

A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health

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High drug prices are creating serious health and fiscal problems in the United States today. This reality is vividly illustrated by recently approved medicines to treat Hepatitis C. These new medicines can cure nearly everyone with this potentially fatal infection and may even enable the elimination of this disease. But the drugs' sticker price—close to \$100,000—has meant that very few patients who could benefit from them can access them. This Article describes an approach, available under existing law, to bring about transformative reductions in the prices of these medicines, at least for federal programs and possibly beyond. Under 28 U.S.C. § 1498, the U.S. government can buy generic versions of these medicines at less than 1% of their list price plus a reasonable royalty. This power has received almost no academic attention, despite the fact that it is regularly used by the government in other sectors, including defense. Indeed, though it has now been forgotten, the federal government relied on this provision numerous times to procure cheaper generic drugs in the 1960s. We recover this history and show how § 1498 can once again be used to increase access to life-saving medicines, addressing several important interpretive questions about the application of the provision along the way. We also offer the first sustained efficiency defense of this approach. This power, we show, can be analogized to the eminent domain power over land and similarly justified as a means to address hold out problems. We show that courts or

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agencies can fashion damages remedies that provide robust returns to investment, and so protect dynamic incentives while permitting radical improvements in static efficiency. Our remedy involves some risk, as do all policy innovations. But the status quo is so deeply dysfunctional—with millions of Americans unable to benefit from medicines that could halt the spread of a major disease—that the case for action is overwhelming.

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I. INTRODUCTION

The soaring cost of pharmaceuticals is one of the most pressing domestic policy issues in the United States today. Nearly one-fifth of the U.S. Gross Domestic Product (GDP) is spent on healthcare, and pharmaceuticals are a key expenditure.¹ In 2014, the United States spent a record \$297.7 billion on pharmaceuticals, over 12% more than the previous year.²

The 2014 increase in prescription drug spending can be attributed almost entirely to recently approved drugs that treat the Hepatitis C virus (HCV).³ With list prices that approach \$100,000 for a twelve-week regimen,⁴ these new medicines have brought the issue of drug pricing roaring to the fore in policy debates. High drug prices are of enormous concern to voters,⁵ policymakers, and politicians across the political spectrum.⁶

High drug prices also have a significant impact on health. The new HCV drugs offer an excellent example. Potentially deadly if untreated, HCV is one of the most

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- ¹ See Anne B. Martin et al., *National Health Spending in 2014: Faster Growth Driven by Coverage Expansion and Prescription Drug Spending*, 35 HEALTH AFF. 150, 152 ex. 2 (2016). See Hagop Kantarjian & S. Vincent Rajkumar, *Why Are Cancer Drugs So Expensive in the United States, and What Are the Solutions?*, 90 MAYO CLINIC PROC. 500, 500 (2015), available at <https://perma.cc/G3ND-KR9A>.
 - ² *Id.*
 - ³ *Id.*
 - ⁴ See *infra* Part II.B. Some payors have received substantial discounts on these list prices. See *infra* notes 80-85 and accompanying text.
 - ⁵ For example, a 2015 poll found that three out of four Americans view drug costs as unreasonable and support significant new measures to bring prices down. Bianca DiJulio, Jamie Firth, & Mollyann Brodie, Kaiser Health Tracking Poll: August 2015, *KAISER FAMILY FOUND.* (Aug. 20. 2015), <https://perma.cc/9FEN-SELL>.
 - ⁶ See Hillary Clinton’s *Plan for Lowering Prescription Drug Costs*, Hillary.com, <https://perma.cc/U9HY-4PBW> (last visited June 11, 2016); *Trump backs Medicare negotiating drug prices*, POLITICO, Jan. 25, 2016, <https://perma.cc/9MQ6-GVBT>; Joseph Walker & Heather Haddon, *Marco Rubio Latest to Speak Out on Prescription Drug Prices*, Wall St. J. (Oct. 19, 2015 8:05 P.M.), <https://perma.cc/8UZ3-GLGW>; *Remarks of CMS Acting Administrator Andy Slavitt at the HHS Pharmaceutical Forum: Innovation, Access, Affordability and Better Health*, Ctrs. For Medicare & Medicaid Servs. (Nov. 20, 2015), <https://perma.cc/5KWU-P5ER>; Peter Loftus, *Bernie Sanders to Introduce Bill Targeting High Drug Prices*, Wall St. J., Sept. 9, 2015, <https://perma.cc/A7R6-J62X>.

pressing health problems facing the United States.⁷ The new drugs are far superior to previous treatments and could potentially enable elimination of the disease.⁸ But treating all of the approximately 5.2 million people who currently have HCV in the United States at the best reported prices offered by Gilead, the sole supplier of the most important new drugs, would cost at least \$234 billion.⁹ Given the budget impact of these new medicines, most payors have sharply restricted their availability—covering them only for the very sickest, or refusing to cover them at all¹⁰—instead of rapidly rolling them out. Medicaid, for example, treated only 2.4% of enrollees estimated to have HCV in 2014, despite spending more than a billion dollars on the new medicines.¹¹ Even with the small number treated, Gilead's earnings have been stratospheric: the company earned \$36 billion from its new HCV medicines in their first twenty-seven months on the market.¹²

Gilead's prices vastly exceed the cost of producing these drugs. Generic versions of the treatments are on the market in

⁷ Erik Chak, *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence*, 31 LIVER INT'L 1090, 1090, 1097 (2011), available at <https://perma.cc/97WG-3GQG>.

⁸ Eradication is defined as the reduction of new disease cases to zero worldwide. In this Article, we use elimination, which refers to the reduction of new disease cases to zero in a particular *country*. Brian R. Edlin & Emily R. Winkelstein, *Can Hepatitis C be Eradicated in the United States?*, 110 ANTIVIRAL RES. 79, 80 (2014).

⁹ As we describe below, the most important and widely prescribed of the new HCV drugs are sofosbuvir-based regimes. Sofosbuvir (brand name Sovaldi) is prescribed most commonly today as a combination drug called Harvoni (generic name sofosbuvir and ledipasvir). See *infra* note 61. In this paper, we often draw on evidence regarding the cost and availability of sofosbuvir alone because this drug has been on the market longer than the combination drug Harvoni and more evidence exists regarding sofosbuvir's pricing, research and development (R&D) expenditures, and availability. For sofosbuvir, Gilead has reported that it offers average discounts of 46%. Based on information provided to Gilead's shareholders, analysts estimate that Gilead is also offering such discounts on Harvoni, pricing it at about \$45,000 per course of treatment on average. See Ed Silverman, *What the 'Shocking' Gilead Discounts on its Hepatitis C Drugs Will Mean*, WALL ST. J. PHARMALOT BLOG (Feb. 4, 2015, 12:13 PM), <https://perma.cc/NE7W-YD28>. Nevertheless, many government payors do not have access to discounts this steep. See *infra* note 76-88 and accompanying text. Assuming all payors had access to these discounts, the drug would cost about \$45,000 for a standard course of treatment, and treatment of 5.2 million people would cost at least \$234 billion. See Chak, *supra* note 7, at 1096. Note that this estimate is simplified: it does not reflect the cost of healthcare delivery, and does not account for disease transmission dynamics and new cases of the disease.

¹⁰ See *infra* notes 86-87 and accompanying text.

¹¹ STAFF OF S. COMM. ON FINANCE, 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTHCARE SYSTEM 82 (2015).

¹² Press Release, Public Citizen, Gilead's Earnings Are Based on Price Gouging Hepatitis C Treatments (Apr. 28, 2016), available at <https://perma.cc/A52Z-8HVV>.

India for under \$500 for a twelve-week course of treatment, and estimates suggest that economies of scale could drive the competitive price of production to less than a couple of hundred dollars.¹³ As we will describe, the full research and development (R&D) cost of these drugs were likely in the hundreds of millions of dollars—a sum that Gilead recouped many times over in just its first year of sales.¹⁴ The HCV situation therefore raises, in urgent form, the problem that economists have long identified with patent-based drug pricing: the potential for massive social “deadweight” losses that stem from supra-marginal cost pricing.¹⁵

Is there a better way to approach HCV treatment and compensation for innovation, one that does not inevitably lead to rationing that dramatically limits the public health benefits available from these new medicines? Most existing proposals to significantly reduce drug prices require new legislation.¹⁶ This Article instead identifies a legal remedy that has been hiding in plain sight. Under existing law, the federal government can purchase and distribute generic versions of patented medicines.¹⁷ 28 U.S.C. § 1498 permits the government to “use”

¹³ Andrew Hill et al., *Rapid Reductions in Prices for Generic Sofosbuvir and Daclatasvir to Treat Hepatitis C*, 2 J. VIRUS ERADICATION 28, 30 (2016); *Generic Sofosbuvir and Ledipasvir Fixed-dose Combination Availability and India Market pricing as of 26 April 2016*, HEPATITIS C IN ASIA (Apr. 25, 2016), <https://perma.cc/N3XP-3VDK>.

¹⁴ See *infra* Part IV.D.

¹⁵ See, e.g., Ian Ayres & Paul Klemperer, *Limiting Patentees' Market Power Without Reducing Innovation Incentives: The Perverse Benefits of Uncertainty and Non Injunctive Remedies*, 97 MICH. L. REV. 985, 1007-08 (1999); Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137, 1140 (1998).

¹⁶ See Philip Rocco et al., *How Much Does Congress Care About Drug Prices? Less than it Should*, HEALTH AFF. BLOG (Jan. 13, 2016), <https://perma.cc/V729-QCRH> (commenting that the majority of drug pricing reform proposals would require congressional action despite a decline in congressional attention to prescription drug spending over the past decade); see also Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w833 (2009) (listing common drug pricing reform proposals, all of which require Congressional action).

¹⁷ In some ways, our proposal resembles the use of the federal government's “march-in rights” under the Bayh Dole Act. 35 U.S.C. § 201(f) (2012). Some members of Congress have encouraged use of these march-in rights to “respond to the soaring cost of pharmaceuticals.” Letter from Rep. Lloyd Doggett, to Sec'y of Health & Human Servs. Burwell and Dir. of the Nat'l Inst. of Health Collins (undated), <https://perma.cc/U8RH-3WUF>. In a similar vein, the Center for American Progress recently recommended that the government rely on march-in rights to use generics for drugs that are excessively priced against benchmarks set by the Secretary of Health and Human Services. TOPHER SPIRO, MAURA CALSYN & THOMAS HUELSKOETTER, ENOUGH IS ENOUGH: THE TIME HAS COME TO ADDRESS SKY-HIGH DRUG PRICES, CTR. FOR AM. PROGRESS 28 (Sept. 18, 2015), available at

patents at any time without permission of the patent holder, as long as reasonable compensation is provided.¹⁸

This legal provision is rooted in the government's sovereign immunity and is regularly used today, for example, in the service of national defense.¹⁹ Where medicines are concerned, it has been invoked only once in recent years. During the anthrax scare in 2001, the government threatened to use § 1498 to buy a generic antibiotic and then quickly cut a deal with the manufacturer for greatly reduced prices.²⁰ Although this provision has been largely forgotten, in the 1960s and early 1970s, federal agencies relied on the statute to procure generic medicines, and understood it as a critical tool to curb drug prices.²¹

With the pharmaceutical industry's prices reemerging as a significant political issue today,²² § 1498 has begun to receive renewed attention. Senator and presidential candidate Bernie Sanders has proposed relying on the provision to treat veterans in the government's care, and his proposal has garnered some support from colleagues in the Senate.²³ But to

<https://perma.cc/884M-YQWK>. These options, however, are limited to drugs that have received significant federal funding. In contrast, our proposal can be applied to any drug, irrespective of funding sources. Our proposal also addresses issues stemming from the FDCA data exclusivity rules, see *infra* Part V.B, which may present a barrier to exercising march-in authority. Rachel Sachs, *March-In Rights Alone Won't Solve Our Drug Pricing Problems*, BILL OF HEALTH (Jan. 12, 2016), <https://perma.cc/HE43-R9X5>.

¹⁸ The provision has been understood as a species of eminent domain, but is more precisely characterized as a limited waiver of sovereign immunity with respect to patent infringement. See *infra* notes 161-163 and accompanying text. By its terms, patent holders may seek damages for, but not enjoin, patent infringement. The provision also insulates private contractors who supply the government. For more on the history of the statute, see *infra* Part III.B.

¹⁹ See *infra* Part III.B.

²⁰ See *infra* note 136 and accompanying text (describing the threat and Bayer's voluntary response).

²¹ See *infra* notes 141-155.

²² See *supra* note 6.

²³ Letter from U.S. Sen. Bernie Sanders to U.S. Dep't of Veterans Affairs Sec'y Robert McDonald (May 12, 2015), available at <https://perma.cc/GH8M-HADS>; see Sen. Richard Blumenthal, Remarks at *Exploring the Implementation and Future of the Veterans Choice Program*, Hearing Before the S. Comm. on Veterans' Aff., (May 12, 2015), available at <http://www.c-span.org/video/?325991-1/hearing-veterans-choice-program-implementation-future> ("Let me say that you will be asked shortly by Senator Sanders urging that he uses authority to break patents on Hepatitis C medication for the treatment of veterans. I strongly urge you consider using your authority to take that action that will make this medication more widely available to veterans."). Importantly, others in the policy space have begun to urge recourse to § 1498 as well. See, e.g., James Love, *KEI Policy Brief: Non-Voluntary use of HCV patents in the United States*, KNOWLEDGE ECOLOGY INT'L, July 18, 2015, available at <https://perma.cc/RNK4-WZPK>; *Hepatitis C*

date, the call has gone unheeded, and the possibility of relying on § 1498 to lower drug prices has received almost no scholarly attention.²⁴

This Article makes a twofold contribution: We offer the first sustained theoretical defense of the government's § 1498 power, and show how this power can be leveraged to improve both efficiency and health, while preserving long-term incentives for research. Second, we show that this statute can and should be used to remedy the national crisis surrounding access to HCV drugs. Resolving several unexplored legal issues regarding the scope of government patent use, we provide a detailed explanation of how § 1498 can be used for federal programs (including the Veterans Health Administration, the Indian Health Service, Bureau of Prisons, Medicare, and Medicaid), state correctional facilities, and perhaps beyond.

in *Veterans Before the S. Comm. on Veterans' Affairs*, 113th Cong. (2014) (statement of Robert Weissman, President, Public Citizen).

