's economic impact is significant. *See, e.g.*, Yee v. City of Escondido, 503 U.S. 519, 529 (1992) (noting that while the government may generally "place ceilings on the rents the landowners can charge" their tenants under the states' "broad power to regulate housing conditions," such regulations may nevertheless be subject to a fact-specific regulatory analysis under *Penn Central* to determine whether such a taking has occurred); Guggenheim v. City of Goleta, 638 F.3d 1111, 1119–22 (9th Cir. 2010) (analyzing a county ordinance that imposed rent control for mobile home parks under the fact-specific *Penn Central* analysis).

[42] *See Ruckelshaus*, 467 U.S. at 1001; Philips v. Wash. Legal Found., 524 U.S. 156, 164 (1998). *See also* Board of Regents of State Colleges v. Roth, 408 U.S. 564, 577 (1972). Another threshold inquiry under the Takings Clause is whether a potential taking is for "public use." While the Clause forbids the government "from taking [one private party's property] for the purpose of conferring a private benefit on a particular private party," the Supreme Court has broadly construed the requirement to encompass any taking that is intended to facilitate a "public purpose." Kelo v. City of New London, 545 U.S. 469, 477 (2005). Here, to the extent the Program would require manufacturers to charge participating commercial plans less than before for certain selected drugs, the Program would arguably reallocate payments from one private party (the manufacturers) to another private party (the plans). The overall aim of the Program, however, would be to address a commonly recognized public policy issue in healthcare—rising drug prices—and would potentially produce certain cost savings to Medicare, a federal health program. Under the Supreme Court's broad interpretation of "public use," the Program would thus likely be considered to facilitate a "public purpose." *See, e.g.*, *id.* (concluding that taking of real property for private economic development pursuant to a carefully considered development plan was for "public use"); Hawaii Housing Auth. v. Midkiff, 467 U.S. 229, 245 (1984) (approving state statute that transferred fee title from one private party to another to reduce the concentration of land ownership).

[43] *See Horne*, 576 U.S. at 359–60 (analyzing whether a regulatory reserve requirement effected a taking of raisin crops, a form of

certain intangible intellectual property interests that raise unique questions under the Takings Clause. While the Supreme Court has recognized that certain intangible property interests, such as a trade secret under applicable state law, could be a protected property interest for purposes of the Takings Clause,[44] the Court has not squarely addressed whether patents—which are granted under federal law—are protected private property for purposes of the Takings Clause.[45] While the Supreme Court has presumed that an issued patent would be protected private property subject to the Fifth Amendment,[46] some lower courts have held that patents, as a "creature of federal law," convey only a more limited form of public right—a public franchise—that is qualified and subject to changes in federal law.[47] Similarly, regulatory exclusivities are rights granted by federal law, including to applicants seeking approval for new drugs or licensure of new biological products, which limit the Food and Drug Administration's (FDA) ability to approve competing generic drugs or biosimilars under certain circumstances.[48] This right thus raises similar uncertainties as to whether it would be a protected property interest for purposes of the Takings Clause.[49]

Assuming the Program affects protected property interests, two potential standards may apply in determining whether the Program effects a regulatory taking of those interests. In *Ruckelshaus v. Monsanto*, the Supreme Court applied a deferential approach. Under this standard, a regulation that requires property owners to dedicate portions of their property for public use does not amount to a taking if: (1) the property is provided as a condition of the owner's voluntary participation in a regulatory scheme; (2) the owner is aware of the condition and derives certain discretionary government benefits in exchange for submitting to the condition; and (3) the condition is rationally related to a legitimate government interest.[50]

Applying this standard in *Ruckelshaus*, the Court concluded that a regulation that required pesticide manufacturers to disclose publicly, under some circumstances, certain trade-secret health and safety data did not constitute a taking. The Court reached this conclusion based on its findings that (1) the disclosure requirement was imposed as a condition of the manufacturer's voluntary participation in a regulatory scheme that required pesticide products to be registered with the federal government; (2) participation in registration allowed the manufacturers to sell their products in the U.S. market—a valuable government

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personal property).

[44] *Ruckelshaus*, 467 U.S. at 1003–04.

[45] *Horne*, 576 U.S. at 359–60. In *Horne*, the Supreme Court, in considering whether a regulatory taking had been effected on raisin crops, the Court noted that it had previously commented that a patent, another form of personal property, "confers upon the patentee an exclusive property in the patented invention which cannot be appropriated or used by the government itself, without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser." *Id.* (quoting James v. Campbell, 104 U.S. 356, 358 (1882)).

[46] *See id.*

[47] *See* Christy, Inc. v. United States, 141 Fed. Cl. 641, 660 & n.13 (Ct. Fed. Cl. 2019) (holding that patents are public franchises and more akin to a federal benefit, rather than private property compensable under the Fifth Amendment), *appeal filed* (Apr. 4, 2019); *see also* Zoltek Corp. v. United States, 442 F.3d 1345, 1348 (Fed. Cir. 2006) (holding that patent rights are not cognizable property interests under the Fifth Amendment), *vacated on other grounds*, 672 F.3d 1309, 1317–22 (Fed. Cir. 2012).

[48] *See* CRS Report R45666, *supra* note 40, at 23.

[49] The argument that regulatory exclusivities constitute protected property interests for purposes of the Takings Clause may be weaker. In contrast to patents, which encompass many attributes of private property such as a private right to exclude by the patent owner, regulatory exclusivities do not directly confer such an exclusion right on the rights holder. Instead, the exclusivities place a restriction on FDA's ability to approve other applications or licenses. *See* CRS Report R45666, *supra* note 40, at 48 n.468.

