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MEMORANDUM October 21, 2019

Subject: **Legal Analysis of Title I of H.R. 3, the Lower Drug Costs Now Act of 2019**

From: [redacted]

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This memorandum examines various constitutional or other legal considerations raised by Title I of H.R. 3, the Lower Drug Costs Now Act of 2019.[1] Title I of H.R. 3 would authorize the Secretary of Health and Human Services (Secretary) to negotiate with drug manufacturers concerning the prices of certain selected drugs,[2] in an effort to lower drug prices.[3] This memorandum begins by describing relevant provisions of Title I, before discussing selected legal issues related to the Takings Clause of the Fifth Amendment, Congress's Taxing Power, the Excessive Fines Clause of the Eighth Amendment, issues related to preclusion of judicial review, and certain statutory interpretation issues.

[1] H.R. 3, 116th Cong. §§101-102 (2019).

[2] This memorandum analyzes the version of H.R. 3 as it was introduced on September 19, 2019 and is limited to an analysis of Title I of the bill. Since H.R. 3 was introduced, the House Committee on Energy and Commerce and House Committee on Education and Labor have held markup sessions on the bill on October 17, 2019, and the House Committee on Ways and Means is scheduled to mark up the bill on October 22, 2019. As to Title I, the amendments to the bill from the markup sessions to date include an amendment to increase the number of selected drugs subject to negotiation and an amendment to add a category of new-entrant drugs subject to negotiation. These amendments do not substantively affect the legal analysis discussed herein.

[3] *See* H.R. 3—The Lower Drug Costs Now Act, https://www.speaker.gov/LowerDrugCosts (last accessed Oct. 16, 2019).

Overview of Title I of H.R. 3

Title I of H.R. 3 would establish a Fair Price Negotiation Program (Program) that would generally require the Secretary to negotiate, on behalf of Medicare[4] and commercial health plans[5] that do 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[6] with their manufacturers.[7] A selected drug's MFP would be the price a manufacturer and the Secretary, following negotiation, agree to for an applicable price year or period.[8] The Program would place a cap on the maximum negotiated prices based on the relevant drugs' prices in certain international markets.[9]

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.[10] These three functions, as well as other provisions of Title I that are relevant to this memorandum, are discussed below.

Selected Drug Identification and Publication

Under the Program, the Secretary would need to annually publish a list of selected drugs that would be subject to price negotiation or renegotiation.[11] The list would include (1) non-insulin, single-source drugs or biological products chosen from a larger pool of negotiation-eligible drugs; and (2) all qualifying insulin products.[12] The Secretary would need to choose a selected drug from a larger pool of negotiation-

[4] 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 physicians' and other outpatient items and services. *See id*. §§ 1395c to 1395i-5 (Medicare Part A); *id*. §§ 1395j to1395w-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); §§ 1395w-101 - 1395w-154 (Medicare Part D). All parts of the Medicare statute are housed within the Social Security Act (SSA).

[5] 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).

[6] The Program would apply to qualifying single source drugs, defined to include a Food and Drug Administration (FDA)-approved drug product that continued to be marketed pursuant to FDA approval and was not the listed drug for any approved generic drug. A qualifying single source drug could also be a biological product that was licensed, including any product that had been deemed to be licensed, and continued to be marketed pursuant to the license and was not the reference product for any biosimilar. If a manufacturer or sponsor marketed both a brand name drug and a generic or a biologic and a biosimilar, the brand or biologic could still be considered a qualified single source drug. An insulin product would be considered a qualifying single source drug if it were FDA-approved or licensed and continued to be marketed under the approval or license. *See* H.R. 3, § 101(a) (creating SSA § 1192(e)).

[7] *Id*. (creating SSA § 1191).

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

[9] *Id*. (creating SSA § 1194(c)).

[10] *Id*. (creating SSA § 1191(a)).

[11] *Id*. (creating SSA § 1192).