²⁴ The Cipro example prompted a few academic responses. See Amanda Mitchell, Comment, *Tamiflu, the Takings Clause, and Compulsory Licenses: An Exploration of the Government's Options for Accessing Medical Patents*, 95 CAL. L. REV. 535, 537 (2007); Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 623, 624-25 (2005); Daniel R. Cahoy, *Treating the Legal Side Effects of Cipro(r): A Reevaluation of Compensation Rules for Government Takings of Patent Rights*, 40 AM. BUS. L.J. 125, 126-27 (2002); see also Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public's Health Is There a Role for Eminent Domain?*, 295 J. AM. MED. ASS'N 434, 435 (2006) (brief discussion targeting the medical community). None of these, however, offer a robust economic justification for use of § 1498 to address excessive drug pricing (as we do in Parts III and IV), and they ignore several important legal issues critical to the use of this power (which we address in Part V). There is a small literature that looks at § 1498 more broadly, providing historical background and summarizing case law under the statute. See, e.g., Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145 (2012) (providing a thorough review of the history of § 1498 and early suits against the government for patent infringement); Matthew S. Bethards, *Condemning a Patent: Taking Intellectual Property by Eminent Domain*, 32 AIPLA Q.J. 81, 88-105 (2004) (surveying the avenues through which federal, state, and local governments might employ eminent domain and offering a cursory discussion of its possible merits); Lionel Marks Lavenue, *Patent Infringement against the United States and Government Contractors under 28 U.S.C. Section 1498 in the United States Court of Federal Claims*, 2 J. INTELL. PROP. L. 389 (1994-1995) (describing the history of patent infringement actions against the United States, comparing § 1498 with more narrow statutes authorizing the infringement of intellectual property rights; and discussing past litigation). There is also a significant literature on the constitutional question of whether intellectual property is a form of property subject to the Takings Clause. See, e.g., Thomas Cotter, *Do Federal Uses of Intellectual Property Implicate the Fifth Amendment?*, 100 COLUM. L. REV. 1177 (2000). But this literature does not seek to defend the government use approach as we do here, nor does it analyze the legal process through which the government exercises that sovereign authority.

Under our approach, the U.S. government could treat all patients with HCV at just 2% of what it would cost using current best-reported prices.²⁵ Use of § 1498 could fundamentally transform the government's approach to HCV, saving the lives of thousands of Americans and improving the lives of millions.

Generalizing from this, we argue that the federal government should invoke § 1498 in cases such as HCV, where there are significant social gains to be had from bringing compensation in line with the risk-adjusted cost of developing a drug. This approach will allow the government to import drugs at the marginal cost of production (or "generic" prices), therein maximizing social benefit. To make this mechanism work as a matter of innovation policy, the government must pay patent holders compensation adequate to protect R&D incentives. Courts' approaches to setting reasonable compensation (damages) under § 1498 should reflect the economic realities of the pharmaceutical industry, and we offer both a theoretical and a doctrinal approach that achieves this. Importantly, courts need not make these calculations perfectly: even with a sizeable margin of error, the social gains in these cases will likely far exceed the possible losses. We also describe political dynamics that can help constrain excessive use of this government power. Companies, we show, can be expected to price in the shadow of the government's authority, yielding efficiency gains beyond the specific cases where the power is used.

The remainder of this paper is organized as follows: Part II describes the "drug-pricing trap" that American laws and policies create when they mandate comprehensive drug coverage on the one hand, and simultaneously demand strong exclusive rights for pharmaceutical innovators on the other. This Part also illuminates the scope of the current HCV crisis as well as the expense, consequent rationing, and public health potential of the new HCV medicines.

Part III offers a theoretical justification for our approach, drawing on information economics and analogizing to the eminent domain literature. It also describes the history of § 1498, bringing to light little known details about previous instances where this statute was used to address high drug prices and procure generic medicines.

Part IV addresses the critical question of how compensation should be set under § 1498. We construct an approach that is not only consistent with the § 1498 jurisprudence, but also reflects the purposes of this statute and patent law more broadly. Courts would begin by using the

²⁵ See *supra* note 9 and *infra* Part IV.D.

standard approach to reasonable compensation, establishing a baseline reasonable royalty calculated as a percentage of the generic drug price. If appropriate evidence is supplied by the patentee, courts would then adjust this compensation award upwards to account for the patentee's risk-adjusted R&D costs and to ensure a reasonable profit. We use the HCV example to show that our method could result in substantial compensation—on the order of billions of dollars—therein ensuring incentives to invest. The HCV example also demonstrates that the power can be used to reduce dramatically the overall cost of treatment, and so generate enormous welfare benefits. Here, reasonable compensation would be very modest, because the company has almost certainly already recouped its risk-adjusted R&D costs many times over. We also discuss when the government should invoke this power and address potential objections to our approach to setting compensation.

Part V resolves two key legal issues regarding § 1498 that arise in the pharmaceutical context. Section 1498 requires any patent use under the statute to be “for the Government” and “with the authorization or consent of the Government.”²⁶ This Part first explores when a particular use of a generic drug may be understood as “for the government” and with the “authorization and consent” of the government. In addressing this issue, we show that § 1498 can have broad effect even in the United States' fragmented healthcare system. Second, we consider the interaction between government patent use and the drug regulatory system, describing the pathways that would permit registration of generic medicines intended for government use with the Food and Drug Administration (FDA).

Finally, Part VI describes how the government, in practice, should use § 1498 to procure generic HCV medications. We describe four possible intervention options. The first three would extend generic access to the nearly 1.5 million Americans with HCV who currently receive care through (1) federally run healthcare programs, including the Veterans Health Administration, Indian Health Service, and Federal Bureau of Prisons; (2) federally sponsored health insurance programs—specifically, Medicare and Medicaid; and (3) state correctional facilities. Collectively, these approaches are viable under existing law and transformative in their health effects. A fourth option, embracing the privately insured and uninsured, is also possible but may require Congressional action.

²⁶ 28 U.S.C. § 1498(a).

II. THE DRUG PRICING TRAP

A. Rising Drug Prices

Drug prices in the United States are among the highest in the world and continue to rise. Since the late 1990s, the average price of an annual course of cancer therapy has increased from \$10,000 to more than \$100,000.²⁷ Americans pay 50 to 100% more for drugs than patients in other countries, largely because other countries have adopted significant measures to lower prices by implementing price controls and leveraging government buying power.²⁸ At a systems level, high drug costs may lead to overstretched health budgets, rationing, and failure to provide the best possible care. At an individual level, these costs may lead to catastrophic expenditures,²⁹ non-adherence to treatment,³⁰ and sickness.³¹

These rising costs have little or nothing to do with the cost of manufacturing pharmaceuticals. Rather, they result from what we call the “drug-pricing trap.” Our patent system, bolstered in various ways by exclusivity offered via the drug regulatory system,³² typically ensures that companies introducing new drugs enjoy a decade or more of market exclusivity.³³ This grant of monopoly allows the manufacturer to charge any price that it believes the market will bear. Such exclusivity has made pharmaceuticals one of the world’s most profitable industries,³⁴ with profit margins for some companies reaching an estimated 42%.³⁵ Economists estimate that the

²⁷ Hagop Kantarjian & S. Vincent Rajkumar, *Why Are Cancer Drugs So Expensive in the United States, and What Are the Solutions?*, 90 MAYO CLINIC PROC. 500, 500 (2015), available at <https://perma.cc/G3ND-KR9A>.

²⁸ *Id.* at 502.

²⁹ See SPIRO, CALSYN, & HUELSKOETTER, *supra* note 17, at 2.

³⁰ See Haiden A. Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224, 2231 (2003).

³¹ See, e.g., Robin A. Cohen et al., *Strategies Used by Adults to Reduce Their Prescription Drug Costs* 1 (NCHS Data Brief, No. 119, 2013), available at <https://perma.cc/SX2F-V8AL> (“Some [prescription drug] cost-reduction strategies used by adults have been associated with negative health outcomes.”).

³² See *infra* Part V.B; 21 U.S.C. § 355 (2012).

³³ C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012) (noting that the average protection for a branded drug is 12.2 years).

³⁴ SPIRO, CALSYN, & HUELSKOETTER, *supra* note 17, at 7 (“On average, the pharmaceutical sector has significantly higher annual net profit margins than almost any other industry—more than double the average net profit margin for Standard & Poor’s, or S&P, 500 companies.”).

³⁵ Liyan Chen, *Best of The Biggest: How Profitable Are The World’s Largest Companies?*, FORBES (May 13, 2014), <http://www.forbes.com/sites/liyanchen/2014/05/13/best-of-the-biggest-how->

average markup for patented drugs is nearly 400%.³⁶ The case of Lipitor, a cholesterol drug, is illustrative: the expiration of its patents were projected to cut the price of the drug in half within six months, leading to savings of over \$4.5 billion by 2014.³⁷ More generally, the FDA has found that introducing generic competition can cause prices to fall to as little as 6% of the patent-protected price.³⁸

Competition within classes of drugs can put downward pressure on the prices of patented medicines. But in many instances there are no close substitutes for a given drug. Additionally, an array of laws restricts the government's ability to effectively leverage this approach. Healthcare payors are often statutorily required to cover new drugs. For example, state Medicaid programs must cover drugs offered by any manufacturer that enters into a rebate agreement with the federal government.³⁹ Medicare Part D Plans, as well as private health insurance plans serving the individual and small group markets, have more leeway, but they still must cover a minimum number of drugs in each category and class.⁴⁰ Public programs and private payors receiving federal funds are also subject to nondiscrimination requirements that may limit their latitude to create restrictive formularies.⁴¹ Prisons, for their part, have a constitutional mandate to provide inmates with adequate healthcare.⁴² While these requirements are intended to help ensure individuals receive the care they need, payors that must cover a drug, whether overpriced or not, have little leverage to bring down prices.

Other federal laws further tie payors' hands. Most controversially, the federal government is prohibited from playing any role in negotiations between Medicare Part D

profitable-are-the-worlds-largest-companies/ (showing profit margins of 42%). In comparison, the highest profit margin in the second most profitable industry—banking—was 29%.

³⁶ Dean Baker, *Financing Drug Research: What Are the Issues?* 7 (Ctr. For Econ. Res., Issue Br., Sept. 22, 2004), available at <https://perma.cc/DUP5-KHRX>.

³⁷ Cynthia A. Jackevicius, *Generic Atorvastatin and Health Care Costs*, 366 NEW ENG. J. MED. 201, 201 (2012).

³⁸ *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN., <https://perma.cc/MJ6E-RJUS> (last visited Feb. 26, 2016).

³⁹ 42 U.S.C. § 1396r-8(a)(1) (2012).

⁴⁰ 42 U.S.C. § 1395w-104(b)(3)(G) (2012) (Medicare Part D Plans); 45 C.F.R. § 156.122(a) (2015) (private individual and small group market health plans).

⁴¹ See, e.g., 42 U.S.C. § 18116 (2012) (prohibiting discrimination on the basis of disability with respect to any health program or activity receiving federal financial assistance, any program or activity administered by an executive agency, or any entity established under title I of the ACA).

⁴² *Estelle v. Gamble*, 429 U.S. 97 (1976) (“deliberate indifference to serious medical needs of prisoners constitutes the unnecessary and wanton infliction of pain, . . . proscribed by the Eighth Amendment” (internal quotation omitted)).

Plans and drug manufacturers.⁴³ Additionally, federal antitrust laws limit private insurers' ability to negotiate prices collectively.⁴⁴ Thus, as we discuss in greater depth in Part III, the effects of competition between patented medicines and price discrimination are necessarily incomplete.

More pointedly, a fundamental conflict between our healthcare and industrial policies is emerging. Our healthcare policy works to guarantee that those with insurance gain access to effective new medicines. Our industrial policy provides companies with expansive opportunities to obtain patents and other forms of exclusivity. Against the background of the healthcare assurance, this industrial policy enables pharmaceutical companies to extract exorbitant rents in the form of high drug prices. We now turn to the example of HCV, which illuminates the problem and its profound human consequences.

B. Narrowing Drug Access: The Case of Hepatitis C

HCV is a blood-borne virus that inflames the liver and can cause fatal complications. In about 80% of cases, patients develop cirrhosis, a chronic infection that can scar the liver and impede its ability to perform vital functions, such as filtering toxins. Left unchecked, the disease can lead to liver failure and cancer.⁴⁵ HCV is also linked to heart disease, cognitive impairment, and diabetes.⁴⁶

In the United States, as many as 5.2 million people suffer from HCV.⁴⁷ The virus is among the most deadly infectious diseases domestically: in 2014, HCV deaths reached a record high of 19,659, more than the combined death toll of sixty other infectious diseases tracked by the Centers for Disease Control and Prevention.⁴⁸ Furthermore, reports suggest available sources vastly underestimate the total number of deaths actually attributable to HCV.⁴⁹

HCV has hit adults born between 1945 and 1965 the hardest. Many individuals in this age group contracted the virus through blood transfusions, wartime exposure, and

⁴³ 42 U.S.C. § 1395w-111(i) (2012).