[50] *Ruckelshaus*, 467 U.S. 1007–08.

benefit; and (3) the disclosure requirement was rationally related to the legitimate government interest in addressing longstanding public concerns regarding pesticide sale and use.[51]

Under a second, less deferential approach, courts apply the "ad hoc, factual inquir[y]" set forth in *Penn Central Transportation Co. v. City of New York*[52] to determine whether a taking has been effected by a regulation. The factors relevant to the *Penn Central* analysis include:

> (1) "[t]he economic impact of the regulation on the claimant," which takes into account any mitigating conditions including whether the claimant can still make a "reasonable return" under the regulation, as well as the proportionality of the economic impact relative to the claimant's conduct;
>
> (2) "the extent to which the regulation has interfered with distinct investment-backed expectations," which considers the degree to which the regulation was within the claimant's reasonable expectations; and
>
> (3) "the character of the government action," which considers whether the regulation effectively appropriated any of the property in question or merely "adjusts the benefits and burdens of economic life to promote the common good."[53]

Courts have applied this standard in circumstances where the regulation at issue cannot be characterized as a condition of a property owner's voluntary participation in a regulatory scheme to obtain a "government benefit."[54] In this line of cases, courts distinguish *Ruckelshaus*'s pesticide registration scheme as conferring a "government benefit" upon which the government may condition certain voluntary yielding of property rights given that the scheme involved the government's longstanding, complex regulation of hazardous substances.[55] By contrast, where a regulation conditions the yielding of property rights on a property owner's ability to engage in general lawful activities—e.g., the ability to sell consumer goods like produce[56] or tobacco products[57] in interstate commerce or to build on one's own property[58]—courts have concluded that such activities do not amount to a government benefit and thus do not meet the "voluntary exchange" element of the *Ruckelshaus* analysis.

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[51] *Id.*

[52] 438 U.S. 104, 124 (1978).

[53] *Id.* at 124, 129; *see also* Connolly v. Pension Ben. Guar. Corp., 475 U.S. 211, 225–27 (1986).

[54] The Supreme Court has identified two circumstances of a categorical or "per se" taking that would bypass the fact-specific *Penn Central* analysis: (1) where a regulation inflicts a permanent physical invasion of private property; and (2) where regulations "completely deprive an owner of all economically beneficial use of her property." Me. Educ. Ass'n Benefits Trust v. Cioppa, 695 F.3d 145, 153 (1st Cir. 2012) (citing Lingle v. Chevron U.S.A., Inc., 544 U.S. 528, 538 (2005); Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1019 (1992)). Neither scenario of *per se* taking appears to be at issue here. The "permanent physical invasion" scenario is inapposite given that no real property is at issue. Nor would the Program deprive "all economically beneficial use" of the selected drugs—the Program would only limit and potentially lower the prices manufacturers may charge for selected drugs.

[55] *See, e.g.*, Horne v. Dep't of Agric., 576 U.S. 350, 365–66 (2015); Philip Morris, Inc. v. Reilly, 312 F.3d, 46–47 (1st Cir. 2002); Nollan v. Cal. Coastal Comm'n, 483 U.S. 825, 833 n.2 (1987).

[56] *See Horne*, 576 U.S. at 365–66 (rejecting the application of *Ruckelshaus* to certain raisin marketing orders that required raisin growers to set aside a portion of their annual crop for the federal government, given that the "[sale] of produce in interstate commerce," unlike the sale of "dangerous pesticides," was "not a special governmental benefit that the Government may hold hostage, to be ransomed by the waiver of constitutional protection").

[57] *See Philip Morris*, 312 F.3d at 46–47 (rejecting the application of *Ruckelshaus* to a state law that required tobacco manufacturers to disclose the ingredients in their product as a condition of selling the product in the state, noting that the manufacturers' right to "sell [their] legal product[s]" in the state was not a "valuable government benefit").

[58] *Nollan*, 483 U.S. 825, 833 n.2 (in a case challenging a state's denial of a permit to build a beachfront property, distinguishing *Ruckelshaus* on the grounds that "the right to build on one's own property . . . cannot remotely be described as a 'governmental benefit'" and thus conditioning such a right on "the yielding of a property interest" did not "establish[] the voluntary exchange . . . that [the Court] found to have occurred in [*Ruckelshaus*]").

Here, *Ruckelshaus*'s deferential approach likely does not apply given that Title I does not appear to condition a manufacturer's participation in the Program upon its receipt of certain "government benefits." While the Program would apply to Medicare, a federal health program that likely provides manufacturers with certain "government benefits" within the meaning of *Ruckelshaus*,[59] Title I does not appear to require the manufacturers' participation in the Program as a condition of their continued receipt of such benefits. Instead, under Title I, the Program would apply to *any* selected drugs—which may be chosen from drugs with the greatest estimated net spending in the United States generally, and not just in Medicare Part D—identified and published by the Secretary.[60] Thus, even a manufacturer that does not currently participate in Medicare, or chooses to opt out of Medicare, may still be subject to the Program and its enforcement mechanisms (including the excise tax) so long as it manufactures a selected drug.[61]

Under this design, participation in the Program may be more akin to a condition imposed on a manufacturer's ability to sell a selected drug generally in interstate commerce.[62] Because this activity is generally lawful, similar to the ability to sell other consumer goods like produce and tobacco products, whether the Program effects a taking is likely subject to the fact-specific *Penn Central* analysis.