[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)(3)).

eligible drugs. A drug would be negotiation-eligible if it: (1) is among the 125 qualifying single source covered Medicare Part D drugs with the greatest estimated net spending in Medicare Parts C and D, (2) is among the 125 qualifying single source drugs in the United States with the greatest estimated net spending; or (3) is a qualifying insulin product.[13] In choosing the 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]

Agreements Between the Secretary and Manufacturers of Selected Drugs

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] Under a central component of these agreements, participating manufacturers of selected drugs would be required to offer these drugs at the negotiated prices to (1) enrollees in Medicare Part D plans (including both standalone prescription drug plans (PDPs) and prescription drug plans offered as part of Part C Medicare Advantage plans (MA-PDs)); (2) enrollees of participating commercial health plans; and (3) specified health care providers that administer selected drugs to Medicare beneficiaries under Parts A and B.[16] Additionally, pursuant to these agreements, the Secretary and manufacturers would also need to renegotiate the MFP for a selected drug if the Secretary determined there was a material change in any item on a list of specified factors considered in price negotiation.[17]

Price Negotiation and Renegotiation Process

Under the agreements between manufacturers of selected drugs and the Secretary, Title I would expressly direct these entities to negotiate (or, if applicable, renegotiate), an MFP.[18] The legislation would instruct the Secretary to develop a consistent methodology for MFP negotiations, subject to certain specified factors.[19] As noted above, 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 such year.[21] The bill would define the AIM price as the net average price (volume weighted, if practicable), for any dosage form and strength of a drug in 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 there was no AIM price for an initial applicability year, for every plan year until there was an AIM price, the MFP or renegotiated MFP could not exceed 85% of the drug's average manufacturer price[23] for a year.

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[13] *Id*. (creating SSA § 1191(d)).

[14] *Id*. (creating SSA § 1192(b)). "Fair price eligible individuals" would include individuals enrolled in Medicare Part D PDPs and MA-PDs, Medicare Part B, or entitled to Medicare Part A. In the private coverage markets, eligibility for the negotiated price for a selected drug would be limited to individuals enrolled in group health plans or health insurance coverage in the group or individual market with which there was in effect an agreement with the HHS Secretary for such a selected drug. H.R. 3, § 101(a) (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)).

[20] *Id*. (creating SSA § 1194(c)).

[21] *Id*. (creating SSA §1194(c).

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

[23] *Id*. (creating SSA § 1194(b)(3)). 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

Manufacturers and the Secretary would be restricted from negotiating a selected drug's MFP above this price threshold.

Title I would also require the Secretary to publish the MFP for a selected drug in the *Federal Register*.[24] In subsequent years, the Secretary would have to publish prices for selected drugs that equal the MFP for the selected drug for the previous plan year increased by the annual percentage increase in the consumer price index for all urban consumers, U.S. city average (CPI-U), as of September of the previous year.[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]

Other Relevant Provisions

Title I includes certain enforcement mechanisms that are generally designed to promote participation in the Program. Relevant to this memorandum 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 would be subject to an escalating excise tax based on the sales price of the drug and the length of time the manufacturer was in a period of non-negotiation. The excise tax is imposed on the sale of selected drugs by a manufacturer, producer, or importer during certain "non-compliance periods."[28] That excise tax is calculated as "a percentage of the sum of the sales price plus the tax imposed," with the percentage escalating from 65 percent to 95 percent as non-compliance continues.[29]

Title I also imposes two civil penalties to promote compliance by participating manufacturers. The first is "a civil monetary penalty" imposed on "[a]ny manufacturer of a selected drug that has entered into an agreement [with the Secretary] ... that does not provide access to a price that is not more than the maximum fair price (or a lesser price) for such drug for such year ...."[30] This penalty is "equal to ten times the amount equal to the difference between the price for such drug ... and the maximum fair price for such drug[.]"[31] The second civil penalty is imposed on a drug manufacturer who "is in violation of a requirement imposed pursuant to section 1193(a)(6)"—which allows the Secretary to impose requirements "for purposes of administering the program."[32] This penalty may not exceed $1 million per violation.[33]

Additionally, Title I also includes 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.[34]

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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, § 102 (creating SSA § 1195).

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

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

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

[28] *Id*.

[29] *Id*.

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

[31] *Id*. (creating SSA § 1198(a)).

[32] *Id*. (creating SSA § 1198(b)).

[33] *Id.*

[34] *Id*. (creating SSA § 1199(d)).

Analysis

The Program created by Title I raises a number of legal considerations. First, because the negotiation under the Program is intended to lower the prices manufacturers can charge for certain selected, single-source drugs, the Takings Clause of the Fifth Amendment may be implicated. Second, the Program's enforcement mechanisms—the excise tax and civil monetary penalties—may raise questions relating to the scope of Congress's taxing power and the Excessive Fines Clause of the Eighth Amendment. Third, the Program's limitation on judicial review may prompt questions regarding Congress's powers to limit the subject matter jurisdiction of Article III courts. Finally, in setting forth the parameters of the Program, the language of Title I may implicate certain statutory interpretation questions. This section discusses each of these issues in more detail below.