⁴⁴ Outterson & Kesselheim, *supra* note 16, at w838 (arguing for limited antitrust waivers to allow joint negotiations by Part D plans).

⁴⁵ A.A. Modi & T.J. Liang, *Hepatitis C: A Clinical Review*, 14 ORAL DISEASES 10, 10 (2008).

⁴⁶ Patrice Cacoub et al., *Extrahepatic Manifestations of Chronic Hepatitis C Virus Infection*, 46 DIGESTIVE & LIVER DISEASE S165, S165-73 (2014).

⁴⁷ Chak, *supra* note 7, at 1096.

⁴⁸ Lena H. Sun, *Hepatitis C-Related Deaths hit Record High in U.S., CDC Says*, WASH. POST, May 4, 2016, <https://perma.cc/HQ88-43WK>.

⁴⁹ *Viral Hepatitis – Statistics & Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/8F5Q-D3EE> (last visited June 3, 2016).

contaminated needle use that occurred before health officials even knew the disease existed.⁵⁰ HCV also disproportionately affects marginalized populations, with the epidemic “concentrated among people disadvantaged by poverty, unemployment, homelessness, substance use, lack of health insurance and access to health services, ethnic discrimination, and the epidemic of incarceration.”⁵¹ Indeed, due at least in part to recent increases in injection drug use, the estimated annual number of new HCV cases grew from 16,500 to 30,500 from 2011 to 2014.⁵²

HCV has been called the “silent epidemic”⁵³ because patients can be asymptomatic for decades.⁵⁴ Until recently, there was little interest in screening for and treating the disease. The only HCV treatments available required months of extremely toxic weekly injections. These injections cured less than half of people with the most common HCV genotype⁵⁵ in the United States and had side effects so intolerable that many patients were forced to discontinue therapy.⁵⁶ But in late 2013, drug-makers introduced a new class of HCV medications with the potential to radically change the course of the epidemic. Sofosbuvir (brand-name Sovaldi) was the first in this new

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- ⁵⁰ *Hepatitis C Testing for Anyone Born During 1945-1965: New CDC Recommendations*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/GV4Q-G2WG> (last visited Feb. 26, 2016); *Baby Boomer Veterans More at Risk for Hepatitis C*, U.S. DEPT OF VETERANS AFF., <https://perma.cc/3YV2-C6UJ> (last visited Feb. 26, 2016).
- ⁵¹ Edlin & Winkelstein, *supra* note 8, at 85. HCV is also re-emerging as a leading public health crisis among young adults who inject drugs, particularly in the Appalachian region. Abby Goodnough, *Costly to Treat, Hepatitis C Gains Quietly in U.S.*, N.Y. TIMES, July 23, 2015, at A14, <https://perma.cc/KU95-HL79>.
- ⁵² *Viral Hepatitis – Statistics & Surveillance*, *supra* note 49.
- ⁵³ See, e.g., U.S. DEPT OF HEALTH & HUMAN SERVS., COMBATING THE SILENT EPIDEMIC OF VIRAL HEPATITIS: 2014-2016 ACTION PLAN FOR THE PREVENTION, CARE AND TREATMENT OF VIRAL HEPATITIS 3 (2014), *available at* <https://perma.cc/W9ZW-RR9N>.
- ⁵⁴ Stephen L. Chen & Timothy R. Morgan, *The Natural History of Hepatitis C Virus (HCV) Infection*, 3 INT’L J. MED. SCI. 47, 49 (2006) (“The progression to cirrhosis is often clinically silent, and some patients are not known to have hepatitis C until they present with the complications of end-stage liver disease or HCC.”).
- ⁵⁵ The word “genotype” refers to the particular strain of the HCV virus that a patient had contracted. There are six major HCV genotypes, and a patient’s particular strain can be determined with a simple blood test. Infection with more than one genotype is rare. The effectiveness of different treatments varies by genotype. *Hepatitis C FAQs for Health Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://perma.cc/HV58-RFVF> (last visited Feb. 26, 2016).
- ⁵⁶ See, e.g., M.P. Manns et al., *Treating Viral Hepatitis C: Efficacy, Side Effects, and Complications*, 55 GUT 1350, 1352-55 (2006), *available at* <https://perma.cc/XYG8-A9BD>.

class, known as direct-acting antivirals (DAAs).⁵⁷ Described as “miracle drugs” by the press,⁵⁸ these oral-only treatments have reported cure rates over 95% in clinical trials for the most common genotype.⁵⁹ They also lack the harsh side effects that defined prior treatments.⁶⁰

Sofosbuvir, typically prescribed in its combination form of sofosbuvir and ledipasvir (brand-name Harvoni), remains the most important and widely used of these drugs to date.⁶¹ Sofosbuvir-based regimes are popular because they are more effective than the alternatives for most patients⁶² and are approved to treat more genotypes.⁶³ They also minimize the

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- ⁵⁷ Press Release, U.S. Food & Drug Admin. FDA Approves Sovaldi for Chronic Hepatitis C (Dec. 6, 2013), *available at* <https://perma.cc/7DSN-4YWG>.
- ⁵⁸ *See, e.g.*, Ronan Farrow, *High Price Miracle Drug Treats Hepatitis C*, MSNBC (July 28, 2014), <https://perma.cc/FSB4-SWQU>.
- ⁵⁹ Diana Gritsenko & Gregory Hughes, *Ledipasvir/Sofosbuvir (Harvoni): Improving Options for Hepatitis C Virus Infection*, 40 PHARMACY & THERAPEUTICS 256, 259 tbl.3 (2015).
- ⁶⁰ Ara A. Kardashian & Paul J. Pockros, *New Direct-Acting Antiviral Therapies for Treatment of Chronic Hepatitis C Virus Infection*, 11 GASTROENTEROLOGY & HEPATOLOGY 458, 460 (2015).
- ⁶¹ HEALTH SECTOR TREND REPORT, ALTARUM INST. CTR. FOR SUSTAINABLE HEALTH SPENDING 1 (July 2015), *available at* <https://perma.cc/4JPZ-2ZB5>.
- ⁶² Different patients may respond to different HCV treatments. On the whole, however, the sofosbuvir plus ledipasvir combination therapy has had the highest cure rates across sub-types of the virus. Brian P. Lam et al., *The Changing Landscape of Hepatitis C Virus Therapy: Focus on Interferon-free Treatment*, 8 THERAPEUTIC ADV. IN GASTROENTEROLOGY 298, 304-307 (2015) (listing cure rates by treatment across stages of disease, HCV genotype, and prior treatment status); *see also* DRUG EVIDENCE REVIEW: ZEPATIER VS. SOVALDI AND HARVONI, ADVERA HEALTH ANALYTICS, INC. (2016), *available at* <https://perma.cc/E2KD-F56E> (“To summarize all the trials conducted in varying designs, Harvoni seems to display a higher SVR rate (99%) in [treatment naïve] patients than Zepatier (95%) and Sovaldi (91%). Zepatier and Harvoni appeared to have similar efficacy in treatment experienced patients as standalone therapy. In HIV co-infected patients, Harvoni and Zepatier may appear to have similar high SVR (96%) than Sovaldi (76%).”).
- ⁶³ The FDA has approved sofosbuvir for treatment of genotypes 1-4. *Gilead Announces Results from Studies Evaluating Sofosbuvir-Based Regimens in Chronic Hepatitis C Patients with Genotypes 2-5*, GILEAD (Apr. 25, 2015), <https://perma.cc/39BY-TB59>. It has approved ledipasvir/sofosbuvir for genotypes 1, 4, 5, and 6. *U.S. FDA Approves New Indications for Harvoni®, Gilead’s Once-Daily Single Tablet Regimen for Chronic Hepatitis C*, GILEAD (Nov. 12, 2015 <https://perma.cc/HU3W-NS5N>). Merck’s new medication, grazoprevir/elbasvir, is only approved for genotypes 1 and 4. *FDA Approves Zepatier for Treatment of Chronic Hepatitis C Genotypes 1 and 4*, FOOD & DRUG ADMIN. (Jan. 28, 2016), <https://perma.cc/9J6E-LMM9>. Viekira Pak is only approved for genotype 1. *FDA Approves Viekira Pak to Treat Hepatitis C*, FOOD & DRUG ADMIN. (Dec. 19, 2014), <https://perma.cc/DBE2-AK8M>. Technivie has been approved for genotype 4. *FDA Approves Technivie for Treatment of Chronic Hepatitis C Genotype 4*, FOOD & DRUG ADMIN. (July 24, 2015), <https://perma.cc/T8P9-L7YB>.

need for certain kinds of pre-treatment testing⁶⁴ and offer a one-pill-per-day regime.⁶⁵ A new sofosbuvir combination therapy, composed of sofosbuvir and a drug called velpatasvir (brand-name Epclusa), was approved in late June 2016 and may become the sofosbuvir-regimen of choice.⁶⁶ It has garnered Breakthrough Therapy designation, which is granted only to investigational medicines that may offer major advances in treatment over existing options.⁶⁷ This combination therapy can be used to treat patients with all six genotypes,⁶⁸ and a recent study found that the cure rate among patients receiving sofosbuvir/velpatasvir was 99%.⁶⁹

These drugs offer the first meaningful opportunity to not only treat HCV successfully in most people, but also contemplate its elimination.⁷⁰ However, most of these new HCV medicines came onto the market with list prices close to \$100,000 for a standard course of treatment (Table 1).

⁶⁴ Certain testing is recommended for patients with genotype 1a prior to starting treatment with Merck's new drug. See *Merck Receives FDA Approval of Zepatier (Elbasvir and Grazoprevir) for the Treatment of Chronic Hepatitis C Virus Genotype 1 or 4 Infection in Adults Following Priority Review*, Business Wire (Jan. 28, 2016), <https://perma.cc/962L-58P2>.

⁶⁵ AbbVie's drugs are not one-pill-per day treatments. Press Release, U.S. Food & Drug Admin., FDA Approves Viekira Pak to Treat Hepatitis C, Food & Drug Admin. (Dec. 19, 2014), available at <https://perma.cc/5B8P-PN2L>; FDA Approves Technivie for Treatment of Chronic Hepatitis C Genotype 4, FOOD & DRUG ADMIN. (July 24, 2015). However, Merck's drug is a one-pill-per day treatment. *Zepatier: Frequently Asked Questions*, PROJECT INFORM (Feb. 2, 2016), <https://perma.cc/9TC4-CGPZ>.

⁶⁶ *FDA Approves Epclusa for Treatment of Chronic Hepatitis C Virus Infection*, FOOD & DRUG ADMIN. (June 28, 2016) (approving Epclusa for use alone and in combination with ribavirin based on the presence and stage of cirrhosis).

⁶⁷ Gilead Announces U.S. FDA Priority Review Designation for Sofosbuvir/Velpatasvir for Treatment of All Genotypes of Chronic Hepatitis C Infection, *GILEAD* (Jan. 4, 2016), <https://perma.cc/ZH6S-NEYG>.

⁶⁸ *Id.*

⁶⁹ Jordan J. Feld et al., *Sofosbuvir and Velpatasvir for HCV Genotype 1, 2, 4, 5, and 6 Infection*, 373 *NEW ENG. J. OF MED.* 2599 (2015).

⁷⁰ See Tarik Asselah & Patrick Marcellin, *Direct Acting Antivirals for the Treatment of Chronic Hepatitis C: One Pill a Day for Tomorrow*, 32 *LIVER INT'L* 88, 101 (2012). Elimination would also require a far stronger commitment to screening people for the disease, as many people remain unaware of their status. Nearly half of people with HCV in the United States may not know they are infected. Maxine M. Denniston et al., *Awareness of Infection, Knowledge of Hepatitis C, and Medical Follow-up Among Individuals Testing Positive for Hepatitis C: National Health and Nutrition Examination Survey 2001-2008*, 55 *VIRAL HEPATITIS* 1652, 1659 (2012).

Table 1. New Direct Acting Antiviral (DAA) Therapies for HCV

Manufacturer	Medication	FDA Approval	List Price
Gilead	Sofosbuvir (brand-name Sovaldi) ⁷¹	December 2013	\$84,000
	Ledipasvir/Sofosbuvir (brand-name Harvoni) ⁷²	October 2014	\$94,500
	Sofosbuvir/Velpatasvir (brand-name Epclusa) ⁷³	June 2016	\$74,760
AbbVie	Ombitasvir-Paritaprevir-Ritonavir; Dasabuvir (brand-name Viekira Pak) ⁷⁴	December 2014	\$83,319
	Ombitasvir-Paritaprevir-Ritonavir; Ribavirin (brand-name Technivie) ⁷⁵	July 2015	\$76,653
Merck	Elbasvir-Grazoprevir (brand-name Zepatier) ⁷⁶	January 2016	\$54,600 ⁷⁷

These high prices triggered a Senate investigation into the price of sofosbuvir, the most important of these drugs, which revealed that Gilead set its list price without reference to R&D expenditures.⁷⁸ Instead, the price reflected a complex set of judgments made by the company about, for example, how

⁷¹ *Hepatitis C Online: Sofosbuvir (Sovaldi)*, U. OF WASH., <https://perma.cc/EF8A-G5KH> (last visited Feb. 26, 2015).