Assuming the *Penn Central* analysis applies,[63] whether the Program effects a taking likely depends on the Program's specific impact on a manufacturer of a selected drug after the Program's implementation.[64] In particular, the strength of a potential Takings Clause claim would likely depend on factors including: (1) the negotiated MFP of a selected drug; (2) the scope of economic loss resulting from offering this price to Medicare beneficiaries and enrollees of participating commercial plans; (3) whether the revenue generated from sales at this price still allows the manufacturer to make a "reasonable return" on the drug; and (4) whether and how this price point would interfere with the manufacturer's investment-backed expectations, including any impact on its ability to recoup the relevant research and development costs or

[59] For instance, under Medicare Part D currently, drug manufacturers, in exchange for receiving coverage for their drugs under Part D (a government benefit), the manufacturers must offer certain product discounts under the Medicare Coverage Gap Discount Program. *See* 42 C.F.R. §§ 423.2310, 423.2315.

[60] *See* H.R. 3, § 101(a) (creating SSA §§ 1192(a), 1192(d), 11194(a)).

[61] *See id.* Title I also does not condition FDA's new drug approval or biological product licensure processes on participation in the Program. While new drugs and biological products must be approved or licensed by FDA to be introduced into interstate commerce—likely a government benefit under *Ruckelshaus*—conditioning receipt of such approval or licensure on the manufacturers' participation in the Program may raise questions about whether such a condition (aimed at lowering drug prices) has a sufficient "essential nexus" to the purpose of the new drug approval process (i.e., to ensure the safety and efficacy of new drugs). *See Nollan*, 483 U.S. at 837 (holding that a permit condition imposed by a state commission that required property owners to provide a public easement across a portion of their beachfront property effected a taking in part because the permit condition did not serve the same governmental purpose as the original development ban, which was aimed at protecting the public's ability to see the beach and at reducing congestion).

[62] Note, however, that the Program would not require the resulting negotiated MFP to be made generally available to all markets in interstate commerce. *See* H.R. 3, § 101(a) (creating SSA § 1191(c)). The negotiated MFP would not apply to, for instance, the uninsured market or non-participating commercial plans.

[63] Under an older line of cases analyzing regulations imposing price controls, the Supreme Court stated that a regulation that imposes maximum rates on prices is constitutional so long as the rates are reasonable and "not confiscatory." *See* FCC v. Fl. Power Corp., 480 U.S. 245, 253 (1987) (citing St. Joseph Stock Yards Co. United States, 298 U.S. 38, 53 (1936); Permian Basin Area Rate Cases, 390 U.S. 747, 770 (1968)). More modern cases on price control regulations, however, indicate that such regulations are subject to the *Penn Central* analysis. *See* Yee v. City of Escondido, 503 U.S. 519, 529 (1992) (in case challenging a local rent control ordinance on mobile home parks, remanding the case to the lower court to determine whether the ordinance effects a regulatory taking under *Penn Central*); Guggenheim v. City of Goleta, 638 F.3d 1111, 1119–22 (9th Cir. 2010) (analyzing a county ordinance that imposed rent control for mobile home parks under the regulatory takings analysis).

[64] *See, e.g.*, Ass'n of Am. Physicians & Surgeons, Inc. v. Brown, Case No. 2:16-cv-2441, 2018 WL 1535531, at *6–7 (E.C. Cal. Mar. 29, 2018) (rejecting plaintiff physician group's facial Takings Clause challenge to a state law that would, in part, impose statutory benchmarked rates for out-of-network services, on the grounds that the actual economic impact on physicians remained unknown prior to the statute's implementation).

fund other research and development.[65] Depending on the Program's specific economic impact on a participating manufacturer, a manufacturer of a selected drug may be able to mount an as-applied Takings challenge.[66] As a practical matter, however, it is generally difficult to prevail on a Takings challenge under the fact-specific *Penn Central* analysis.[67]

Congress's Taxing Power

As described above, Title I imposes an escalating excise tax to promote manufacturers' participation in the Program. Because the excise tax in question falls only on manufacturers who do not have an MFP agreement with the Secretary, or are not progressing towards such an agreement, there may be questions regarding whether the excise tax is actually within Congress's constitutional power to levy taxes. Article I, section 8 of the Constitution states: "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." The Supreme Court has recognized that Congress's power to tax is extremely broad.[68] For example, the Court has stated:

> It is beyond serious question that a tax does not cease to be valid merely because it regulates, discourages, or even definitely deters the activities taxed. . . . The principle applies even though the revenue obtained is obviously negligible . . . or the revenue purpose of the tax may be secondary . . . Nor does a tax statute necessarily fall because it touches on activities which Congress might not otherwise regulate. As the Court pointed out in *Magnano Co. v. Hamilton*, 292 U.S. 40, 47 (1934): "From the beginning of our government, the courts have sustained taxes although imposed with the collateral intent of effecting ulterior ends which, considered apart, were beyond the constitutional power of the lawmakers to realize by legislation directly addressed to their accomplishments."[69]

Where a challenged tax's character may be more accurately described as a penalty, however, it may not be supportable under the taxing power alone; courts have generally asked whether Congress has the authority to regulate the underlying subject matter.[70] If such regulation is authorized under a provision of the Constitution independent of the taxing power, the exaction might be sustained as an appropriate

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[65] *See, e.g.*, Sierra Med. Servs. Alliance v. Kent, 883 F.3d 1216, 1225–26 (9th Cir. 2018) (analyzing a Takings Clause challenge against a state law that set reimbursement rates for emergency response services by considering whether the law caused plaintiffs to "operate at a loss" and whether there was "any distinct [investment-backed] expectations"); Cienega Gardens v. United States, 331 F.3d 1319, 1137–54 (Fed. Cir. 2003) (concluding that a change in federal law that prevented owners of certain low-income apartments from prepaying their federally subsidized mortgages after 20 years effected a taking of their vested property interest in their contractual rights to prepay and exit the relevant housing programs, to the extent certain owners wanted to prepay but were not allowed to do so, and as a result suffered a "serious" financial loss that amounted to a loss of 96% of the possible rate of return on their investments).