Takings Clause of the Fifth Amendment

The Takings Clause of the Fifth Amendment prohibits private property from being "taken for public use, without just compensation."[35] The Takings Clause "does not prohibit the taking of private property, but instead places a condition on the exercise of that power" by requiring the government provide just compensation for an otherwise proper governmental interference with property rights.[36] 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."[37] 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.[38] Here, because the Program under Title I of the LDCNA 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 be entitled to a temporary monopoly resulting from the applicable patent protection and regulatory exclusivities,[39] the operation of the Program could result in certain economic losses to the manufacturers and thus implicate a regulatory taking.[40]

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[35] U.S. CONST. Amend. V.

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

[37] *Id.* at 537; *see also* Horne v. Dep't of Agric., 135 S. Ct. 2419, 2427 (2015); Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001 (1983).

[38] *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.").

[39] *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.

[40] In general, regulations that impose price control—that is, certain ceiling price that a property owner may charge for the use or transfer of its properties—may raise Takings 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).

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 state law, ordinances, or express and implied contracts—must be at issue.[41] 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 ambit of the Takings Clause.[42] Second, for selected drugs that are single-source drugs or biological products, there may be certain intangible intellectual property interests that raise unique questions under the Takings Clause. While the Supreme Court has recognized that certain intangible property interest, such as a trade secret under applicable state law, could be protected property interest for purposes of the Takings Clause,[43] the Court has not squarely addressed whether patents—which are granted under federal law—are protected private property for purposes of the Takings Clause.[44] While the Supreme Court has presumed that a granted patent would be protected private property subject to the Fifth Amendment,[45] 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.[46] 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.[47] This right thus raises similar uncertainties as to whether it would be a protected property interest for purposes of the Takings Clause.[48]

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[41] *See* Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1001 (1983); 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, is 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).

[42] *See Horne*, 135 S. Ct. at 2427 (analyzing whether a regulatory reserve requirement effected a taking of raisin crops, a form of personal property).

[43] *Ruckelshaus*, 467 U.S. at 1003-04.

[44] *Horne*, 135 S. Ct. at 2427. In *Horne*, the Supreme Court, in considering whether a regulatory taking had been effected on raisin crops, a personal property, 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)).

[45] *See id.*

[46] *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 interest under the Fifth Amendment), *vacated on other grounds*, 672 F.3d 1309, 1317-22 (Fed. Cir. 2012).

[47] *See* CRS Report R45666, *supra* note 39, at 23.

[48] 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 to the rights holder. Instead, the exclusivities place a restriction on FDA and its ability to approve other applications or licenses. *See* CRS Report R45666, *supra* note 39, at 48 n.468.

Assuming the Program affects protected property interests, two potential standards may apply in determining whether the Program effects a regulatory taking of those interests. Under the more deferential approach, which the Supreme Court applied in *Ruckelshaus v. Monsanto*, a regulation that requires property owners to dedicate portions of their property for public use does not amount to a taking if the property is provided as a condition of the owner's voluntary participation in a regulatory scheme, the owner derives certain discretionary government benefits in exchange for submitting to the condition, and the condition is rationally related to a legitimate government interest.[49] In *Ruckelshaus*, for instance, the Court concluded that a regulation that required pesticide manufacturers to publicly disclose, under some circumstances, certain trade-secret health and safety data did not constitute a taking because 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, participation in registration allowed the manufacturers to sell their products in the U.S. market—a valuable government benefit, and the disclosure requirement was rationally related to the legitimate government interest to address longstanding public concerns regarding pesticide sale and use.[50] Under a second, less deferential approach, courts have applied an "ad hoc, factual inquir[y]" set forth under *Penn Central Transp. Co. v. City of New York*[51] to determine whether a taking has been effected by a regulation, where the regulation cannot be characterized as a condition of a property owner's voluntary participation in a regulatory scheme to obtain a "government benefit."[52] In this line of cases, courts construe *Ruckelshaus*'s pesticide registration scheme to confer 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.[53] 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[54] or tobacco products[55] in interstate commerce, or to build on one's own property[56]—courts have concluded that such activities do not confer a government benefit and thus cannot establish the "voluntary exchange" found in *Ruckelshaus*.

Here, *Ruckelshaus*'s deferential approach likely does not apply given that Title I does not appear to impose a manufacturer's participation in the Program as a condition of its receipt of certain "government

[49] *Ruckelshaus*, 467 U.S. 1007-08.

[50] *Id.*

[51] 438 U.S. 104, 124 (1978).