⁷² *Hepatitis C Online: Ledipasvir-Sofosbuvir (Harvoni)*, U. OF WASH., <https://perma.cc/S6LD-ZGLK> (last visited Feb. 26, 2015).

⁷³ *Caroline Chen, Gilead's New Hepatitis C Drug Approved by FDA, Priced at \$74,760*, BLOOMBERG NEWS (June 28, 2016), <https://perma.cc/T7NA-F287>.

⁷⁴ *Hepatitis C Online: Ombitasvir-Paritaprevir-Ritonavir and Dasabuvir (Viekira Pak)*, U. OF WASH., <https://perma.cc/3STG-9UWK> (last visited Feb. 26, 2015).

⁷⁵ *Hepatitis C Online: Ombitasvir-Paritaprevir-Ritonavir (Technivie)*, U. OF WASH., <https://perma.cc/E7P3-3DPK> (last visited Feb. 26, 2015).

⁷⁶ *Hepatitis C Online: Elbasvir-Grazoprevir (Zepatier)*, U. OF WASH., <https://perma.cc/JW68-WN7R> (last visited Feb. 26, 2016).

⁷⁷ The list price of Merck's HCV medication is significantly lower than the others because Merck entered the market nearly two years after Gilead and AbbVie. Merck's list price, therefore, likely reflects the discounted rates that many purchasers are actually paying for Gilead and AbbVie's drugs.

⁷⁸ STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 29-30 (showing that Gilead considered, in setting the launch price of the drug, not R&D costs, but, for example, the risk of prescribing restrictions at different price points, "costs for the existing standard of care for HCV treatment," and concerns about the reaction of professional societies and Congress).

many prescribing restrictions and how much political outcry different price points would generate.⁷⁹

As competing regimens have come onto the market, some payors have negotiated discounts for sofosbuvir.⁸⁰ In February 2015, Gilead reported that it expected U.S. discounts to average 46%.⁸¹ These reductions appear to be the result of both automatic statutory rebates for some payors and payors' efforts to reduce prices by playing manufacturers against one another and offering concessions, such as preferred status or reduced restrictions on access.⁸² However, many payors do not receive discounts this substantial. Medicaid programs, for example, are entitled to a statutory rebate of 23.1%.⁸³ While they are also permitted to negotiate supplemental rebates directly with companies, only five states had received additional discounts from Gilead in 2014.⁸⁴ The vast majority of states have been unwilling to accept Gilead's conditions, such as demands for "unrestricted access to the drug."⁸⁵

Even at discounted prices, most of those who need the drug are unable to access it. Payors continue to restrict access significantly through prior authorization criteria lacking any medical basis as well as through restrictive formularies.⁸⁶ For example, thirty-one of the forty-two state Medicaid programs with known reimbursement criteria for sofosbuvir restricted access to persons with advanced liver damage, while thirty-one had some form of clinically unsupported sobriety restrictions.⁸⁷

⁷⁹ *Id.*

⁸⁰ Andrew Pollack, *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to \$10.3 Billion*, N.Y. TIMES (Feb. 3, 2015), available at <https://perma.cc/W9A3-S2QA>.

⁸¹ Meg Tirrell, *Pricing Wars Heat up Over Hepatitis C Drugs*, CNBC (Feb. 4, 2015, 12:13 PM), <https://perma.cc/DQ3P-YH22>.

⁸² Robert Langreth, *How Gilead Priced Its \$20 Billion Blockbuster*, BLOOMBERG NEWS (Dec. 10, 2015, 5:37 PM), <https://perma.cc/455L-RT5U>.

⁸³ 42 U.S.C. § 1396r-8(c)(1)(B).

⁸⁴ STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 81.

⁸⁵ *Id.* (quoting Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress 3 (Oct. 28, 2014)); *see also id.* at 106 (detailing access obligations imposed by Gilead for Medicaid discount offers that ranged from 6-10%).

⁸⁶ *Examining Hepatitis C Virus Treatment Access*, CTR. FOR HEALTH LAW & POL'Y INNOVATION 6 (2015), available at <https://perma.cc/75Y6-FRK8>; *see also* Paul Barrett & Robert Langreth, *Pharma Execs Don't Know Why Anyone Is Upset by a \$94,500 Miracle Cure*, BLOOMBERG NEWS (June 3, 2015, 4:40 PM), <https://perma.cc/S6CA-9AB8> ("More than two dozen state Medicaid programs for low-income patients, as well as for-profit insurers such as Anthem, have restricted coverage for Sovaldi to those with severe liver damage.").

⁸⁷ Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States Medicaid Restrictions of Sofosbuvir for Hepatitis C*, 163 ANNALS OF INTERNAL MED. 215, 216-17 (2015). The Centers for Medicare & Medicaid Services (CMS) released a notice in November 2015 expressing concern that some state access restrictions, including limiting treatment before patients displayed

Providers may not always know what constitutes “enough” liver damage to warrant treatment, but delaying treatment can lead to severe, irreversible liver damage.⁸⁸ Overall, Medicaid treated only 2.4% of enrollees believed to have HCV with sofosbuvir in 2014.⁸⁹

Even with prescribing restrictions, payors still face budgetary crises from the discounted prices of these medicines. In Kentucky, for instance, treating just 861 people with HCV cost \$50 million—7% of the state’s total Medicaid budget.⁹⁰ The Federal Bureau of Prisons (BOP) treated 40% *fewer* patients from 2013 to 2015, but increased its spending on HCV drugs more than three-fold.⁹¹

Providing widespread access at current prices is simply infeasible. While disputes over formularies and drug coverage are not unknown in the United States, the HCV landscape presents the most extreme modern example of an exceptionally effective new drug—indeed, a cure—deliberately being rationed solely because of its price. As a result of these practices, many patients continue to suffer from preventable liver damage that may reduce the quality and duration of their lives. Some of them will also infect others, most frequently through injection drug use and, to a lesser degree, through sexual and community transmission.⁹²

Yet this need not be. A twelve-week course of sofosbuvir costs only \$483 in India⁹³ and \$900 in Bangladesh⁹⁴; it can be

significant liver damage, may violate federal Medicaid law. The agency encouraged states to review any restrictions for compliance, but it also acknowledged that it shares states’ concerns about the potential budgetary impacts of expanded access to treatment. It encouraged states to negotiate supplemental rebates with manufacturers and indicated it was exploring whether the manufacturers would consider offering value-based purchasing arrangements to states. *Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs*, CTR. FOR MEDICAID & CHIP SERVS. 2 (2015), <https://perma.cc/8A9U-FW5M>.

⁸⁸ Lauren A. Beste & George N. Ioannou, *Prevalence and Treatment of Chronic Hepatitis C Virus Infection in the US Department of Veterans Affairs*, 37 EPIDEMIOLOGIC REV. 131, 141 (2015).

⁸⁹ STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 82.

⁹⁰ Goodnough, *supra* note 51.

⁹¹ STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 93, tbl.4.

⁹² HCV is primarily transmitted through exposures to infectious blood, including injection drug use, blood and organ donation, needle stick injuries, and birth to an HCV-infected mother. It also may be spread through sex and sharing personal items that have been contaminated with infectious blood, including household objects like toothbrushes and razors. *Hepatitis C FAQs for Health Professionals*, *supra* note 55.

⁹³ Hill, *supra* note 13, at 30. Medical tourism is an obvious possible response, though Gilead has imposed prescribing restrictions aiming to prevent this practice. See Ed Silverman, *Gilead is Criticized for Restrictions on Generic Hepatitis C Deal*, WALL ST. J. PHARMALOT BLOG (Mar. 19, 2015, 1:39 PM),

manufactured sustainably for as little as \$200.⁹⁵ Though they are not yet approved in the United States,⁹⁶ many of these generic drugs are produced by FDA-approved manufacturers in FDA-approved facilities.⁹⁷ If HCV treatment were available in the United States at these prices, our national approach to the disease could be transformed, with millions more quickly treated, and tens of thousands of new infections averted.

The consequences of high-priced drugs, such as sofosbuvir, are dire in health and human terms. But are they an evil necessary to support the cost of innovation? Every proposal to lower drug costs must consider not only the static (short-term) impact on drug prices, but also the dynamic (long-term) implications for innovation incentives. The appropriate balance between the two is the core policy question in the drug pricing debate. When we pay for medicines, we pay for not merely their manufacture, but also the cost of their development, including clinical trials to prove their safety and efficacy in humans. Therefore, to justify competitive government procurement of medicines, we must account for the economic implications of such procurement as well as of unconstrained monopoly pricing of drugs.

III. THE THEORETICAL CASE FOR GOVERNMENT USE OF DRUG PATENTS

A. *The Problem of Patent-Based Deadweight Loss*

While public debate in this area focuses on high drug prices, the central economic issue is the efficiency of the

<https://perma.cc/TKC3-HQZG> (reporting that “Gilead requires patients to present national identification and residency papers”).

⁹⁴ *Incepta Pharmaceuticals Launches Generic Version of Sovaldi*, HCV ADVOCATE AND NEWS PIPELINE BLOG (March 11, 2015), <https://perma.cc/7WEK-GPGA>.

⁹⁵ Hill, *supra* note 13, at 30.

⁹⁶ For a discussion of the routes to FDA approval of these drugs, see *infra* Part V.B.

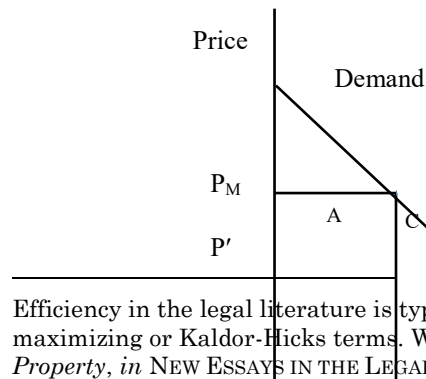
⁹⁷ See e.g., Press Release, Cipla, Cipla Announces the Launch of Generic Drug Sofosbuvir in India under the Brand Name ‘Hepcvir’ (Mar. 25, 2015), available at <https://perma.cc/36YQ-6J9S>. Government procurement of foreign products is subject to the Trade Agreements Act, 19 U.S.C. § 2501 *et seq.*, which mandates that U.S. agencies may only acquire “US-made or designated country end products.” India is not listed as a designated country. See Off. of Acquisition & Logistics, *Trade Agreement Act — Designated Countries*, U.S. DEPT OF VETERANS AFF., <https://perma.cc/C8AN-CQ48> (last visited June 11, 2016). However, agencies can import products from non-designated countries when they are not available otherwise (e.g., in the case of generic HCV medications). 48 C.F.R. §25.403(c).

development and distribution of pharmaceuticals.⁹⁸ The aim is appropriate allocation of resources; in this case, it is the appropriate allocation of investment in R&D and maximization of the social gains generated by the resulting medicines.

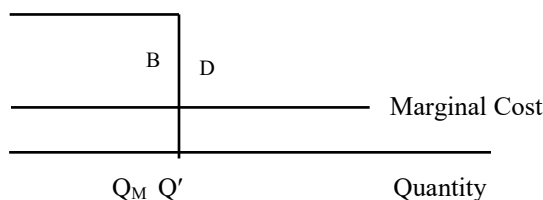
There are clear reasons to think that our current drug pricing system produces not merely high prices, but *inefficiently* high prices. They flow directly from the core insights of information economics. Information is a classic public good: it is non-rival and difficult to exclude, with a marginal cost of zero. In other words, once a scientific formula has been developed, a novel written, or a drug compound proven safe and effective, that information (conceptually separate from the information-embedded good—here, the pill) can be used an infinite number of times without being reinvented. Accordingly, the efficient static price for that information is zero. Anything more would inefficiently depress uptake by imposing a price higher than marginal cost.

The conventional graph depicting the implications of monopoly pricing in the context of information helps illustrate the point. Marginal cost here is zero, represented by a horizontal line. The monopolist has an incentive to charge the monopoly price (P_M), and reduce supply (to Q_M), if the profits of *Area A* (which he gains) are larger than the profits in *Area B* (which he loses). Critical to the efficiency case here are *Areas B, C* and *D*, which at P_M represent deadweight loss, enjoyed neither by the patent holder nor the public. Lowering a monopolist's prices (here, from P_M to P') diminishes deadweight loss. Even if P' exceeds marginal cost, reducing price diminishes deadweight loss (here, to *Area D*, with *Area B + C* as net social welfare gain). The size of welfare gains increases substantially if we assume steep demand curves (*i.e.*, low elasticity of demand) and larger price reductions.

Figure 1. Monopoly Pricing



⁹⁸ Efficiency in the legal literature is typically defined either in wealth-maximizing or Kaldor-Hicks terms. William Fisher, *Theories of Intellectual Property*, in *NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY* 168, 169, 177 (Stephen R. Munzer ed., 2001). The latter is clearly more defensible and the form of efficiency analysis we invoke here.