[66] *See, e.g.*, *Cienega Gardens*, 331 F.3d at 1137–54.

[67] In the 40 years since *Penn Central* was decided, the Supreme Court has found a regulatory taking occurred under the *Penn Central* factors in only a handful of cases. *See, e.g.*, *Ruckelshaus*, 467 U.S. at 1013 (concluding that public disclosure by EPA of certain submitted data effected a taking during the years when a federal statute contained a confidentiality guarantee). *See also* Gregory M. Stein, *Regulatory Takings and Ripeness in the Federal Courts*, 48 VAND. L. REV. 1, 26 (1995) (noting that "courts only rarely find regulatory takings"); Barton H. Thompson, Jr., *The Endangered Species Act: A Case Study in Takings and Incentives*, 49 STAN. L. REV. 305, 329 (1997) (noting that "lower courts typically give no consideration to the possibility of requiring compensation outside the context of existing categorical takings").

[68] *See*, *e.g.*, United States v. Doremus, 249 U.S. 86, 93 (1919) ("If the legislation enacted has some reasonable relation to the exercise of the taxing authority conferred by the Constitution, it cannot be invalidated because of the supposed motives which induced it.").

[69] United States v. Sanchez, 340 U.S. 42, 44 (1950).

[70] Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381, 393 (1940) (citing Head Money Cases, 112 U.S. 580, 596 (1884)).

enforcement mechanism.[71] Absent such independent authority, such nominal taxes have been found to be invalid where they fail to be supportable by the taxing power alone.[72]

When distinguishing between taxes and penalties, the Court has noted:

> the difference between a tax and a penalty is sometimes difficult to define and yet the consequences of the distinction in the required method of their collection often are important . . . . Taxes are occasionally imposed in the discretion of the legislature on proper subjects with the *primary* motive of obtaining revenue from them and with the *incidental* motive of discouraging them by making their continuance onerous. They do not lose their character as taxes because of the incidental motive. But there comes a time in the extension of the penalizing features of the so-called tax when it loses its character as such and becomes a mere penalty with the characteristics of regulation and punishment.[73]

In cases examining this distinction, the Supreme Court has identified a number of factors that are indicative of a regulatory, rather than revenue, motive,[74] including whether:

- The provision at issue imposes "a heavy exaction" if the taxpayer does not follow "a detailed and specified" course of conduct;[75]
- The amount of the tax is proportional to the "extent or frequency" of the departure from such course of conduct;[76]
- The departure from a course of conduct is only taxed if the taxpayer "knowingly" departs from the specified conduct;[77]
- The administration of the tax is undertaken by agencies that are not normally involved in the collection of taxes.[78]

In the case of the excise tax created in Section 102, the tax would be a heavy exaction that only falls on manufacturers of selected drugs that do not enter into an agreement with the Secretary or comply with other requirements.[79] However, the presence of the three other factors is not as clear. The Bill would impose the tax on each sale during a period of noncompliance and would increase as the period of noncompliance lengthens.[80] It does not appear to be a defense to the tax that the manufacturer was unaware that it was selling a selected drug without an agreement in place. Lastly, while the HHS

[71] *Id.* at 393–94 (upholding a tax on coal producers who did not meet certain federal requirements because imposing federal requirements was a valid exercise of Congress's power to regulate interstate commerce).

[72] Child Labor Tax Case, 259 U.S. 20, 39 (1922) (invalidating tax on the employment of children because regulation of child labor had previously been held, in *Hammer v. Dagenhart*, 247 U.S. 251, 276–77 (1918), to not fall within Congress's authority under the Commerce Clause at the time). Congress's authority under the Commerce Clause has since been recognized by the Supreme Court to be much broader. *See, e.g.*, United States v. Darby, 312 U.S. 100, 116 (1941).

[73] *Child Labor Tax Case*, 259 U.S. at 38 (emphasis added).

[74] *Id.* at 36. *See also* Nat'l Fed'n Indep. Bus. v. Sebelius, 567 U.S. 519, 565–66 (2012) (applying the factors from the *Child Labor Tax Case* to a tax penalty imposed on individuals who did not maintain adequate health insurance during the year).

[75] *Child Labor Tax Case*, 259 U.S. at 36.

[76] *Id.*

[77] *Id.* at 37.

[78] *Id.*

[79] As described above, the excise tax would capture 65% to 95% of total revenues from covered sales. *See* discussion *supra* notes 27–30 and accompanying text.

[80] H.R. 3, § 102 (creating new IRC § 4192(b), (c)).

Secretary may trigger a period of noncompliance in some cases,[81] it would appear that the Treasury Department would still be responsible for assessing and collecting the tax.[82]

It is unclear whether all of these factors must be met to determine that a tax is principally regulatory, or whether an extremely high exaction, for example, would render a tax regulatory or punitive, even if the other factors are not present. However, even if it is assumed that Congress's taxing power cannot be the basis for the excise tax in Section 102, courts may look to other congressional powers that may be used in conjunction with the taxing power to authorize a particular exaction. For example, in *Sunshine Anthracite Coal Co. v. Adkins*, the Supreme Court upheld a federal tax that imposed a 19.5% tax on coal that a mining company sold after the company did not agree to participate in a Bituminous Coal Code that, among other things, set minimum and maximum prices for coal.[83] The Court acknowledged that "[c]learly this tax is not designed merely for revenue purposes. In purpose and effect it is primarily a sanction to enforce the regulatory provisions of the Act."[84] However, the Court went on to say:

