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What's the Latest on Medicare Drug Price Negotiations?

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Introduction

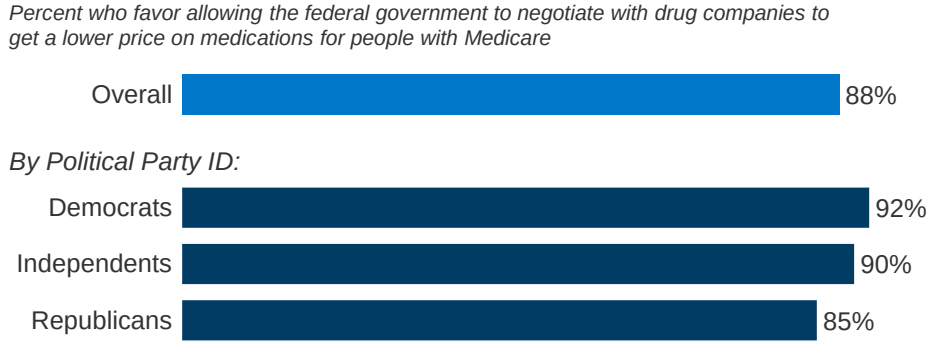
Prescription drug costs are a major concern for consumers and a fiscal challenge for public and private payers. In response, lawmakers are considering a broad range of policy options, including allowing the federal government to negotiate the price of prescription drugs on behalf of people enrolled in Medicare Part D drug plans, a proposal which has strong and bipartisan public support (Figure 1).

Members of the 116th Congress have introduced bills to change the law and allow government drug price negotiation. This proposal is a key feature of the drug price legislation recently announced by Speaker Nancy Pelosi (D-CA) (H.R. 3, the Lower Drug Costs Now Act of 2019), which would require the Secretary of the Department of Health and Human Services (HHS) to negotiate the price of at least 25 (and no more than 250) brand-name drugs without generic competitors, and would make the negotiated price available to both Medicare and private payers. Several Democratic candidates in the 2020 presidential campaign have also stated their support for authorizing federal negotiation of drug prices for Medicare Part D.[1]

This issue brief begins with a brief description of the statutory prohibition on government drug price negotiations and its history and then describes several legislative proposals introduced in the current Congressional session that would give the HHS Secretary authority to negotiate Medicare drug prices. The brief also reviews analysis from the Congressional Budget Office (CBO) of the potential savings that government negotiations may generate for the Medicare program and its beneficiaries.

Figure 1

Majority of the Public Favors Allowing the Federal Government to Negotiate Drug Prices for Medicare Beneficiaries



SOURCE: KFF Health Tracking Poll (conducted October 3-8, 2019). See topline for full question wording and response options.

A Brief History of Medicare Drug Price Negotiation

Even before the Medicare Part D benefit took effect in 2006, some policymakers were proposing a change in law that would allow the Secretary of HHS to negotiate prescription drug prices with drug manufacturers on behalf of Medicare beneficiaries. The Medicare Modernization Act of 2003 (MMA), the law that established the Part D benefit, includes a provision, known as the "noninterference" clause, which stipulates that the HHS Secretary "may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." In effect, this provision means that the government can have no direct role in negotiating or setting drug prices in Medicare Part D.

In the years leading up to passage of the MMA, lawmakers debated whether to add a prescription drug benefit directly to Medicare, similar to coverage of hospital and physician services, or whether the benefit should be provided through a marketplace of private plans that compete for business based on costs and coverage. The latter approach was adopted in the MMA, whereby Medicare contracts with private plan sponsors to provide a voluntary prescription drug benefit, and gives plans authority to negotiate drug prices with pharmaceutical companies, establish formularies, and apply utilization management tools to control costs. This approach contrasts with how drug prices are determined in some other federal programs, such as mandatory drug price rebates in Medicaid, and the use of ceiling prices and minimum discounts, in conjunction with a national formulary, in the Department of Veterans Affairs (VA).

Since the enactment of the MMA, some lawmakers have continued to press for legislation that would give the Secretary of HHS authority to negotiate drug prices for Medicare beneficiaries. During the first several years of the Part D program, these proposals did not get much attention in Congress, both for philosophical reasons and because Part D benefit spending growth was relatively flat—and lower than initially projected—with a large number of brand-name drug patent expirations and growing use of generic drugs helping to keep drug spending in check.