[52] 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 a regulation "completely deprive an owner of all economically beneficial use of her property." Maine Educ. Ass'n Benefits Trust v. Cioppa, 695 F.3d 145, 153 (1st Cir. 2012) (citing *Lingle*, 544 U.S. at 538 and 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.

[53] *See, e.g.*, *Horne*, 135 S. Ct. 2419, 2430-31; Philip Morris, Inc. v. Reilly, 312 F.3d, 46-47 (1st Cir. 2002) (Torruella, J.); Nollan v. Cal. Coastal Comm'n, 483 U.S. 825, 833 n.2 (1987).

[54] *See Horne*, 135 S. Ct. 2419, 2430-31 (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").

[55] *See Philip Morris*, 312 F.3d at 46-47 (Torruella, J.) (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").

[56] *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*]").

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*,[57] Title I does not appear to impose 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.[58] 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.[59] 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.[60] Because this activity is a generally lawful activity 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,[61] the relevant factors 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 extent to which the regulation was within the reasonable expectations of the claimant; 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."[62]

Because the *Penn Central* analysis is highly fact-specific, 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.[63] In particular, the strength of a potential takings claim would depend on the negotiated MFP of a selected drug, the scope of economic loss resulting from offering this price to Medicare beneficiaries and enrollees of participating commercial plans, whether the revenue generated from sales at

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[57] 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.

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

[59] *See id.*

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

[61] Under an older line of cases analyzing regulations imposing price control, the Supreme Court has 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) and 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).

[62] *Penn Central*, 438 U.S. at 124, 129; *see also* Connolly v. Pension Ben. Guar. Corp., 475 U.S. 211, 225-27 (1986).

[63] *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 challenge of 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).

this price still allows the manufacturer to make a "reasonable return" on the drug, and whether and how this price point would interfere with investment-backed expectations, including any impact on the manufacturer's ability to recoup the relevant research and development costs or fund other research and development.[64] 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.[65] As a practical matter, however, it is generally difficult to prevail on a Takings challenge under the fact-specific *Penn Central* analysis.[66]

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 a MFP agreement with the Secretary, or are not progressing towards such an agreement, there may be questions regarding whether it is actually within Congress's power to levy taxes under the Constitution. Article I, section 8 of the Constitution states that "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.[67] 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.'[68]

But where a challenged tax's character may be more accurately described as a penalty, it may not be supportable under the taxing power alone, and courts have generally asked whether Congress has the authority to regulate the underlying subject matter.[69] If such regulation is authorized under a provision of

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[64] *See, e.g.*, Sierra Med. Servs. Alliance v. Kent, 883 F.3d 1216, 1225-26 (9th Cir. 2018) (analyzing a Takings 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 was not allowed to do so, and as a result suffered a "serious" financial loss that amounted to a loss of 96 percent of the possible rate of return on their investment).

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

[66] In the 40 years since *Penn Central* was decided, the Supreme Court has found a regulatory taking under the *Penn Central* factors in only a small 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").

[67] *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.").

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

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

the Constitution other than the taxing power, the exaction has been sustained as an appropriate enforcement mechanism.[70] Absent such authority, such nominal taxes have been found to be invalid where they fail to be supportable by the taxing power alone.[71]

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

> 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.[72]

In cases examining this distinction, the Supreme Court has identified a number of factors that are indicative of a regulatory, rather than revenue, motive,[73] including whether:

- The provision at issue imposes "a heavy exaction" if the taxpayer does not follow "a detailed and specified" course of conduct;[74]
- The amount of the tax is proportional to the "extent or frequency" of the departure from such course of conduct;[75]
- The departure from a course of conduct is only taxed if the taxpayer "knowingly" departs from the specified conduct;[76]
- The administration of the tax is undertaken by agencies that are not normally involved in the collection of taxes[77]

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.[78] However, the presence of the other factors is not as clear. The bill would impose the tax on each sale during a period of noncompliance and increases as the period of noncompliance lengthens.[79] It does not appear it would 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 Secretary may trigger a

[70] *Id.*, 310 U.S. 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).

[71] 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. U.S. v. Darby, 312 U.S. 100, 116 (1941).

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

[73] *Id.* at 36. *See also* Nat'l Fed'n Indep. Bus. v. Sebelius, 567 U.S. 519, 565-566 (2012) (applying the factors from the *Child Labor Tax Case* to a tax penalty imposed on individuals that did not maintain adequate health insurance during the year).

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

[75] *Id.*

[76] *Id.* at 37.