> But that does not mean that the statute is invalid and the tax unenforceable. Congress may impose penalties in aid of the exercise of any of its enumerated powers. The power of taxation, granted to Congress by the Constitution, may be utilized as a sanction for the exercise of another power which is granted it. . . . It is so utilized here.
>
> The regulatory provisions are clearly within the power of Congress under the commerce clause of the Constitution (article 1, s 8, cl. 3). These provisions are applicable only to sales or transactions in, or directly or intimately affecting, interstate commerce. The fixing of prices, the proscription of unfair trade practices, the establishment of marketing rules respecting such sales of bituminous coal constitute regulations within the competence of Congress under the commerce clause.[85]

Insofar as the provisions of Title I of H.R. 3, which establish the Secretary's authority to enter into maximum price agreements with manufacturers of selected drugs, are permissible regulatory provisions under Congress's authority over interstate commerce,[86] it would appear that Congress could rely upon that authority, combined with its authority to levy taxes, to impose an excise tax on covered sales by noncompliant drug manufacturers. While Congress likely has the power to impose such a tax, the external limits on the *extent* of that tax are discussed in the next section.

The Eighth Amendment's Excessive Fines Clause

Though Congress likely has the constitutional authority to impose the excise tax as discussed in the previous section, its ability to do so may be subject to constitutional limitations—specifically the Eighth Amendment's Excessive Fines Clause.[87]

The Eighth Amendment provides that "excessive fines" "shall not be . . . imposed."[88] The Supreme Court has held that "a punitive forfeiture violates the Excessive Fines Clause if it is *grossly disproportional* to

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[81] *Id.* § 102 (creating new IRC § 4192(b)(4) which creates a noncompliance period that is initiated when HHS Secretary certifies that required information from manufacturer is overdue).

[82] The excise tax would be codified in Chapter 32 of the IRC; Section 7801(a) of the IRC provides that the Department of the Treasury shall perform or supervise the administration and enforcement of the IRC.

[83] Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381, 387–89 (1940).

[84] *Id.* at 393.

[85] *Id.*

[86] *See* West Lynn Creamery v. Healy, 512 U.S. 186, 192 (1994) ("The Commerce Clause vests Congress with ample power to enact legislation providing for the regulation of prices paid to farmers for their products.").

[87] Title I also imposes civil penalties on drug manufacturers for violating terms of agreements entered into between the manufacturer and the Secretary. *See* H.R. 3, § 101(a) (creating SSA § 1198).

[88] U.S. CONST. amend. VIII.

the gravity of a defendant's offense."[89] The Court adopted this standard (rather than one of "strict proportionality") out of a recognition that "any judicial determination regarding the gravity of a particular criminal offense will be inherently imprecise" and that "judgments about the appropriate punishment for an offense belong in the first instance to the legislature."[90] Courts applying the Excessive Fines Clause have concluded that the Clause extends to monetary exactions, whether "a payment in kind, *i.e.*, a forfeiture, or a payment in cash,"[91] including civil penalties.[92] However, the Excessive Fines Clause only serves to "'limit[] the government's power to extract payments . . . *as punishment* for some offense.'"[93] Thus, the Excessive Fines Clause "applies only to those forfeitures that may be characterized, at least in part, as 'punitive'";[94] it does not apply to fines that are "remedial" and "compensat[e] the government for lost revenues."[95]

The Supreme Court laid out these principles in *United States v. Bajakajian*, holding that a $357,144 forfeiture was grossly disproportional to the defendant's offense of failing to report he intended to transport that money out of the country.[96] The Court noted that the defendant's crime was "solely a reporting offense" that was "unrelated to any other illegal activities," and the defendant did "not fit into the class of persons for whom the statute was principally designed."[97] Further, the court noted that the maximum fine under the Sentencing Guidelines for this offense was $5,000[98]—far less than the forfeited amount. Finally, the Court observed that the defendant caused "minimal" harm, depriving the government "only of the information that $357,144 had left the country."[99] Taken together, the Court concluded that the $357,144 forfeiture was grossly disproportional to the defendant's offense.[100]

Courts have considered several factors distilled from *Bajakajian* to determine whether a fine is grossly disproportional: "(1) the essence of the crime; (2) whether the defendant fits into the class of persons for whom the statute was principally designed; (3) the maximum sentence and fine that could have been imposed; and (4) the nature of the harm caused by the defendant's conduct."[101] However, courts have also recognized that "[t]hese factors 'hardly establish a discrete analytic process,'"[102] and so have considered additional factors as well, such as "whether the [fine] would deprive an offender of his livelihood, *i.e.*, his

[89] United States v. Bajakajian, 524 U.S. 321, 334 (1998).

[90] *Id.* at 336. *See also* United States v. Viloski, 814 F.3d 104, 112 (2d Cir. 2016) ("Our role in reviewing criminal forfeitures is solely to examine them for gross disproportionality; in other respects, we must defer to Congress.").

[91] von Hofe v. United States, 492 F.3d 175, 182 (2d Cir. 2007).

[92] Collins v. SEC, 736 F.3d 521, 526 (D.C. Cir. 2013) ("A civil penalty violates the Excessive Fines Clause if it 'is grossly disproportional to the gravity of' the offense."). *See also* Towers v. City of Chicago, 173 F.3d 619, 623–24 (7th Cir. 1999) ("The parties have not disputed that the Eighth Amendment's Excessive Fines Clause applies to the civil penalties at issue in this case.").

[93] *Bajakajian*, 524 U.S. at 328 (quoting Austin v. United States, 509 U.S. 602, 609–10 (1993)).

[94] *Viloski*, 814 F.3d at 109.

[95] *von Hofe*, 492 F.3d at 182.

[96] *Bajakajian*, 524 U.S. at 337–38.

[97] *Id.*

[98] *Id.* at 338.

[99] *Id.* at 339.

[100] *Id.* at 339–40.