In light of recent concerns about the high and rising price of medications, and with government actuaries projecting a more rapid rise in Medicare drug spending in the years to come, there is renewed interest in allowing the federal government to negotiate drug prices for Medicare Part D enrollees. This policy concept has also recently gained more attention in Congress because Democrats, who have historically been its strongest supporters, now hold a majority in the U.S. House of Representatives. Thus far, the Trump Administration has not proposed this change in law nor taken a position on the Congressional proposals to allow the government to negotiate drug prices, although the president did express support for the idea prior to taking office. The Administration has promoted several other policies as part of a broader effort to reduce prescription drug spending.

Proponents of changing this law believe that giving the HHS Secretary the authority to negotiate drug prices would provide the leverage needed to lower drug costs, particularly for high-priced drugs for which there are no competitors, where private plans may be less able to negotiate lower prices. Opponents counter that the current system of private plan negotiation is working well, and that government

involvement in price negotiations could dampen incentives for pharmaceutical companies to invest in research and development.

What are the current approaches to allowing Medicare to negotiate drug prices?

Lawmakers in the 116th Congress have introduced a variety of bills to allow the federal government to negotiate drug prices in Medicare Part D, with the goal of lowering Part D program spending and enrollees' out-of-pocket costs. Some are stand-alone bills, while others are incorporated in broader legislation to expand health insurance coverage. This discussion focuses on five bills where the primary (or sole) purpose is to allow the Secretary to negotiate drug prices:

- H.R. 3, Lower Drug Costs Now Act of 2019, introduced by Speaker Pelosi and sponsored by Representatives Frank Pallone (D-NJ), Richard Neal (D-MA), and Bobby Scott (D-VA), the respective Chairmen of House Committees Energy & Commerce, Ways & Means, and Education & Labor (as amended on October 16, 2019)
- H.R. 1046/S. 377, Medicare Negotiation and Competitive Licensing Act of 2019, sponsored by Representative Lloyd Doggett (D-TX) in the House and Senator Sherrod Brown (D-OH) in the Senate
- H.R. 448/S. 99, Medicare Drug Price Negotiation Act, sponsored by Representative Elijah Cummings (D-MD) in the House and Senator Bernie Sanders (I-VT) in the Senate
- S. 62, Empowering Medicare Seniors to Negotiate Drug Prices Act of 2019, sponsored by Senator Amy Klobuchar (D-MN)[2]
- H.R. 275, Medicare Prescription Drug Price Negotiation Act of 2019, sponsored by Representative Peter Welch (D-VT)

While these bills seek to achieve the same overall goal of reducing drug prices in Medicare Part D by allowing the Secretary to negotiate prices with drug manufacturers, they take different approaches to achieve that end. The proposals vary in terms of how much direction is given to the Secretary regarding the negotiation process itself; the criteria for determining which drugs would be subject to negotiations; the factors to be considered in determining a negotiated price; the extent to which the Secretary is provided leverage to secure price concessions from drug manufacturers; and fallback approaches that may apply in the event of unsuccessful negotiations.

The Pelosi bill (H.R. 3) amends the non-interference clause under current law by adding an exception that allows for the price negotiation process established by the legislation. The negotiation process applies to at least 25 and up to 250 brand-name drugs lacking generic or biosimilar competitors (including insulin), and would prioritize the 125 drugs with the highest Medicare Part D spending and 125 drugs with the highest spending in the U.S. (net of rebates). The minimum number of drugs subject to negotiation increases to 30 between 2028 and 2032 and 35 in 2033. Newly-approved drugs with prices at or above median household income may also be subject to negotiation, based on projected spending. The proposal requires the Secretary to consider research and development costs, market data, production

and distribution costs, and existing therapeutic alternatives in determining the maximum fair price for a drug.

H.R. 3 establishes an upper limit for the negotiated price equal to 120% of the Average International Market (AIM) price paid by six economically prosperous countries (Australia, Canada, France, Germany, Japan, and the United Kingdom), and the negotiated price applies to both Medicare and commercial payers in group and individual markets. (None of the other bills explicitly mention an upper limit on the negotiated price, nor do they extend the Part D negotiated price to other payers.) H.R. 3 also establishes limits on drug prices for which there is no AIM price available, not to exceed 85 percent of the average manufacturer price (AMP). The AMP is defined as the average price charged by drug companies to wholesalers and pharmacists, net of discounts.