[77] *Id.*

[78] As described above, the excise tax would capture 65%-95% of total revenues from covered sales. *Supra*, note 27-29 and accompanying text.

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

period of noncompliance in some cases,[80] it would appear that the Treasury Department would still be responsible for assessing and collecting the tax.[81]

It is not clear whether all of these factors would need to be met to determine that a tax was principally regulatory, or whether an extremely high exaction, for example, would render a tax regulatory or punitive, even if the other factors were 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 Company 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 under a Bituminous Coal Code that, among other things, set minimum and maximum prices for coal.[82] 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."[83] 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.[84]

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,[85] 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 of this memorandum.

Excessive Fines Clause of the Eighth Amendment

Though Congress likely has the constitutional authority to impose the excise tax discussed in the previous section, its ability to do so may be subject to constitutional limitations, specifically the Excessive Fines Clause of the Eighth Amendment.[86]

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

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

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

[83] *Id.* at 393.

[84] *Id.*

[85] *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.").

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

The Eighth Amendment provides that "excessive fines" "shall not be . . . imposed."[87] The Supreme Court has held that "a punitive forfeiture violates the Excessive Fines Clause if it is *grossly disproportional* to the gravity of a defendant's offense."[88] The Court adopted this standard (rather than one of "strict proportionality") out of 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."[89] 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,"[90] including civil penalties.[91] However, the Excessive Fines Clause only serves to "'limit[] the government's power to extract payments … *as punishment* for some offense.'"[92] Thus, the Excessive Fines Clause "applies only to those forfeitures that may be characterized, at least in part, as 'punitive,'"[93] and does not apply to fines that are "remedial" and "compensat[e] the government for lost revenues."[94]

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 that he intended to transport that money out of the country.[95] The Court noted that the defendant's crime was "solely a reporting offense" that was "unrelated to any other illegal activities" and that the defendant did "not fit into the class of persons for whom the statute was principally designed."[96] Further, the court noted that the maximum fine under the Sentencing Guidelines for this offense was $5,000[97]—far less than the forfeited amount. Finally, the Court observed that the defendants caused "minimal" harm, depriving the government "only of the information that $357,144 had left the country."[98] Taken together, the Court concluded that the $357,144 forfeiture was grossly disproportional to the defendant's offense.[99]

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."[100] However, courts have also recognized that "[t]hese factors 'hardly establish a discrete analytic process,'"[101] and so have considered additional factors as well, such as "whether the [fine] would deprive an offender of his livelihood, *i.e.*, his

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

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

[89] *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.").

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

[91] 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.").

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

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

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

[95] *Bajakajian*, 524 U.S. at 337-38.

[96] *Id*.

[97] *Id*. at 338.

[98] *Id*. at 339.

[99] *Id*. at 339-40.

[100] 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)).

[101] *Id*. at 795.

'future ability to earn a living'"[102] Applying these factors, courts have upheld a variety of fines (whether forfeiture or penalty).[103]

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 non-compliant periods.[104] 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 manufacturers' gains derived from the sale of a drug during a non-compliance period, thus suggesting that it is not punitive. On the other, the size of the tax and the fact that it is imposed only when a manufacturer is in a state of non-compliance could lead a court to conclude that the tax is "at least in part ... 'punitive,'"[105] making it subject to the Excessive Fines Clause.[106]

If the excise tax were deemed punitive, some of the factors courts consider could suggest that it is excessive. Starting with the "essence of the offense," the excise tax is imposed on sales that occur within specified non-compliant periods, such as the period before a drug price agreement has been reached, as well as during periods of non-compliance with reporting requirements.[107] The essence of these violations—particularly non-compliance with reporting requirements—appears to be similar to the offense identified in *Bajakajian*, which the Court deemed less severe. Further, a drug manufacturer would likely "fit into the class of persons for whom [H.R. 3] was principally designed."[108] Thus, a court could conclude that these factors weigh in favor of an Excessive Fines Clause violation.

However, it is unclear whether the other factors courts consider would support an excessiveness determination. The "nature of the harm" from the sale of a selected drug during a non-compliance period could be viewed as either administrative in nature—if non-compliance results from failure to comply with the reporting requirements—or financial—to the extent the tax is passed on to consumers through higher prices. But it is uncertain how substantial a court might view these harms, particularly as the degree of harm will depend (at least in part) on which of the non-compliance periods triggered the excise tax and how much the sale price exceeded the maximum fair price. But even if such harms are viewed as less severe, the excise tax arguably is no less proportional to those harms than were the exactions upheld in other cases, such as the $24 million penalty in *Bunk v. Gosselin World Wide Moving, N.V.* for a False

[102] 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.").