[101] United States v. Bikundi, 926 F.3d 761, 795 (D.C. Cir. 2019) (quoting United States v. Varrone, 554 F.3d 327, 331 (2d Cir. 2009)).

[102] *Id.*

'future ability to earn a living.'"[103] Applying these factors, courts have upheld a variety of fines (whether forfeiture or penalty).[104]

Assuming the excise tax is not authorized by Congress's taxing power alone, and is actually a means of enforcing a regulatory drug pricing statutory scheme, it could be viewed as a punitive measure subject to the Excessive Fines Clause. As noted above, the excise tax would impose an escalating tax on the manufacturer's sale of a drug during one of the noncompliance periods.[105] On one hand, the excise tax could be viewed by a court as having the remedial function of clawing back a portion of a drug manufacturer's gains derived from the sale of a drug during a noncompliance period, thus suggesting that it is not punitive. On the other hand, the size of the tax and the fact that it is imposed only when a manufacturer is in a state of noncompliance could lead a court to conclude that the tax is "at least in part . . . 'punitive,'"[106] thus subjecting it to the Excessive Fines Clause.[107]

If the excise tax were deemed punitive, some of the factors courts might consider could suggest it is excessive. With respect to the "essence of the offense," for instance, the excise tax is imposed on sales that occur within specified noncompliance periods, such as the period during which a manufacturer declines to negotiate or fails to reach an agreement on a negotiated price with the Secretary, as well as during periods of noncompliance with reporting requirements.[108] Unlike the conduct at issue for most fines that courts have upheld under the Eighth Amendment, the essence of these violations under Title I is not criminal, fraudulent, or even negligent in nature.[109] The violations involving reporting requirements also appear similar to the offense identified in *Bajakajian*, which the Court deemed less severe than other offenses, which weighed in favor of the Court's conclusion that the fine was excessive.

Given the lack of analogous case law in this context, however, it is unclear how courts would consider other relevant factors in making the excessiveness determination. While a drug manufacturer would likely "fit into the class of persons for whom [H.R. 3] was principally designed,"[110] it is uncertain how

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[103] United States v. Viloski, 814 F.3d 104, 111 (2d Cir. 2016); *see also* United States v. Levesque, 546 F.3d 78, 84–85 (1st Cir. 2016) ("The Supreme Court has made it clear that the notion that a forfeiture should not be so great as to deprive a wrongdoer of his or her livelihood is deeply rooted in the history of the Eighth Amendment.").

[104] *See, e.g.*, *Bikundi*, 926 F.3d at 776, 795 (sustaining a forfeiture order totaling $80 million for each of the defendants, reasoning there was a "close match" between "the amounts of the illicit funds" the defendant's obtained via fraud "and the [forfeiture amounts]"); Collins v. SEC, 736 F.3d 521, 522, 526–27 (D.C. Cir. 2013) (holding that a civil penalty of $310,000 imposed for violation of the securities laws was not unconstitutional because (1) the defendant's "violations of securities laws were grave," (2) he "fit[] within the class of persons for whom the statute was designed," (3) he "may have been eligible for an even larger penalty," and (4) the violations inflicted significant financial harm on vulnerable groups); Bunk v. Gosselin World Wide Moving, N.V., 741 F.3d 390, 395, 400–01, 408–10 (4th Cir. 2013) (holding that a $24 million penalty under the False Claims Act was constitutional given that the defendant was "precisely within the class of wrongdoers contemplated by" the False Claims Act, that his "misdeeds were of substance," and that his scheme resulted in financial harm and "sh[ook] the public's faith in the government's competence").

[105] H.R. 3, § 102 (creating 26 U.S.C. § 4192).

[106] *Viloski*, 814 F.3d at 109.

[107] *Cf.* Kitt v. United States, 277 F.3d 1330, 1337 (Fed. Cir. 2002) (holding that a 10% tax on the withdrawal of funds from an IRA was not a penalty subject to the Excessive Fines Clause); Moser v. United States, 166 F.2d 1214, 1998 WL 833714, at * 1–2 (6th Cir. Nov. 20, 1998) (reasoning that a 2% tax on wagers was likely not punitive and was not excessive in any vent).

[108] H.R. 3, § 102 (creating 26 U.S.C. § 4192).

[109] *See, e.g.*, *Collins*, 736 F.3d at 526–27 (upholding civil penalty against a supervisor of a financial broker where the supervisor's conduct "involv[ed] deceit to enable the fraudulent actions of [the financial broker]"); Towers v. City of Chicago, 173 F.3d 619, 625–26 (7th Cir. 1999) (upholding a city ordinance that imposed a $500 civil penalty on vehicle owners for illegal items found in their vehicles because they may be "held responsible for allowing their vehicles to be misused" even though "the gravity of [their] offence is not high").

[110] *See* United States v. Bikundi, 926 F.3d 761, 795 (D.C. Cir. 2019).

substantial courts would consider the "nature of the harm" at issue.[111] The "nature of the harm" from the sale of a selected drug during a noncompliance period could be viewed as either administrative in nature—if noncompliance results from failure to comply with the reporting requirements—or economic—to the extent consumers and Medicare would pay higher prices for the selected drug during that period. To the extent the harm is economic, the degree of harm will depend (at least in part) on several factors, including which of the noncompliance periods triggered the excise tax, how much the sale price exceeded the MFP, and the affected patient populations.