H.R. 3 imposes financial penalties on drug companies that do not comply with the negotiating process as well as in the event that negotiations fail. Manufacturers that fail to negotiate successfully with the Secretary would face an escalating excise tax on the previous year's gross sales of the drug in question, starting at 65% and increasing by 10% every quarter to a maximum of 95%. In addition, manufacturers that refuse to offer an agreed-upon price to any payer would pay a civil monetary penalty equal to ten times the difference between the price charged and the maximum fair price (based on AIM, as explained above).

As of this publication date, H.R. 3 is the only one of the above-listed bills with a cost estimate from CBO. According to its preliminary score, CBO estimates that the negotiation provisions of H.R. 3 would reduce federal direct spending for Medicare by $345 billion over the period between 2023 and 2029 (described in greater detail below).

The Doggett/Brown bill (H.R. 1046/S. 377) strikes the non-interference clause and directs the Secretary to negotiate drug prices with manufacturers. This proposal does not set a limit on the number of drugs covered under Medicare Part D that would be subject to negotiation, in contrast to H.R. 3. The legislation specifies certain factors that must be considered when determining a negotiated price, including clinical and cost effectiveness, the budgetary impact of covering a certain drug, consumer financial burden, the number of therapeutic alternatives with similar effectiveness, revenue from global sales and associated research and development costs, and unmet need for the drug.

In the event of unsuccessful negotiation between the Secretary and manufacturers, the Doggett/Brown proposal authorizes the Secretary to circumvent a manufacturer's exclusivity rights and issue a competitive license to another manufacturer to produce a generic or biosimilar version of the drug for sale to Part D plans. The ability of the HHS Secretary to issue competitive licenses for prescription drugs rests on existing federal power to exercise compulsory licensing authority encoded in 28 U.S.C. section 1498, a law establishing government immunity from patent claims in cases where infringement serves the public good.[3] *(For additional details, see Appendix: Background on Competitive Licensing)*

Under the Doggett/Brown proposal, any manufacturer producing a drug under this licensing authority would need to provide "reasonable compensation" to the original manufacturer. Questions have been raised with regard to implementation of this approach, however, including whether there would be delays in the availability of competitively licensed products if another company lacks current capacity to manufacture an equivalent generic or biosimilar product.

The Cummings/Sanders bill (H.R. 448/S. 99) has many similar provisions to the Doggett/Brown bill, however it prioritizes negotiation of the most costly drugs as well as those with the steepest annual price increases. Like the Doggett/Brown proposal, it does not specify how many drugs would be subject to negotiation, if not all drugs. The proposal outlines several factors to be considered when determining a negotiated price, including clinical and cost effectiveness, the budgetary impact of covering a certain drug, the number of therapeutic alternatives with similar effectiveness, and unmet need for the drug. This proposal also directs the HHS Secretary to establish a Part D formulary, a practice used by private plans in negotiating price discounts with manufacturers.

The Cummings/Sanders bill includes a mechanism to establish a fallback price for a given drug if negotiations fail. The fallback price is determined based on the lowest price paid by other federal programs such as the VA or Medicaid, or prices paid for prescription drugs in certain OECD (Organization for Economic Cooperation and Development) countries, whichever is lower.

The bills sponsored by Klobuchar (S. 62) and Welch (H.R. 275) simply strike the non-interference clause. The Welch bill explicitly requires the Secretary to negotiate Part D drug prices, but without specifying the criteria for choosing which drugs would subject to negotiations or how prices would be set, or a mechanism for establishing a price in the event of unsuccessful negotiations between the Secretary and drug manufacturers.

What has CBO said about the potential for savings from Medicare drug price negotiation?

Preliminary Estimate for H.R. 3

In an October 2019 letter to Chairman Pallone, CBO provided a preliminary estimate of the effects of the drug price negotiation provisions of H.R. 3 on Medicare spending. In prior analyses of drug price negotiation, CBO has said that repealing the non-interference clause and allowing price negotiations between the Secretary and drug manufacturers would yield negligible savings, primarily because the Secretary would have insufficient leverage to secure price concessions. In its analysis of H.R 3, however, CBO indicates that the provision to levy an excise tax on drug companies that do not enter into negotiations or agree to the maximum fair price provides the Secretary with needed leverage to achieve lower drug prices and federal savings.