The problem of deadweight loss redounds to R&D allocations as well. Patents raise funds for research by imposing narrow and very high taxes—often on the order of several thousand percent. These taxes are almost certainly sub-optimal.⁹⁹

The distortions associated with deadweight loss can be reduced by price discrimination. In the above, for example, with perfect price discrimination each consumer would be charged his or her willingness to pay, eliminating the deadweight loss associated with *Areas B, C* and *D*. Perfect price discrimination, however, is not expected, even in theory.¹⁰⁰ Imagine, for example, a drug company trying to find, and impose, an individual price for each of the five million people in the United States with HCV. Even absent the complexity of third-party payors, approximating these prices would be extraordinarily expensive. With HCV drugs, moreover, price differences are based not on willingness to pay, but on other factors, such as statutory rebates and the purchasing power and legal constraints on different entities. Notably, prices are often highest for those whose ability to pay is most circumscribed, such as state correctional facilities.¹⁰¹

⁹⁹ See, e.g., Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q. J. ECON. 1137, 1140 (1998).

¹⁰⁰ See Yochai Benkler, *An Unhurried View of Private Ordering in Information Transactions*, 53 VAND. L. REV. 2063, 2072 (2000) (arguing that because price discriminators must, for example, determine the appropriate price and prevent arbitrage, “[t]he product is never sold to each and every consumer at his or her valuation, but is instead sold in categories the size of which is determined by the costs of identifying and implementing price discrimination for that group of consumers”).

¹⁰¹ See Am. Ass’n for the Study of Liver Diseases & Infectious Diseases Soc. of Am., *Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens*, HCV GUIDANCE: RECOMMENDATIONS FOR TESTING, MANAGING, AND TREATING HEPATITIS C (Feb. 2016), available at <https://perma.cc/D5AZ-HJXD> (“State prisons and jails are usually excluded from Medicaid-related rebates and often do not have the negotiating leverage of larger organizations and may end up paying higher prices than most other organizations.”). This is an appropriate moment to note just one of the problematic assumptions that conventional efficiency reasoning adopts. Prices are presumed to reflect “willingness” rather than “ability” to pay. In practice, ability to pay is constrained, particularly for some, and prices will not closely track social welfare where this is the case—as is surely true of many in prison, for example. For more on this point, see Amy Kapczynski,

Market substitutes can also diminish deadweight loss (for example, by pushing price from P_M toward P'). The size of this effect depends on the degree of substitution.¹⁰² As described above, this form of competition has reduced the price of new HCV drugs. But even the discounted prices are very high and far exceed the marginal cost of production.¹⁰³ This likely reflects the fact that, as the Federal Trade Commission has shown, the pharmaceutical industry displays oligopolistic dynamics.¹⁰⁴ Some reasons for limited market competition among new pharmaceuticals are legal: competition is impeded by formulary restrictions and the third-party insurance that pervades the pharmaceutical market.¹⁰⁵ Others are social: elasticity of demand for pharmaceuticals is estimated to be very low.¹⁰⁶ Put another way, individuals are extremely sensitive to even small differences in health outcomes, making it difficult for medicines to be true market substitutes for one another.¹⁰⁷

Despite some price discrimination and competition between medicines within a class, the problem of deadweight loss in pharmaceuticals remains. Projections of the magnitude vary, but invariably suggest that it is significant. Michael Kremer, for example, estimates that the social value of new medicines is 2.7 times greater than the profits that can be extracted by a monopolist, if that monopolist cannot price

Cost of Price: Why and How to Get Beyond Intellectual Property Internalism, 59 UCLA L. REV. 970, 981-93 (2012).

¹⁰² See our discussion above of the reasons that there is imperfect substitution across different HCV drugs, *supra* text accompanying notes 78-81. As Oren Bracha and Talha Syed have shown, deadweight loss remains, even with perfect substitutes, because price exceeds marginal cost. Oren Bracha & Talha Syed, *Beyond the Incentive-Access Paradigm? Product Differentiation & Copyright Revisited*, 92 TEXAS L. REV. 1841, 1852 n.31 (2014).

¹⁰³ They also, as we will describe later, exceed the sum of marginal cost of production and average costs of these drugs, *i.e.*, factoring in estimated R&D costs.

¹⁰⁴ FEDERAL TRADE COMMISSION, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY i (2002).

¹⁰⁵ See, e.g., F.M. Scherer, *The Pharmaceutical Industry—Prices and Progress*, 351 NEW ENG. J. MED. 927, 928 (2004) (describing several ways that U.S. pharmaceutical markets depart from a competitive ideal).

¹⁰⁶ Peter Siminski, *The Price Elasticity of Demand for Pharmaceuticals Amongst High-Income Older Australians: A Natural Experiment*, 43 APPLIED ECON. 4835, 4844 (2011).

¹⁰⁷ See generally Richard G. Frank & David S. Salkever, *A Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT STRATEGY 75 (1997) (detailing consumer inelasticity of demand for pharmaceutical products); Henry Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J. OF LAW & ECON. 331 (1992) (exploring the comparative “sales and prices of the pioneer and generic products” for eighteen pharmaceuticals).

discriminate.¹⁰⁸ Dean Baker, estimating deadweight loss a decade ago by comparing patented drug prices with the estimated marginal cost of such medicines, reached a figure of \$11 to \$55 billion a year (depending on assumptions about input and elasticity of demand).¹⁰⁹ As prices increase, deadweight loss likely rises too. Consider HCV drugs: if we assume an average patented price of \$45,000 per course of treatment and a production cost of \$450, the associated markup is 99%. Deadweight loss calculations easily reach several billion dollars for this one class of drugs alone. Of course, the losses as measured in human welfare created by the restrictive pricing of HCV drugs are severe—particularly when we compare the current scenario to the health gains associated with the competitive pricing of these medicines.

HCV also illustrates the compounding effects of externalities common in the health context. (Externalities are costs that are difficult to price into a transaction, because they are incurred by individuals who are not parties to the transaction.) Treatment of communicable diseases often produces major positive externalities.¹¹⁰ This is absolutely the case with HCV: treatment eliminates the virus and so protects others from infection. While the government can, in theory, internalize these kinds of externalities, the political constituency for widespread treatment is likely far smaller than the attendant social benefit.¹¹¹ Furthermore, our healthcare system often imposes a portion of the treatment cost on individuals. Insurers often require patients to contribute several thousand dollars in cost-sharing for HCV treatment, when the drugs are covered.¹¹²

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- ¹⁰⁸ Kremer, *Patent Buyouts*, *supra* note 15, at 1141. Kremer measures deadweight loss in drugs from the perspective of diminished quantities consumed, and using data from U.S. household income distribution and assuming that willingness to pay for drugs is proportional to income. *Id.*
- ¹⁰⁹ Dean Baker, *Financing Drug Research: What Are the Issues?*, Ctr. For Econ. Res., Issue Br. 7 (Sept. 22, 2004), <https://perma.cc/VSS3-P7HX>; *see also* Ayres & Klemperer, *supra* note 15, at 998-99, 1019; F.M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 450 (2d ed., 1980). For an earlier estimate, based on slightly more complex methodology, see Guell et. al, *Allocative Efficiency in the Drug Industry*, 73 *MILBANK Q.* 2, 219-20 (1995) (estimating dead weight loss from \$3 billion to \$30 billion).
- ¹¹⁰ *See* David Woodward & Richard D. Smith, *Global Public Goods and Health: Concepts and Issues* 8 (2015), WORLD HEALTH ORG., <https://perma.cc/2Z9T-2378> (last visited June 5, 2016).
- ¹¹¹ This is the basic point of the public choice literature. *See generally*, MANCUR OLSON, *THE LOGIC OF COLLECTIVE ACTION* (1965).
- ¹¹² *See, e.g.*, Jack Hoadley et al., *Medicare Part D in its Ninth Year: The 2014 Marketplace and Key Trends, 2006-2014*, KAISER FAMILY FOUND. (Aug. 18, 2014), <https://perma.cc/8FAU-SMTQ> (estimating that a one-month supply of Sovaldi, which typically requires twelve weeks of treatment, may cost Medicare enrollees more than \$5,000).

Harold Demsetz's classic defense of patents, despite these accepted efficiency problems, suggests that patents are more efficient than more direct forms of government funding.¹¹³ He urged skepticism about the quality of government information and argued that patents provide a superior means of guiding decisions about the allocation of inventive resources, because markets and prices gather decentralized information about costs and benefits.¹¹⁴ In contemporary information economics, patents' primary advantage over alternatives such as government funded prizes and grants is thought to be their reliance on markets to establish the value of the proposed innovation.¹¹⁵ However, there are many ways to improve the government's information about the value of new inventions. Some of the most influential proposed reforms of our patent system in recent years are novel means of guiding government decision-making about which inventions to prioritize. For example Michael Kremer has examined ex ante government prizes (which rely on an auction mechanism)¹¹⁶ and Aidan Hollis and James Love have discussed linking compensation for new drugs to their effects as measured in quality-adjusted life years.¹¹⁷

These alternatives would require major legislative change and would typically apply only prospectively, making them of little help with respect to current bottlenecks such as the one limiting HCV treatment. Solutions that use existing law therefore have much to recommend them. They may take effect far more quickly, and draw persuasive power from existing experience.

We turn next to a short review of § 1498's history to demonstrate its logic. We then explore the potential efficiencies of our approach, drawing both on the recent wave of information economics described above and the leading efficiency defenses of the power of eminent domain in land.

B. A Brief History of § 1498

Until the turn of the twentieth century, patent holders could not directly sue the U.S. government for patent infringement because the federal government had not waived

¹¹³ See Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1, 11-12 (1969).

¹¹⁴ See *id.* at 11-13.

¹¹⁵ See *id.* at 7, 3.

¹¹⁶ See Kremer, *Patent Buyout*, *supra* note 15.

¹¹⁷ See James Love & Tim Hubbard, *Prizes for Innovation in New Medicines and Vaccines*, 18 ANNALS OF HEALTH L. 155, 159-60 (2009); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation*, 2 (Working Paper, June 2004), <https://perma.cc/6N98-5RW6>.

its sovereign immunity in this area.¹¹⁸ In 1910, Congress chose to provide patent holders with limited relief by partially waiving the federal government's immunity for patent infringement in a precursor to § 1498.¹¹⁹ This statute provided patent holders with a forum in which they could seek reasonable compensation, but not injunctive relief, for government use of their patents.¹²⁰ The House Committee on Patents' Report accompanying the bill reveals that the law was clearly understood not only to excuse inadvertent infringement, but also to permit the government to intentionally infringe patents to secure benefits for the public:

[T]he Government ought to have the right to appropriate any invention necessary or convenient for natural defense or for beneficent public use, and that, too, without previous arrangement or negotiation with the owner. Nevertheless, the appropriation having been made, it would seem that justice to the citizen demands that in due time he should receive fair compensation for his property.¹²¹

¹¹⁸ See, e.g., Sean M. O'Connor, *Taking, Tort, or Crown Right? The Confused Early History of Government Patent Policy*, 12 J. MARSHALL REV. INTELL. PROP. L. 145, 180-84 (2012) (describing the *de facto* immunity that the government enjoyed until the 1910 version of § 1498 was adopted). The Federal Court of Claims did entertain some patent suits premised on breach of implied contract theories. But such claims had to be plausible, and not merely an attempt to recover for patent infringement. See, e.g., *Pitcher v. United States*, 1 Ct. Cl. 7, 11 (1863) (explaining that patentees may not simply assert an implied contract cause of action where no plausible agent to enter into the contract with existed). If a patent holder could not make a viable implied contract claim, their sole remaining remedy was to petition Congress for compensation. Supporters of the 1910 Act preceding § 1498 argued that this method was ineffective. Many claims would not make it out of the Committee on Claims. See, e.g., 56 CONG. REC. 8758 (1910) (statement of Rep. Graham) ("As a member of the Committee on Claims, I can state that we have had a dozen applications requiring the Government to be honest to a patentee. We have not passed out but a single one of those claims. We have not time to investigate them. This bill simply allows the Court of Claims to pass on the cases.").

¹¹⁹ Act of June 25, 1910, ch. 423, 36 Stat. 851, 851.

¹²⁰ *Id.*

¹²¹ H.R. Rep. No. 1288, at 2 (1910). This sentiment was repeated by supporters of the bill when it reached the House floor. See, e.g., 56 CONG. REC. 8780 (1910) (statement of Rep. Dalzell) ("Now, I assume no one will contend that the Government ought to be prohibited from appropriating to its use any patent that it deems to be necessary, in the interest of the public service. This bill will not interfere with the present system and practice so far as that is concerned. It only proposes that where the Government, in the exercise of its power and discretion, sees fit without making a contract with the patentee, to use his patent, the patentee shall have the right to go into court and by due process of law have his damages ascertained.").

After the 1910 law was passed, government contractors were unsure whether the federal government's cloak of sovereign immunity protected them when they manufactured patented goods for the government. The issue came to a head in March 1918, less than one year after the United States officially entered World War I. In a unanimous opinion, the Supreme Court held that the 1910 law did not protect such contractors.¹²² A few months later, at the behest of then-Acting Secretary of the Navy Franklin D. Roosevelt, the statute was amended to clarify that contractors manufacturing infringing goods on behalf of the government were also immune from suit.¹²³

Two additional clarifications were adopted in 1942. First, Congress explicitly expanded the scope of contractor protection to cover subcontractors and others acting on behalf of the government.¹²⁴ Second, Congress clarified that the provision immunized third parties only when they were acting "with the authorization or consent of the Government." The aim was apparently to codify a federal district court opinion that held that the government's immunity should not extend to cases involving the "convenience" or "purposes" of a third party contractor.¹²⁵

The legislative history of the 1942 amendments also reaffirms Congress's understanding that the federal

¹²² William Cramp & Sons Ship & Engine Bldg. Co. v. Int'l Curtis Marine Turbine Co., 246 U.S. 28 (1918).