Courts have upheld substantial exactions based on certain generalized harm. In *Bunk v. Gosselin World Wide Moving, N.V.*, for instance, the U.S. Court of Appeals for the Fourth Circuit upheld a $24 million False Claims Act penalty based on harm not "confined strictly to the economic realm," but on the ability of the defendant's fraud, when publicized, to undermine the public's faith in the government's competence.[112] In *Collins v. SEC*, the U.S. Court of Appeals for the D.C. Circuit upheld a $310,000 civil penalty against a supervisor of a financial broker who violated securities law, based not only on harm to elderly customers caused by the broker, but also the harm from "the failure of supervision [that] created a more general risk of wrongdoing in the office."[113] Although it is also possible that the excise tax could be viewed as excessive if it were to "deprive [a drug manufacturer] of [its] livelihood,"[114] such an argument would ultimately depend on the manner in which the excise tax affects each manufacturer.[115]

Ultimately, even if certain factors suggest the excise tax is disproportional, it is unclear whether a court would consider the excise tax to be *grossly* disproportional to the gravity of a drug manufacturer's offense given the fact-intensive nature of the inquiry, the deference courts afford to Congress in this area, and the absence of directly relevant case law.

Preclusion of Judicial Review

Title I also exempts certain agency action from judicial scrutiny, including the "determination of the [MFP] of a selected drug."[116] Generally speaking, Congress can withhold jurisdiction from the federal courts as it sees fit.[117] Similarly, the Administrative Procedure Act expressly contemplates that a statute may preclude agency action from judicial review.[118] However, the Supreme Court has stated that "serious questions" about constitutionality would result if Congress were to attempt to "deny any judicial forum

[111] *See supra* note 104.

[112] *See id.*

[113] *See id.*

[114] United States v. Levesque, 546 F.3d 78, 84–85 (1st Cir. 2016).

[115] The third factor courts consider—the maximum sentence and fine that could have been imposed—does not appear to be applicable in this situation.

[116] H.R. 3, § 101(a) (creating SSA § 1199(d)(3)).

[117] *See* Sheldon v. Sill, 49 U.S. 441, 449 (1850) ("Congress may withhold from any court of its creation jurisdiction of any of the enumerated controversies. Courts created by statute can have no jurisdiction but such as the statute confers. No one of them can assert a just claim to jurisdiction exclusively conferred on another, or withheld from all."). *See also Ex parte* McCardle, 74 U.S. 506, 514 (1868) ("We are not at liberty to inquire into the motives of the legislature. We can only examine into its power under the Constitution; and the power to make exceptions to the appellate jurisdiction of this court is given by express words.").

[118] 5 U.S.C. § 701(a)(1) ("This chapter applies, according to the provisions thereof, except to the extent that . . . statutes preclude judicial review."). *See also* Dep't of Commerce v. New York, 139 S. Ct. 2551, 2567 (2019) ("Review is not available [under the APA], however, to the extent that a relevant statute precludes it, or the agency action is committed to agency discretion by law." (internal quotations and citations omitted)). *But see* INS v. St. Cyr, 533 U.S. 289, 298 (2001); City of Chicago v. Int'l Coll. of Surgeons, 522 U.S. 156, 183 (1997) ("[J]udicial review of [federal] administrative action is the rule, and nonreviewability an exception which must be demonstrated." (alterations in original) (quoting Barlow v. Collins, 397 U.S. 159, 166 (1970))).

for a colorable constitutional claim."[119] As a result, the Court has held that "where Congress intends to preclude judicial review of constitutional claims its intent to do so must be clear."[120] In practice, this rule has meant that courts generally interpret federal statutes creating exemptions from judicial review to permit review of constitutional issues that those laws or actions might raise.[121]

With respect to Title I, it could be argued that some of the potential constitutional challenges discussed above, particularly with respect to a potential Takings Clause challenge contesting the negotiated MFP, fall within the Title I's clause exempting those decisions from scrutiny. However, given past precedent and the lack of a clear intent in the statute to preclude constitutional claims, the most likely outcome of such a challenge would be that a court would uphold the right of the challenging party to proceed with its constitutional claim.

For example, in the Supreme Court case *Johnson v. Robinson*, an action was brought against the Administrator of the Veterans' Administration (VA) by a conscientious objector, who argued that the Administrator had violated his First and Fifth Amendment Rights by denying him benefits pursuant to the relevant statutes.[122] The VA sought to dismiss the case, citing a law that provided that decisions of the VA "on any question of law or fact under any law administered by the Veterans' Administration" were unreviewable by any court.[123] Despite this language, the Court concluded that it had jurisdiction, determining that the plaintiffs' challenges were not challenges to a "decision of the Administrator" but rather "to a decision of Congress."[124] Constitutional challenges to Title I would likely be treated in a similar fashion to avoid the "serious questions" that might arise if Congress actually foreclosed review of such issues. As a consequence, in spite of the Bill's language, issues relating to the MFP, if framed as constitutional questions, might be examined by a court.

Statutory Interpretation

Finally, in examining Title I's proposed language, questions may arise about the meaning of a particular word or phrase, or the lack of explicit language concerning a particular application of a provision. In these types of cases involving statutory interpretation, courts typically begin an analysis with an evaluation of the statute's text.[125] As the Supreme Court has declared, if the language of a statute is clear, there is no need to look outside the statute in order to ascertain the statute's meaning.[126] However, in examining

[119] Webster v. Doe, 486 U.S. 592, 603 (1988) (citing Johnson v. Robison, 415 U.S. 361 (1974)). As one commentator noted, "[t]he scope of Congress's power to withhold federal court jurisdiction is notoriously uncertain," and a complete preclusion of review could implicate constitutional questions related to the scope of Article III, the Due Process Clause, and structural separation of powers concerns. Nicholas Bagley, *The Puzzling Presumption of Reviewability*, 127 HARV. L. REV. 1285, 1313–14 (2014).

[120] *Webster*, 486 U.S. at 603.