CBO estimates the drug price negotiation provisions in H.R. 3 would achieve $345 billion in Medicare savings over the period between 2023 (the first year in which maximum fair prices would be used in Part D) and 2029. CBO expects that the lower drug prices resulting from this policy would lead to lower

revenues for drug manufacturers, higher drug prices in other countries, higher use of prescription drugs in the U.S., improved health outcomes resulting from greater medication adherence due to reduced costs, and lower utilization and spending for other Medicare-covered services due to higher adherence.

CBO also estimates that the loss in revenue for drug manufacturers would lead to lead to 8 to 15 fewer drugs coming to market over the next 10 years, of the approximately 300 drugs expected to be approved during this period. CBO has not yet estimated the effects of H.R. 3 on private health plans, nor the effect on out-of-pocket costs and premiums for Medicare Part D enrollees.

Prior Assessments of Medicare Drug Price Negotiations

In its initial assessments of the Medicare drug price negotiation concept in 2004 and 2007, CBO concluded that giving the Secretary authority to negotiate lower prices for a broad set of drugs on behalf of Medicare beneficiaries would have "a negligible effect on federal spending." This conclusion was based on CBO's view that the Secretary would not be able to leverage deeper discounts for drugs than risk-bearing private plans, given the incentives built into the structure of the Part D market, where plan sponsors bid to participate in the program, compete for enrollees based on cost and coverage, and bear some risk for costs that exceed their projections. CBO questioned whether the Secretary would be willing to exclude certain drugs or impose limitations on coverage, as private plans do, "given the potential impact on stakeholders."

At the same time, CBO suggested that savings could potentially be achieved under a defined set of circumstances; for example, if the Secretary were given the authority to establish a formulary that included some drugs and excluded others and imposed other utilization management restrictions, in much the same way that private Part D plans do. Savings could also be achieved if the Secretary were authorized to set drug prices administratively or take regulatory action against companies that did not offer discounts of a certain magnitude.

> *"Negotiation is likely to be effective only if it is accompanied by some source of pressure on drug manufacturers to secure price concessions. The authority to establish a formulary, set prices administratively, or take other regulatory action against firms failing to offer price reductions could give the Secretary the ability to obtain significant discounts in negotiations with drug companies". CBO, April 2007.*

In addition, CBO suggested there is some potential for savings if the Secretary had authority to negotiate prices for a select number of drugs or types of drugs, such as unique drugs that lack competitor products or therapeutic alternatives. This would include many of today's high-priced specialty drugs and biologics. At the same time, based on CBO's assessment of this approach, if only a small share of Medicare drug spending was attributable to the selected drugs, overall federal savings from price negotiations would be "modest" and manufacturers could offset potential losses by setting higher launch prices.

In a more recent assessment of the potential for savings from Medicare drug price negotiation in a May 2019 letter to Senator Chuck Grassley, CBO generally adhered to its previous conclusions: providing the

Secretary with broad authority to negotiate without also exerting some form of pressure on drug manufacturers to lower their prices would likely produce negligible savings. According to CBO, “modest” cost savings could be generated by allowing the Secretary to negotiate prices for a targeted set of drugs, such as those with few substitutes and/or high prices.

CBO also affirmed its previous position that, in order to achieve significant savings, the Secretary would have to exercise greater leverage over drug companies than now occurs with competing Medicare Part D plans, noting that “in the absence of such pressure, the Secretary’s ability to issue credible threats or take other actions in an effort to obtain significant discounts would be limited.”

As noted earlier, H.R. 3 would apply this pressure by imposing financial penalties on drug manufacturers that fail to negotiate with the Secretary. The Doggett/Brown bill relies on competitive licensing, and the Cummings/Sanders bill uses prices in other federal programs and other countries as a fallback. The degree to which these various approaches are effective in securing lower prices from drug manufacturers would have significant implications for Medicare program savings and for Medicare beneficiaries’ out-of-pocket drug costs. CBO has not yet estimated the potential savings attributable to the other bills discussed above.

What are the prospects for Medicare drug price negotiation?

With Medicare Part D prescription drug spending on the rise, and strong and bipartisan public support for policymakers to take action to ensure the affordability of medications (Figure 2), many policy options to lower drug prices are under consideration, including allowing Medicare to negotiate drug prices. A large majority of the public favors a policy to allow the government to negotiate drug prices, although public views can shift substantially when people hear arguments against the policy often used by opponents, including the pharmaceutical industry.