¹²³ Act of July 1, 1918, ch. 113, 40 Stat. 704, 705 ("That whenever an invention described in and covered by a patent of the United States shall hereafter be used *or manufactured by or for* the United States without license of the owner thereof or lawful right to use *or manufacture* the same . . .") (changes from Act of 1910 italicized). Roosevelt's support for the change is documented in a letter to Senator Tillman read into the record of a hearing of the House Committee on Naval Affairs on June 3, 1918. Committee on Naval Affairs Serial No. 21, at 705 (1918). As the Supreme Court subsequently explained, "[t]he intention and purpose of Congress in the act of 1918 was to stimulate contractors to furnish what was needed for the war, without fear of becoming liable themselves for infringements to inventors or the owners or assignees of patents." *Richmond Screw Anchor Co. v. United States*, 275 U.S. 331, 345 (1928).

¹²⁴ Act of October 31, 1942, 77 P.L. 768 § 6, ch. 634, 56 Stat. 1013, 1014 ("[F]or the purposes of the Act of June 25, 1910, as amended (40 Stat. 705; 85 U.S. 8.CO. 68), the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."); John TeSelle, *Authorization or Consent to Infringe Patents in Production for the Government*, 26 GEO. WASH. L. REV. 583, 591-92 n.31 (1957-1958).

¹²⁵ Act of October 31, 1942, 77 P.L. 768 § 6, ch. 634, 56 Stat. 1013, 1014; *see also* TeSelle, *supra* note 124, at 589-92.

government could invoke § 1498 to address excessive pricing. Congress expressed acute concern over wartime price gouging¹²⁶ and noted that the government could “use unhesitatingly” any patent for which no license agreement existed “by the simple expedient of expropriation and infringement.”¹²⁷

Since 1942, the pertinent statutory language has remained intact and was re-codified at 28 U.S.C. § 1498.¹²⁸ It reads:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture. . . . For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States.¹²⁹

The government may negotiate a license in the shadow of its § 1498 power. Alternatively, the government may simply make or purchase the patented invention, leaving the patent holder to sue for damages if it is dissatisfied with the

¹²⁶ See S. Rep. No. 1640, at 3-4 (1942); H.R. Rep. No. 2602, at 2-5 (1942).

¹²⁷ S. Rep. No. 1640, at 2 (1942). Congress even adopted a special provision to give department or agency heads the temporary power to adjust the amount of royalties paid under existing licenses to a level determined to be “fair and just, taking into account the conditions of wartime production.” Act of October 31, 1942, 77 P.L. 768 § 1, ch. 634, 56 Stat. 1013, 1013. This was a reaction to what Congress saw as the hold-up problem created by wartime demand: pre-wartime licenses were seen as imposing excessive payments once war broke out because they contractually bound the government to royalty rates calculated on the basis of far fewer units. S. Rep. No. 1640, at 3-4 (1942).

¹²⁸ Act of June 25, 1948, 80 P.L. 773, §1498, ch. 646, 62 Stat. 869, 941. In 1949, Congress revised § 1498 to remove changes in phraseology made by the 1948 recodification and conform the text to the original statute. Act of May 24, 1949, 81 P.L. 72, § 87, ch. 139, 63 Stat. 89, 102. In 1951, Congress transferred the language added by the Act of October 31, 1942 to § 1498. Act of October 31, 1951, 82 P.L. 248, § 50(c), ch. 655, 65 Stat. 710, 727.

¹²⁹ 28 U.S.C. § 1498(a) (2012).

compensation offered. The present statute, like the 1910 Act, provides the only remedy available to a patent holder is *reasonable and entire compensation*; the patent holder may not seek injunctive relief.

Though it receives little attention in the intellectual property literature, the government today routinely relies on § 1498 to use or acquire patented inventions from non-patent holders. Subjects range from electronic passports¹³⁰ to genetically mutated mice.¹³¹ In 2009, the Department of Treasury used § 1498 to shield private banks from liability for using software to help detect fraudulent checks.¹³² In another case, the U.S. Army Corp. of Engineers used patented waste removal methods to clean up hazardous waste.¹³³ Over the past decade, the National Institute of Health, National Gallery of Art, National Park Service, and General Services Administration have also utilized § 1498.¹³⁴ Furthermore, the government has invoked § 1498 not only when the patent holder is unwilling or unable to negotiate a license with the federal government and infringement is the only way for the government to use the patented technology, but also when the patent holder is willing and able to negotiate.¹³⁵

¹³⁰ IRIS Corp. v. Japan Airlines Corp., 769 F.3d 1359, 1360 (Fed. Cir. 2014).

¹³¹ Letter from Francis S. Collins, Dir., Nat'l Insts. Of Health, to David Einhorn House Counsel, The Jackson Library, Re: the Government's Authorization and Consent to Practice Inventions Covered by U.S. Patents in the Performance of Grants and Cooperative Agreements to The Jackson Laboratory (June 17, 2011) (on file with authors).

¹³² Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis, 583 F.3d 1371, 1378-79 (Fed. Cir. 2009).

¹³³ Severson Env'tl Servs., Inc. v. Shaw Env'tl, Inc., 477 F.3d 1361, 1363 (Fed. Cir. 2007).

¹³⁴ *Judgment Fund Payment Search*, U.S. Department of Treasury, <https://perma.cc/B5WB-NP58> (last visited Feb. 25, 2016) (database listing § 1498 judgments issued against government agencies).

¹³⁵ For example, in *Leesona Corp. v. United States*, the Marine Corps initially issued a negotiated letter contract to Leesona for the production of the particular batteries for which Leesona held the patent. However, the Marine Corps subsequently withdrew the letter contract and proceeded with a competitive bidding procedure, through which it awarded the contract to Eagle Picher, Inc., the lowest bidder, rather than Leesona. *Leesona Corp. v. U.S.*, 599 F.2d 958, 963-64 (Ct. Cl. 1979). Overturning the trial court judge, who had described the government's conduct as "despicable," *id.* at 966, the Court of Claims commented that "[i]n essence, and however clumsily [the government] was attempting to break Leesona's patent monopoly in a manner the law made permissible. The trial judge seemed to have difficulty with the idea that the law accorded the United States rights not conferred on private parties." *Id.* at 970; *see also* IRIS Corp. *Berhard v. U.S.*, 82 Fed. Cl. 488, 490-91 (2008) (the government had purchased several electronic passport readers produced by plaintiff for testing and limited operational use abroad, but subsequently contracted with a third party to manufacture electronic passport readers that allegedly infringed the plaintiff's patents for domestic use); *Wright v. U.S.*, 53 Fed. Cl. 466, 468-69 (2002) (government

The sole recent use of § 1498 in the pharmaceutical context was in 2001, when then-Secretary of Health and Human Services (HHS) Tommy Thompson raised the possibility of invoking § 1498 during the anthrax scare that followed the September 11th terrorist attack. Thompson's public discussion of importing generic versions of the antibiotic ciprofloxacin under § 1498 drove the relevant patent holder, Bayer, to cut its prices by half.¹³⁶ This example illustrates the power of § 1498 in the pharmaceutical context: It provides the government with the necessary leverage to obtain major price reductions, whether through voluntary agreements or generic procurement.

Though it has been largely forgotten,¹³⁷ there is also precedent for the use of § 1498 to purchase generic versions of patented medicines. The practice appears to have begun in the wake of a 1958 opinion by the U.S. Comptroller General that concluded that a supplier's possible patent infringement should not be considered when selecting between competing proposals for government procurement.¹³⁸ A later decision affirmed that

turned down multiple production and licensing proposals from patent holder); *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1058-59 (Fed. Cir. 1986) (infringing party was a competitor of patent holder for a government contract to supply thermal targets to the military).

¹³⁶ See Aaron S. Kesselheim & Jerry Avorn, *supra* note 24, at 435; Keith Bradsher & Edmund L. Andrews, *A Nation Challenged: Cipro; U.S. Says Bayer Will Cut Cost of Its Anthrax Drug*, N.Y. Times, Oct. 24, 2001, <https://perma.cc/V2WC-UH88>; Shankar Vedantam & Terence Chea, *Drug Firm Plays Defense in Anthrax Scare*, Washington Post, Oct. 21, 2001, <https://perma.cc/YT6K-GW52>.

¹³⁷ See, e.g., *President's Fiscal Year 1992 Budget Proposals: Hearing Before the S. Comm. on Finance*, 102nd Cong. 23 (1991) (Sen. Pryor commenting to then-Secretary of the Department of Health and Human Services, Louis W. Sullivan, that "we have never used it [§ 1498], to my knowledge, in pharmaceutical or drug patents."); Memorandum from Am. Law Div., Cong. Research Serv., to John Monahan, Senate Special Comm. on Aging 4 (July 13, 1989) *reprinted in* MAJ. STAFF OF S. SPECIAL COMM. ON AGING, 101ST CONG., *PRESCRIPTION DRUG PRICES: ARE WE GETTING OUR MONEY'S WORTH* app. M, at 42 (Comm. Print 1989) ("it does not appear that there has been a case involving the government's 'taking' of a pharmaceutical patent"). *But see* Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 868 (2003) (stating that "[i]n the 1960s and 1970s, the U.S. government made and used tetracycline and meprobamate for the military without permission from patent holders." (footnotes omitted)); Lars Noah, *Triage in the Nation's Medicine Cabinet: The Puzzling Scarcity of Vaccines and Other Drugs*, S.C. L. REV. 741, 768 n.131 (2003) (noting that before the anthrax scare, "[t]he government previously has used this power to procure certain needed drugs such as the antibiotic tetracycline from sources other than the patent holder or its licensees").

¹³⁸ Op. of the Comptroller Gen. of the United States, 119 U.S.P.Q. 187 (Comp. Gen.), at *2 (1958) (citing the government's overriding interest in competition, and concluding that it "is not consistent with any duty on the part of a contracting agency of the Government to protect the interests of

this rule applies even in instances where the unlicensed supplier has no obligation to indemnify the government.¹³⁹ As of the mid-1960s, then, the firm rule had become that “every federal department and agency refuses to consider the possible infringement liability of the Government in evaluating bids or proposals in the procurement of patented items.”¹⁴⁰

This rule was quickly applied to patented pharmaceuticals, with multiple federal agencies deliberately “purchas[ing] certain drug products covered by U.S. product and process patents, from unlicensed sources for use in the United States in deliberate violation of these patents.”¹⁴¹ According to industry representatives, the justification was largely that “the prices quoted by suppliers of infringing dosage forms are often lower than those quoted by the U.S. patent owners and their licensees.”¹⁴² In the most prominent case, the Defense Department negotiated to purchase an antibiotic, tetracycline hydrochloride, from an Italian supplier instead of from the U.S.-based, patent-holding company, Pfizer, because the Italian drugs were 72% cheaper.¹⁴³ (Italy did not issue

patentees or licensees with respect to articles which it proposes to purchase, since the statute itself defines and provides an exclusive remedy for enforcement of the patentee's rights as to the Government”). This reversed an earlier decision finding that bidders for government contracts should be required to show a legal right to produce the goods in question. *See* Comptroller Gen. McCarl to the Sec'y of Commerce, 13 Comp. Gen. 173, 176 (1933). The patent-holder challenged the decision in federal district court, arguing that the Defense Department could not rely on § 1498 unless it had no possibility of supply at a reasonable price from a licensed manufacturer, but the case was dismissed. *See* Gerald J. Mossinghoff & Robert F. Allnutt, *Patent Infringement in Government Procurement: A Remedy Without a Right*, 42 NOTRE DAME L. REV. 5, 10 n.31 (1966) (citing *F.T. Roberts v. United States*, Civil No. 1876-58 (D.D.C. 1958)).

¹³⁹ *Globe Indus., Inc.*, B-148135, 133 U.S.P.Q. 496 (Comp.Gen.), (1962).

¹⁴⁰ *See* Mossinghoff & Allnutt, *supra* note 138, at 12.

¹⁴¹ *Patent Infringement: Hearing on S. 1047 Before the Subcomm. on Patents, Trademarks, & Copyrights of the S. Comm. on the Judiciary*, 89th Cong. 15 (1965). The practice was apparently used particularly frequently in the Defense Department and Veterans Administration. *Id.* at 28, 40.

¹⁴² *Id.* at 16; *see also id.* at 23 (“The Federal Government has said that it has adopted this practice recognizing the validity of the patents involved, simply because it feels that it is saving money which really means in the case of the procuring agency that it is doing nothing more largely speaking than saving its own appropriations to the extent that it can buy the infringing drugs at a lesser price than the lawful drugs, and it is inevitable that that can be done. It is inevitable.”); U.S. Dep't of Health, Educ. & Welfare, Office of the Sec'y, Task Force on Prescription Drugs, *The Drug Makers and The Drug Distributors* 41 (1968) (“The Defense Supply Agency (DSA) of the Department of Defense, for example, has found it necessary at times to purchase patented prescription drugs from unlicensed domestic or foreign manufacturers because the domestic patent holder's prices (and those of his licensees) were considered too high.”).