[121] *See, e.g.*, Bakran v. DHS, 894 F.3d 557, 564 (3d Cir. 2018) ("Unlike Bakran's APA challenges to the Secretary's actions, we have jurisdiction to review these [constitutional] challenges to the statute."); Alvarez v. ICE, 818 F.3d 1194, 1201–02 (11th Cir. 2016) (provision stating that courts lacked jurisdiction to review "any cause or claim by or on behalf of any alien arising from the decision or action by the Attorney General to commence proceedings, adjudicate cases, or execute removal orders" did not bar alien's constitutional claims arising out of detention); Bartlett v. Bowen, 816 F.2d 695, 700 (D.C. Cir. 1987) (section precluding judicial review of decisions in which amount in controversy is less than $1,000 did not prevent constitutional challenges to the statute itself).

[122] 415 U.S. 361, 363–65 (1974).

[123] *Id.* at 366.

[124] *Id.* at 367–68.

[125] *See, e.g.,* Intel Corp. Inv. Policy Comm. v. Sulyma, 140 S. Ct. 768, 776 (2020) (citing Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242, 251 (2010)).

[126] *See, e.g.*, King v. Burwell, 135 S. Ct. 2480, 2489 (2015); Barnhart v. Sigmon Coal Co., 534 U.S. 438, 450 (2002). *See also* Conn. Nat'l Bank v. Germain, 503 U.S. 249, 253–54 (1992) ("Where the language Congress chose to express its intent is clear

ambiguous statutory text, reviewing courts may consider additional, extrinsic factors to ascertain a provision's meaning, including a provision's legislative history or the underlying public policy at issue.[127]

In Title I, there are examples of legislative text that might present statutory interpretation questions. For example, Title I would direct the Secretary and drug manufacturers to renegotiate an MFP for a selected drug if the Secretary determines there is a "material change" in any item on a list of specified factors considered in price negotiation.[128] The legislation does not provide additional detail as to what constitutes a "material change" for the purpose of MFP renegotiation, which may raise questions about what sorts of changes may trigger the renegotiation process. In a variety of contexts, courts have found "materiality" to be an ambiguous legal principle, subject to judicial interpretation.[129]

As another example, as part of the drug-selection process, Title I would compel the Secretary to request certain drug price information from manufacturers on an "ongoing basis."[130] One may question how frequently the Secretary must ask manufacturers to provide this information. Additionally, in determining which non-insulin drugs to select for the negotiation process, the Bill would allow the Secretary to choose a subset of drugs from a larger group of either (1) the 125 drugs with the greatest estimated net spending under Medicare Parts C and D or (2) the 125 drugs with the greatest net spending in the United States more broadly.[131] Pursuant to this language, it appears unclear whether the provision would require the identification of 250 drugs each year, or whether some drugs could be on both lists.

The Secretary may be able to address the meaning of these or other provisions of the legislation as part of Program implementation. Title I would generally compel the Secretary to carry out numerous administrative duties with respect to the Program, as well as promulgate regulations concerning a number of the Program's requirements.[132] With respect to the scope of the Secretary's authority to implement a particular requirement, the Supreme Court has held that if a statute "leaves a gap or is ambiguous," that courts should "typically interpret it as granting the agency leeway to enact rules that are reasonable in light of the text, nature, and purpose of the statute."[133] An analysis of whether the Secretary is authorized to interpret a Program requirement in a particular manner would depend on the precise legislative language at issue.

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and unambiguous, that is as far as we go to ascertain its intent because we must presume that Congress said what it meant and meant what it said.").

[127] *See, e.g.*, Muransky v. Godiva Chocolatier, Inc., 979 F.3d 917, 939–45 (11th Cir. 2020) (court analyzes statutory text, legislative history, and public policy to ascertain Congress's intent in passing the Fair and Accurate Credit Transactions Act); Dirty Boyz Sanitation Serv. v. City of Rawlins, 889 F.3d 1189, 1199 (10th Cir. 2018) (citing Russell v. United States, 551 F.3d 1174, 1178 (10th Cir. 2008)) (quoting United States v. Manning, 526 F.3d 611, 614 (10th Cir. 2008)) ("If the statute's plain language is ambiguous as to Congressional intent, we look to the legislative history and the underlying public policy of the statute.").

[128] H.R. 3, § 101(a) (creating SSA § 1194).

[129] *See generally, e.g.*, Rayamajhi v. Whitaker, 912 F.3d 1241, 1246 (9th Cir. 2019) (Bennett, J. concurring) (noting that the word "material" in the context of the statute at issue "is patently ambiguous" and that "'[m]aterial' has several definitions, ranging from 'more or less necessary' to 'important' to merely 'having influence or effect'"). *See also generally* Universal Health Servs. v. United States ex rel. Escobar, 136 S. Ct. 1989 (2016) (analyzing "materiality" for purposes of the False Claims Act).

[130] H.R. 3, § 101(a) (creating SSA § 1192). *See generally* Bid for Position, LLC v. AOL, LLC, 2008 U.S. Dist. LEXIS 108391 (E.D. Va. 2008) (noting that the term "ongoing" has multiple meanings in the dictionary).

[131] H.R. 3, § 101(a).

[132] *See, e.g., id*. (creating SSA § 1196).

[133] Cuozzo Speed Techs., LLC v. Lee, 136 S. Ct. 2131, 2142 (2016) (citing United States v. Mead Corp., 533 U.S. 218, 229 (2001); Chevron U.S.A., Inc. v. Nat. Res. Def. Council, 467 U.S. 837, 843 (1984)) (internal quotation marks omitted). For a discussion of judicial review of federal agency action, see CRS Report LSB10558, *Judicial Review under the Administrative Procedure Act (APA)*, by Jonathan M. Gaffney.