Figure 2

Most Proposals For Lowering Prescription Drug Costs Are Popular Across Parties

% who strongly/somewhat favor each of the following:	Total	Democrats	Independents	Republicans
Allowing the government to negotiate with drug companies to get a lower price for people on Medicare	88%	92%	90%	85%
Allowing the government to negotiate with drug companies to get a lower price for both Medicare and private insurance	85	94	84	84
Placing an annual limit on out-of-pocket costs for seniors enrolled in Medicare Part D plans	81	83	81	82
Allowing Americans to buy prescription drugs imported from licensed Canadian pharmacies	78	75	82	75
Allowing Medicare to place limits on how much drug companies can increase the price of drugs based on annual inflation rates	76	78	77	77
Increasing taxes on drug companies that refuse to negotiate the price of medications with the federal government	72	79	71	69
Lowering what Medicare pays for some drugs based on amounts in other countries where governments more closely control prices	62	73	62	52

SOURCE: KFF Health Tracking Poll (conducted October 3-8, 2019). See topline for full question wording and response options.

Because allowing Medicare to negotiate drug prices would require a change in the law, bipartisan support would be needed for current proposals to move forward in Congress and become law. Congressional Republicans have generally been opposed to allowing the Secretary to negotiate drug prices under Medicare, instead preferring the current market-based approach in Part D. The pharmaceutical industry continues to express its resistance to this proposal based on concerns that it would lower revenue, have a dampening effect on research and development, and limit access to new drugs. Congressional Democrats are generally supportive of government negotiations on drug prices, as is the public, and President Trump endorsed the idea prior to taking office, but it was not included in the Administration's 2018 blueprint to lower drug prices nor in its proposed budgets to date.

While the immediate prospects for allowing the federal government to negotiate drug prices in Medicare are unclear, the strength of public support for this idea suggests that it will continue to have traction among policymakers in the near future.

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Appendix: Background on Competitive Licensing

Allowing the HHS Secretary to issue competitive licenses for prescription drugs, as has been proposed recently, rests on existing Federal power to exercise compulsory licensing authority encoded in 28 U.S.C. section 1498, a law establishing government immunity from patent claims in cases where infringement serves the public good, while affirming the right of the patent holder to "reasonable compensation" in exchange.[4] In the case of pharmaceuticals, if a drug remains under patent protection, the government can authorize production of an equivalent, lower-priced product provided the patent holder receives royalties from its sales. Section 1498 has not been invoked for pharmaceutical products since the early 1970s, but has been used in other more recent cases, including one in 2009 when the U.S. Treasury exercised its authority under section 1498 to allow banks to use patented check fraud software, and another in 2014 when the Department of Defense invoked section 1498 to obtain patent-violating lead-free bullets.[5]

Section 1498 originates from a 1910 law waiving total government immunity from liability for patent infringement.[6] Until the law was enacted, private patent holders had no legal recourse for government violation of exclusivity rights, and Congress sought to provide a partial remedy by allowing patent holders to pursue reasonable compensation. In other words, a patent holder cannot stop the government from producing (or authorizing the production of) a patented good, but can seek reasonable royalties when this occurs. The law conveyed the government's willingness to issue just compensation for the appropriation of patented intellectual property while maintaining its sovereign immunity from liability for the same. A congressional report accompanying the bill clearly stipulated the need to maintain government power to override patent protections when necessary for the public good.

The 1910 law from which section 1498 originated was amended at various points between 1910 and 1942 in order to clarify the immunity of contractors and subcontractors acting on behalf of the government when the latter invokes section 1498 in order to produce a patented good or license its production. In amending the law, Congress also made clear that the government's power to circumvent patent law could be utilized in cases of excessive pricing, and, in fact, section 1498 was invoked multiple times in the 1950s and 1960s in order to obtain reasonably priced generic drugs. Veterans Affairs and the Department of Defense routinely used section 1498 in the 1960s to obtain generic forms of U.S.-patented medications from overseas. Use of section 1498 for pharmaceuticals trailed off in the 1970s, which some attribute to the rising political influence of the drug industry during that time.[7]

In 2001, former HHS Secretary Tommy Thompson considered invoking section 1498 in order to import generic versions of the antibiotic ciprofloxacin, or Cipro, amidst pressure by some members of Congress and consumer advocacy groups due to the threat of an anthrax epidemic at that time. Faced with a potential override of its exclusivity rights by the federal government, Bayer, Cipro's manufacturer, agreed to offer the drug at a significantly reduced price.[8]

Similarly, following the introduction of a group of hepatitis C drugs with high list prices in 2013 and 2014, it was suggested that the federal government should invoke its compulsory licensing power in order to more

affordably procure this treatment for a larger number of Medicaid beneficiaries, prisoners, and uninsured individuals with hepatitis C for whom these drugs were unaffordable.[9] In 2017, the Secretary of Health for the state of Louisiana urged the federal government to invoke its sovereign immunity under section 1498 in order to treat underserved populations with Hepatitis C.[10] In order to qualify for hepatitis C treatment with these first-in-class curative drugs, individuals were required to demonstrate severe liver damage bordering on cirrhosis and imminent need for a transplant. The question of federal intervention into this matter has not been addressed by the current Administration.