¹⁴³ *Charles Pfizer & Co., Inc.*, B-141459, 119 U.S.P.Q. 187 (Comp. Gen.), at *1 (1960); *see* Mossinghoff & Allnutt, *supra* note 138, at 11 n.33.

patents on drugs at the time.)¹⁴⁴ The procurement was upheld by the Comptroller General, despite the fact that no indemnity was required by the Italian company¹⁴⁵ and that Pfizer was ready and willing to fully supply the government's needs for "considerably" less than it sold the drug in the private market.¹⁴⁶

In the wake of the Pfizer decision, the patent-based drug industry lobbied strenuously against the practice and sought an amendment to limit § 1498 to instances where "national security" required it.¹⁴⁷ The Comptroller General and representatives of agencies argued emphatically against the change. They noted that the amendment would impose the burden of evaluating claims of patent infringement on agencies. They also argued that such an amendment would "forgo one of the valuable powers which the Government has to assure fair prices," and to remedy "exorbitant pricing" where it was present.¹⁴⁸ Ultimately, the industry's entreaties were rejected, and § 1498's language remains identical to that enacted in 1942.¹⁴⁹ The rule set by the 1958 Comptroller General opinion also remains in effect.¹⁵⁰

Federal agencies continued to procure generic drugs at steep discounts throughout the 1960s. According to one source, the Department of Defense's Military Medical Supply Agency relied on § 1498 to procure approximately fifty drugs in one three-year period, producing savings of \$21 million.¹⁵¹ In one

¹⁴⁴ *Id.*

¹⁴⁵ *Id.* (citing *Globe Indus., Inc.*, B-148135, 133 U.S.P.Q. 496 (Comp. Gen.), at *40 (1962)).

¹⁴⁶ *Forum*, 4 PAT. TRADEMARK & COPY. J. RES. & ED. 249, 251 (1960). Interestingly, Pfizer noted that these lower prices "still reflect the cost of research and labor in this country." *Id.* (emphasis in original).

¹⁴⁷ S. 1047, 89th Cong. (1965).

¹⁴⁸ *Patent Infringement: Hearing on S. 1047 Before the Subcomm. on Patents, Trademarks, & Copyrights of the S. Comm. on the Judiciary*, 89th Cong. 70 (1965); see also *id.* at 2-3 (statement of Robert E. Giles, Comptroller Gen.) (arguing that "no Federal agency should be prevented by the patent statutes from carrying out any program beneficial to the public at reasonable compensation to the patent owner").

¹⁴⁹ The patent-based drug industry was able to secure a minor victory in 1961, however, when the House of Representatives adopted an amendment to what would become the Foreign Assistance Act of 1961 prohibiting foreign aid funds from being expended on drug or pharmaceutical products manufactured outside of the United States if the manufacture of such product would involve the unauthorized use of an invention covered by a valid patent in the United States. See 107 CONG. REC. 16,284 (1961); see also 22 U.S.C. § 2356(c) (2012).

¹⁵⁰ See, e.g., *Hutchinson Indus. Inc. v. Accuride Corp.*, No. 09-1489 (FLW), 2010 WL 1379720, at *4 (D.N.J. Mar. 30, 2010), *dismissed*, 449 F. App'x 26 (Fed. Cir. 2010); *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 n.6 (D.C. Cir. 1986).

¹⁵¹ MILTON SILVERMAN & PHILP R. LEE, *PILLS, PROFITS, AND POLITICS* 187 (1974).

instance, the federal government procured the drug nitrofurantoin from generic sources for nearly four times less than the patent holder's price.¹⁵²

Because these cases tended to settle rather than go to judgment, no case law regarding compensation in this context was created.¹⁵³ But practices under the law are instructive of the parties' understandings. Hearing testimony suggests that the parties typically agreed to a reasonable and apparently modest royalty, rather than a measure of lost profits. In the nitrofurantoin settlement, for example, the government agreed to pay a royalty set at 2% of the patented price.¹⁵⁴ Patentees presumably concluded that little more would have come from pressing the case to judgment, or wanted to avoid setting clear judicial precedent regarding royalties, which in turn might invite more government use.

Use of § 1498 appears to have tailed off in the 1970s, but the reason for this decline in use is unclear.¹⁵⁵ When

¹⁵² *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8,015 (1971).

¹⁵³ *Id.* at 8,016 ("There is no decision of the Court of Claims with respect to the purchase of foreign drugs or the purchase of drugs of a foreign country."). The only exception we identified occurred subsequent to this statement. In this instance, however, the Court of Claims dismissed the patent-holder's petition for compensation after the patent at issue was found invalid in a separate action. *See Carter-Wallace, Inc. v. United States*, 496 F.2d 535 (Ct. Cl. 1974).

¹⁵⁴ *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8,015 (1971).

¹⁵⁵ In 1971, the Comptroller General Elmer Staats reported that "neither the Veterans' Administration nor the Defense Personnel Support Center [were] currently making extensive use of foreign sources for their drug procurements." *Id.* at 8024. According to Comptroller General Staats, between 1968 and 1970, the Defense Personnel Support Center reduced the number of foreign procured drugs from five to one. The Veterans Administration had also stopped soliciting foreign bids. *Id.* We have not found evidence of generic procurement in reliance on § 1498 since the 1970s. The last instance we found comes from the late 1970s when Zenith Laboratories, Inc. invoked § 1498 as an affirmative defense in a suit brought by Hoffman-La Roche Inc. Zenith had filed a new drug application with the FDA seeking approval to supply the government with generic diazepam under § 1498. *See Answer, Counterclaim and Demand for Jury, Hoffman-La Roche Inc. v. Zenith Labs., Inc.*, No. 75-2221, at 3-4 (D.N.J. Mar. 26, 1976) reprinted in *Innovation & Patent Law Reform, Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 958-59 (1984). The parties agreed to a consent judgment before reaching the merits of Zenith's claims, however. *See Consent Judgment, Hoffman-La Roche Inc. v. Zenith Laboratories, Inc.*, No. 75-2221, at 6 (D.N.J. Aug. 2, 1979) reprinted in *Innovation & Patent Law Reform, Hearings on H.R. 3285, H.R. 3286, and H.R. 3605 Before the Subcomm. on Courts, Civil Liberties & the Admin. of Justice of the H. Comm. on the Judiciary*, 98th Cong. 970 (1984) (providing

pressed in a 1971 Congressional hearing about the possibility of using § 1498 more often, the Comptroller General cited concerns about the uncertainty of damage awards.¹⁵⁶ However, agencies had for years made use of § 1498 without the comfort of clear case law. We suspect the shift had more to do with new drug regulatory practices and expectations,¹⁵⁷ changes in the political tides (for example, from the Johnson to Nixon administration), and the rise in “propertarian” thinking about intellectual property in the 1970s and 1980s.¹⁵⁸

If this is so, then the recent criticisms of propertarian thinking in IP,¹⁵⁹ combined with the profound national concern about high drug prices,¹⁶⁰ make this an opportune time to reengage the potential of § 1498. Its renewed use, however, will require concerted attention to appropriate royalty calculations, and to drug regulatory barriers, issues to which we now turn.

IV. THE EMINENT DOMAIN ANALOGY & DAMAGES UNDER § 1498

“[t]hat nothing herein shall be construed as limiting, expanding or otherwise affecting any applicability of Title 28, United States Code, Section 1498(a), to Zenith’s past or future activities”).

¹⁵⁶ At the 1971 hearing, Comptroller General Staats noted that one factor for this was the threat of exposure to suit. *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8,024 (1971). As another official explained earlier in the hearing, the purchasing agency cannot know in advance how much, if anything, it will save if it relies on § 1498 to procure a good and cannot reach a settlement with the patent holder. *Id.* at 8,014. This is not unique to pharmaceuticals, however.

¹⁵⁷ When questioned by a member of Congress about why the Veterans Administration was not consistently procuring cheaper drugs from overseas in 1970, for example, an official cited concerns about quality control. *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 91st Cong. 7476 (1970). This may, in turn, reflect changes in drug regulatory law introduced by the 1962 Kefauver-Harris amendments. These amendments created new complexities for the registration of generic drugs. See PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, *FOOD AND DRUG LAW: CASES AND MATERIALS* 996-1000 (2014). After the 1984 Hatch-Waxman Act, generic companies also have to certify that their products do not infringe a U.S. patent before they can be registered. 21 U.S.C. § 355(b)(2)(A).

¹⁵⁸ By propertarian we mean the view that intellectual property is—and ought to be treated as—a form of property, and subject to property rather than liability rules. This trend is often thought to have begun in the 1970s and dramatically accelerated in the 1980s and 1990s. See Mark Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031, 1034 (2005) (describing the trend, and providing evidence via increased use of the use of the term “intellectual property”).

¹⁵⁹ For just one leading example, see Lemley, *supra* note 158.

¹⁶⁰ See *supra* notes 5-6.

The government patent use statute has often been referred to as an example of the “eminent domain” power as applied to the patent context.¹⁶¹ As the preceding paragraphs show, it can more precisely be described as a suspension of the government’s sovereign immunity.¹⁶² Importantly, courts have repeatedly affirmed that government patent use is not subject to the U.S. Constitution’s Takings Clause.¹⁶³ Patent holders

¹⁶¹ See, e.g., *Zoltek Corp. v. United States*, 442 F.3d 1345, 1353 (Fed. Cir. 2006), *opinion vacated on other grounds reh’g en banc*, 672 F.3d 1309 (Fed. Cir. 2012); *Leesona*, 599 F.2d at 966.

¹⁶² H.R. Rep. No. 1288, at 2 (1910) (“The United States can not be sued except where it has consented thereto by statute, and unless this or some similar bill shall be passed the owners of patents will continue to be the only persons who are outside the protection of the fifth amendment to the Constitution . . .”). In this sense, it parallels recent cases asserting state sovereign immunity to patent infringement suits. *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999). In *Florida Prepaid Postsecondary Education Expense Board v. College Saving Bank*, the Court effectively held that the States are immune to patent infringement suits under federal law. Presumably, if the absolute immunity for state actors causes no takings problems, neither would the partial immunity expressed in § 1498.

¹⁶³ See *Schillinger v. United States*, 155 U.S. 163, 172 (1894) (rejecting a claim for compensation for patent infringement against the federal government as a claim in tort, rather than a claim with a constitutional basis under the Takings Clause); see also *Zoltek*, at 1351-53 (“As the Supreme Court has clearly recognized when considering Fifth Amendment taking allegations, ‘property interests . . . are not created by the Constitution. Rather, they are created and their dimensions are defined by existing rules or understandings that stem from an independent source such as state law.’ Here, the patent rights are a creature of federal law. . . . Congress provided a specific sovereign immunity waiver for a patentee to recover for infringement by the government. Had Congress intended to clarify the dimensions of the patent rights as property interests under the Fifth Amendment, there would have been no need for the new and limited sovereign immunity waiver.” (quoting *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1001 (1984))). Some suggest that *Horne v. Department of Agriculture*, 135 S. Ct. 2419 (2015), “left no doubt” that “patents are subject to the Takings Clause.” Gregory Dolin & Irina D. Manta, *Taking Patents*, 73 WASH. & LEE L. REV. 719, 775 (2016). But *Horne* simply recited the dicta of an earlier Supreme Court case, *James v. Campbell*, 104 U.S. 356 (1882), that concluded that patent holders had no effective remedies against the government. That point was affirmed and taken further in *Schillinger*, *supra*, in which the Court held that government use is not a Fifth Amendment taking. While existing case law does not clearly establish that “patents can *never* be subject to takings,” it does establish that government patent use does not generate a constitutionally cognizable taking. See Camilla A. Hrdy & Ben Picozzi, *The AIA Is Not a Taking: A Response to Dolin & Manta*, 72 WASH. & LEE L. REV. ONLINE 472, 476 (2016). Even those who argue that some government interventions related to patents *should* be subject to the Takings Clause treat § 1498’s requirement of “reasonable and entire compensation” as satisfying the clause’s requirements. See, e.g., DAVID A. DANA & THOMAS W. MERRILL, PROPERTY TAKINGS 238 n.373 (2002). Dana and Merrill discuss the baseline for compensation we adopt here—risk-adjusted R&D—as one of the two most plausible baselines for a takings analysis in this context. *Id.* at 244-45. But they prefer an approach

have never had a right to prevent government use, and so in this respect have never enjoyed property to be taken. The analogy of eminent domain is nonetheless a powerful one, because the economic justification for § 1498 parallels the case for a government power of eminent domain in important ways.

The economic case for eminent domain in land is well understood: market exchanges suffer transaction costs, and when these costs are high, they can preclude exchanges that would result in net social gain.¹⁶⁴ The classic example involves a hold-out to a new railroad project, where the last property-holder whose land is needed for a new railroad line can demand a price that would extract the full social value of the railroad, leading to bargaining breakdown.¹⁶⁵ This problem is also sometimes described as one of monopoly. Where the government undertakes this kind of public works project,

each owner is a monopolist, effectively dominating a resource needed to complete the project. Each owner can thereby engage in monopoly pricing, that is, can set his price well above the opportunity cost of the needed resource. The result: fewer oil pipelines will be constructed, and those few that are built will cost a higher than optimal price.¹⁶⁶

When a pharmaceutical company holds a key patent on a drug, it generates a similar kind of problem. The company knows that government programs, with their commitment to cover lifesaving medicines, must be “routed” through its intellectual property. It may then demand prices that far exceed its investment, appropriate maximum social welfare to itself, and limit the welfare potential of its inventions. Government insurance programs, as intimated above, exacerbate deadweight loss from patents: because it “makes patient demand highly price-inelastic, insurance creates the potential and incentives for manufacturer prices that exceed

keyed more closely to expected profits due to the risk of error within agencies and courts, *id.* at 246-47. Our proposed approach addresses both limitations, by accounting for risk of error and awarding a premium to ensure supra-competitive profits. *See infra* Part IV.A.