[103] *See, e.g.*, *Bikundi*, 926 F.3d at 776, 795 (sustained a forfeiture order totaling $80 million for each of the defendants, reasoning that 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. given that the defendant's "violations of securities laws were grave," that he "fit[] within the class of persons for whom the statute was designed," that he "may have been eligible for an even larger penalty," and that 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 the defendant's scheme resulted in financial harm and "sh[ook] the public's faith in the government's competence").

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

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

[106] *Cf.* Kitt v. United States 277 F.3d 1330, 1337 (Fed. Cir. 2002) (holding that a 10 percent 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 percent tax on wagers was likely not punitive and was not excessive in any event).

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

[108] *See Bikundi*, 926 F.3d at 795.

Claims Act violation where the defendant's fraud resulted in substantial financial harm and "sh[ook] the public's faith in the government's competence,"[109] or the $310,000 penalty imposed in *Collins v. SEC* for "grave" securities law violations that inflicted significant financial harm on vulnerable groups.[110] And, though it is also possible that the excise tax could be viewed as excessive if it were to "deprive [a drug manufacturer] of [its] livelihood,"[111] such an argument would ultimately depend on the manner in which the excise tax affects each manufacturer.[112]

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 on-point 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."[113] Generally speaking, Congress can withhold jurisdiction from the federal courts as it sees fit.[114] Similarly, the Administrative Procedure Act expressly contemplates that a statute may preclude agency action from judicial review.[115] However, the Supreme Court has stated that "serious questions" about constitutionality would result if Congress were to attempt to "deny any judicial forum for a colorable constitutional claim."[116] 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."[117] 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.[118]

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[109] *See supra* note 84.

[110] *See supra* note 84.

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

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

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

[114] *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.").

[115] 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))).

[115] 415 U.S. 361, 633-365 (1974).

[116] 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).

[117] *Id.*

[118] *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

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 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 their constitutional claim. For example, in the Supreme Court case *Johnson v. Robinson*, an action was brought against the Administrator of the Veterans' Administration 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.[119] 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.[120] 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."[121] 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 language in the bill, issues relating to the MFP, if framed as constitutional questions, could end up being litigated in court.

Statutory Interpretation

In examining the proposed language of Title I, 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.[122] As the Supreme Court has declared, if the language of the statute is clear, there is no need to look outside the statute in order to ascertain the statute's meaning.[123] However, in examining 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.[124]

In Title I, there are examples of legislative text that may 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 that there is a "material change" in any item on a list of specified factors considered in price negotiation.[125] 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 negotiation process. In a variety of contexts, courts have found "materiality" to

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).

[119] 415 U.S. 361, 633-365 (1974).

[120] *Id.* at 366.

[121] *Id.* at 367-68.

[122] *See, e.g.*, CSX Transp., Inc. v. Ala. Dep't of Revenue, 562 U.S. 277, 283 (2011) (citing Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242, 251 (2010)).

[123] *See, e.g.*, King v. Burwell, 135 S. Ct. 2480, 2489 (2015); Hardt v. Reliance Standard Life Ins. Co., 560 U.S. 242, 251, 130 (2010); 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 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.").

[124] *See, e.g.*, Dirty Boyz Sanitation Serv. v. City of Rawlins, 889 F.3d 1189 (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.").

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

be an ambiguous legal principle, subject to judicial interpretation.[126] Under 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."[127] 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, using the numbers set forth in the September 19, 2019 version of the bill, 125 with the greatest estimated net spending under Medicare Parts C and D, and 125 drugs greatest net spending drugs in the United States.[128] 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 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.[129] 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."[130] 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.

[126] *See generally, e.g.,* Rayamajhi v. Whitaker, 912 F.3d 1241, 1246 (9th Cir. 2019)(Bennett, J. concurring)(court notes 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).

[127] *Id*. (creating SSA § 1192). *See generally* Bid for Position, LLC v. AOL, LLC, 2008 U.S. Dist. LEXIS 108391 (E.D. Va. 2008)(court notes that the term "ongoing" has multiple meanings in the dictionary).

[128] *Id*.

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

[130] 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 R44699, *An Introduction to Judicial Review of Federal Agency Action*, by Jared P. Cole, and CRS Report R44954, *Chevron Deference: A Primer*, by Valerie C. Brannon and Jared P. Cole.