Importantly, the government's compulsory licensing power under section 1498 differs from other patent "march-in rights" outlined in the Bayh-Dole Act of 1980. The latter applies to products invented with federal government support, allowing their patents to be held by private sector contractors in order to incentivize the use of federal research funds for private sector development.[11] Under Bayh-Dole, the federal government may invoke "march-in rights" to authorize outside production of a patented good developed with federal funding in certain limited circumstances, including to address public health or safety concerns.

By contrast, section 1498 applies to all patented inventions, regardless of whether or not they were produced with federal funding. Further, march-in rights under Bayh-Dole can be requested by a private enterprise, whereas under section 1498, the federal government must initiate compulsory licensing by producing a product itself or requesting a contractor to do so. Lastly, when march-in rights are bestowed, the recipient must comply with established "reasonable terms" which may include royalties paid to the patent holder. Under section 1498, the patent holder obtains compensation from the licensee by initiating court proceedings.

Endnotes

[1] As of October 8, 2019, virtually all of the 12 Democratic presidential candidates appearing in the October 15, 2019 debate have expressed support for Medicare drug price negotiation, based on a review of their 2020 campaign websites and sponsorship or co-sponsorship of legislation introduced in the 116th Congress.

[2] Senator Klobuchar is also a co-sponsor of S. 377, Medicare Negotiation and Competitive Licensing Act of 2019.

[3] Kapczynski, A., and Kesselheim, A.S. 'Government patent use': A legal approach to reducing drug spending. *Health Affairs, 35*(5), 2016; Rizvi, Z., Kapczynski, A., and Kesselheim, A.S. "A simple way for the government to curb inflated drug prices." *The Washington Post,* May 12, 2016; Zaitchik, A. "How the government can bring down drug prices," *American Prospect,* June 29, 2017; Lee, J. "Can an obscure, 100-year-old patent law take on big pharma?" *Bloomberg,* May 21, 2018; "How the government can lower drug prices [Editorial]" *The New York Times,* June 20, 2018.

[4] Kapczynski and Kesselheim, 2016; Rizvi, Kapczynski, and Kesselheim, 2016; Zaitchik, 2017; Lee, 2018; How the government can lower drug prices [Editorial]. *The New York Times,* June 20, 2018.

[5] Kapczynski and Kesselheim, 2016; Zaitchik, 2017.

[6] Brennan, H., Kapczynski, A., and Monahan, C.H. "A prescription for excessive drug pricing: Leveraging government patent use for health." *Yale Journal of Law and Technology, 18*(1), 275-354, 2017; Bruns, B.S. The Pharmaceutical Access Act: An administrative eminent domain solution to high drug prices. *California Law Review, 106*(6), 2023-2066, 2018; KEIWashDC. (2017, April 19). *Feb. 24, 2017 compulsory licensing workshop - panel discussion, 28 U.S.C. 1498* [Video file], available at http://www.youtube.com/watch?v=Za9RbL0jtds.

[7] How the government can lower drug prices [Editorial]. *The New York Times,* June 20, 2018.

[8] Lee, 2018; How the government can lower drug prices [Editorial]. *The New York Times,* June 20, 2018.

[9] Kapczynski and Kesselheim, 2016; Rizvi, Kapczynski, and Kesselheim, 2016; Zaitchik, 2017; Hepatitis C: Louisiana's plan to increase access to treatment [Amicus]. *Harvard Civil Rights-Liberties Law Review,* 2017.

[10] Hepatitis C: Louisiana's plan to increase access to treatment [Amicus], 2017; Johnson, C.Y. "Louisiana considers radical step to counter high drug prices: Federal intervention." *The Washington Post,* July 3, 2017.

[11] Thomas, J.R. *March-in rights under the Bayh-Dole Act*, CRS Report No. R44597, Congressional Research Service, 2016.