¹⁶⁴ See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rule, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1106 (1972).

¹⁶⁵ See Abraham Bell & Gideon Parchomovsky, *Pliability Rules*, 101 MICH. L. REV. 1, 62-63 (2002).

¹⁶⁶ Thomas W. Merrill, *The Economics of Public Use*, 72 CORNELL L. REV. 61, 75 (1986).

the level that would result from patents alone.”¹⁶⁷ Yet the government’s power of eminent domain is essential where private property rights prevent the government from realizing the key function of providing public goods.¹⁶⁸ Our case merely extends the analysis from one kind of hold-out problem (the bilateral monopoly enjoyed by the last homeowner) to another—the pricing premium a patent holder enjoys when exclusive rights translate into pricing that exceeds marginal cost, or even marginal cost plus average cost.

In the land context, we treat a price akin to the private market price as an efficient one, assuming that land is relatively fungible as a commodity and markets are thus reasonably competitive.¹⁶⁹ However, the pharmaceutical context is more complex. “Market” prices here are set against the backdrop of exclusive rights, meaning that market prices may also be—indeed, almost certainly are—set inefficiently high.¹⁷⁰ This is the implication of the theoretical discussion and the deadweight loss estimates described above. Where medicines are concerned, the question of appropriate valuation, and thus appropriate royalties under § 1498, is critical. We therefore return to the discussion of information economics begun above.

A. Establishing Royalty Rates for Government Use of Patents

The key challenge for the appropriate use of § 1498 is compensation, *i.e.*, damages or royalties. Patentees are entitled to “reasonable and entire compensation” under the statute.¹⁷¹ If royalties are set too low, use of the power will result in too little research in the private sector.¹⁷² If royalties are set too high,

¹⁶⁷ See, *e.g.*, Patricia M. Danzon, Adrian K. Towse, & Jorge Mestre-Ferrandiz, *Value-Based Differential Pricing: Efficient Prices for Drugs in a Global Context*, at 2 (Nat’l. Bureau Econ. Res. Working Paper, No. 18593, Dec. 2012), <https://perma.cc/Z9Y7-BHFA>.

¹⁶⁸ See Bell & Parchomovsky, *supra* note 165, at 61.

¹⁶⁹ A more substantial puzzle centers on why the government is allowed to use eminent domain in land in settings where strategic bargaining is less of a concern. If one landowner tries to hold out against an attempt to site a post office, for example, there will be many other appropriate plots. Absent collusion, the government should be able to procure land at market rates. See *e.g.* Merrill, *supra* note 166, at 76-78 (arguing that the case for eminent domain is weaker where there are “thicker” markets).

¹⁷⁰ See generally DANA & MERRILL, *supra* note 163, at 234-47.

¹⁷¹ 28 U.S.C. § 1498(a). The text differs than that of the Patent Act, which requires “adequate” compensation. 35 U.S.C. § 284.

¹⁷² There is, of course, substantial public investment in research. For example, in 2004, federal agencies funded roughly one-third of all U.S. biomedical R&D and the National Institutes of Health (NIH) was itself responsible for three-quarters of this amount. BHAVEN N. SAMPAT, *Appendix D: The Impact of*

§ 1498 duplicates the deadweight loss problem associated with patents. But how, then, should such compensation be measured?

In answering this question, we seek to reconcile the existing case law (which is far from pellucid)¹⁷³ with the understanding of § 1498 developed above, as well as the values that patents are understood to protect in the United States: social welfare or “progress,” rather than mere private rights.¹⁷⁴ Taking § 1498’s purpose and precedent into account, courts should set royalties in a way that allows the government to prevent hold up while also protecting incentives to invest.

Three key principles can be distilled from the case law, and provide us with a starting point. First, “lost profits” are strongly disfavored, and perhaps entirely unavailable, under § 1498.¹⁷⁵ As the courts have stressed in these cases, “[i]t is

Publicly Funded Biomedical and Health Research: A Review, in MEASURING THE IMPACT OF FEDERAL INVESTMENTS IN RESEARCH: A WORKSHOP SUMMARY 153 (2011). Scaling up such research alongside exercise of § 1498 would be possible, but a refinement we will not discuss here.

¹⁷³ Courts in § 1498 cases, as in patent damages cases more generally, frequently consider a very broad array of factors. *See, e.g.*, *Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 386 (2014) (“The determination of a reasonable royalty requires a highly case-specific and fact-specific analysis, relying upon mixed considerations of logic, common sense, justice, policy and precedent.”). Because so many factors are available to courts, certainty in damages calculations will invariably be difficult to come by. Our approach is intended to provide some certainty, though more could surely be generated in other ways, for example through agency guidance (which might shape expectations and negotiations) and Congressional amendment.

¹⁷⁴ *See, e.g.*, *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) (“The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge.”); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 511 (1917) (“[T]he primary purpose of our patent laws is not the creation of private fortunes for the owners of patents but is ‘to promote the progress of science and useful arts.’” (quoting U.S. CONST. art. I, § 8)). Welfarism—or efficiency (typically understood in Kaldor-Hicks or wealth maximizing terms)—is widely considered the central value of intellectual property law today in the United States. *See* William Fisher, *Theories of Intellectual Property*, in NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168, 169 (Stephen R. Munzer ed., 2001); *see also* Lemley, *supra* note 158, at 1031 (“Intellectual property protection in the United States has always been about generating incentives to create.”).

¹⁷⁵ *See* DONALD S. CHISUM, 7 CHISUM ON PATENTS § 20.03 (2015) (“There is some doubt whether lost profits is a permissible basis for recovery against the United States.”); *see also* *Tektronix, Inc. v. United States*, 552 F.2d 343, 348 (Ct. Cl. 1977), *opinion modified on denial of reh’g*, 557 F.2d 265 (Ct. Cl. 1977) (“[E]ven if we assume that lost profit is still a viable measure of recovery under 28 U.S.C. § 1498, we cannot adopt that standard in this case because it has not been sufficiently shown by clear and convincing evidence . . .” (emphasis added)). In a recent case, the Federal Circuit suggested in dicta that “lost profits should be recoverable in at least some [1498] infringement actions against the government, even though the Fifth Amendment is implicated.”

equally a fundamental component of fairness to avoid excessive compensation to the [patent owner] as it is to be sure not to pay him too little.”¹⁷⁶ Because patent holders are not entitled—indeed, never have been entitled—to enjoin use for the federal government, a lost profits approach risks overcompensation of the patent holder. For this reason, the Federal Circuit has repeatedly stressed that, in § 1498 cases, “[t]he proper measure [of damages] is what the [patent] owner has lost, not what the taker has gained.”¹⁷⁷ The court’s conclusion has been driven by the eminent-domain-like nature of the statute¹⁷⁸ and by the important distinctions between § 1498 and ordinary infringement actions.¹⁷⁹

As one commentator has put it,

The purpose of awarding damages under Title 35 is “to make the patent owner whole for losses caused by the infringer’s illicit activity. The patent owner is to be restored financially to the position he would have occupied but for the infringement.” This is consistent with the tort-based foundation of Title 35. Section 1498, however, does not seek to restore the patentee to a position it would have occupied but for the Government’s “taking” of a license under the patent, because it recognizes the Government’s right to effect that “taking.” The only issue is the

Gargoyles, Inc. v. United States, 113 F.3d 1572, 1576 (Fed. Cir. 1997). The reference to the Fifth Amendment refers to the statement in *Leesona* that “[b]ecause recovery is based on eminent domain, the proper measure is ‘what the owner has lost, not what the taker has gained.’” See *id.* (internal citations omitted).

¹⁷⁶ *Tektronix*, 552 F.2d at 351.

¹⁷⁷ *Dow Chem. Co. v. United States*, 226 F.3d 1334, 1348 (Fed. Cir. 2000) (quoting *Leesona*, 599 F.2d at 969 (citing *United States v. Chandler–Dunbar Water Power Co.*, 229 U.S. 53, 76 (1913))).

¹⁷⁸ *Leesona*, 599 F.2d at 969 (citing eminent domain principles in reference to government infringement).

¹⁷⁹ *Tektronix*, 552 F.2d at 351 (under § 1498, the “goal of ‘complete justice’ implies that only a reasonable, not an excessive, royalty should be allowed where the United States is the user—even though the patentee, as a monopolist, might be able to exact excessive gains from private users”). It is also notable that § 1498 not only limits injunctions, for example, but also prevents the federal government from being sued on theories of secondary infringement or from being subject to punitive damages or normal attorney’s fees. David R. Lipson, *We’re Not Under Title 35 Anymore: Patent Litigation Against the United States Under 28 U.S.C. § 1498(a)*, 33 PUB. CONT. L.J. 243, 250, 259-60 (2003).

measure of the “reasonable compensation,” not making the patentee “whole.”¹⁸⁰

In every modern § 1498 case, then, the measure of royalties has not been lost profits but rather a “reasonable royalty.”¹⁸¹ This approach, in particular, aligns with the legislative record and the historical use of the provision, both of which reveal the law as, in part, a means to constrain excessive pricing.¹⁸²

The second key principle to emerge from the case law is that “an established royalty is the best measure of compensation [but] [a]bsent such a royalty, the Court of Claims determines a reasonable royalty.”¹⁸³ If licenses (and even mere offers to license) exist, they are typically very influential.¹⁸⁴ But appropriate benchmark licenses sometimes do not exist. Indeed, they are unlikely to be present in pharmaceutical cases because pharmaceutical patent holders do not commonly license their lucrative patents after their products have come to market. In the absence of existing licensing agreements, courts often rely on the “willing-buyer, willing-seller rule,” and consult the wide range of factors (known as the *Georgia-Pacific* factors) considered in most patent infringement cases.¹⁸⁵ In § 1498 cases, courts have referenced government cost savings as a benchmark against which the royalty calculated under the willing-buyer, willing-seller approach can be compared, but this has been disfavored in more recent cases.¹⁸⁶ Furthermore,

¹⁸⁰ Lipson, *supra* note 179, at 254 (internal citations omitted).

¹⁸¹ CHISUM, *supra* note 175 § 20.03 (listing all awards under § 1498, and showing that there has not been a lost profits award since 1930); *see also* Decca Ltd. v. United States, 640 F.2d 1156, 1173 (Ct. Cl. 1980) (“The reasonable royalty method is the preferred method of ascertaining the value of patent rights taken by the Government.”).

¹⁸² *See supra* Part III.B.

¹⁸³ CHISUM, *supra* note 175 § 20.03.

¹⁸⁴ *See* Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1572 (Fed. Cir. 1996) (upholding the trial court’s reliance on amounts specified in a licensing offer); *see also* Boeing Co. v. United States, 86 Fed. Cl. 303, 312 (2009) (“[Past] agreements ‘carry considerable weight in calculating a reasonable royalty rate.’”) (internal citations omitted); *cf.* Gaylord v. United States, 678 F.3d 1339, 1344 (Fed. Cir. 2012) (in a copyright government use case under § 1498(b), remanding where evidence showed that the patentee had established royalty rates from which the lower court had diverged).

¹⁸⁵ In § 1498 patent cases, courts have largely used the fifteen-factor analysis established in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified sub. nom.* *Georgia-Pac. Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971); *see* *Tektronix, Inc. v. United States*, 552 F.2d 343, 349 (Ct. Cl. 1977), *opinion modified on denial of reh’g*, 557 F.2d 265 (Ct. Cl. 1977).

¹⁸⁶ *Leeson*, 599 F.2d at 971 (“[While] savings to the government may be considered in determining reasonable compensation,” its best use “is in estimating what royalty willing buyers and sellers would agree to. It has

courts have repeatedly refused to adopt the patentee's claimed profit margins as a royalty baseline.¹⁸⁷ Instead, courts, in several more recent cases, have started with a baseline calculated from the *infringer's* profits.¹⁸⁸ This method, outlined in the influential *Tektronix* decision, seeks to establish a "residual share" of profits that can be allocated to the patentee by "start[ing] with the infringers price, deduct[ing] its costs in order to find its gross profit, then allocat[ing] to the infringer its normal profit," and awarding the remainder, as the residual share, to the patentee.¹⁸⁹

Awards may also be adjusted from the baseline established through the residual share method, bringing us to the third key principle of compensation in § 1498 cases. Adjustments to royalties may be warranted, the courts have held, if the patentee "took the risks and bore the expense of developing the [infringing products] and creating a market for them."¹⁹⁰ Most instructive is the Federal Circuit's decision in *Leesona v. United States*: There, the court treated the minimum royalty that the patentee would be willing to accept as equivalent to the "total development costs for its inventions plus a reasonable profit, all allocated over the total estimated quantity of procurement of sales."¹⁹¹ The court also imposed the

been done infrequently in the past and generally only when the calculation of a reasonable royalty was difficult. . . . Even where savings to the government are used as an acceptable measure of just compensation, no court has awarded the total savings to the infringer as just compensation.").

- ¹⁸⁷ See *Honeywell Int'l v. U.S.*, 107 Fed. Cl. 659, 693 (2012). As the court explained in *Leesona*, lost profits and government savings serve as "as guidelines—none totally controlling but all testing [the] determination of the reasonable royalty and compensation base." *Leesona*, 599 F.2d at 973.
- ¹⁸⁸ See *Tektronix*, 552 F.2d at 350; *Honeywell*, 107 Fed. Cl. at 693; *Standard Mfg. Co. v. United States*, 42 Fed. Cl. 748, 766 (1999). When parties have not claimed a royalty based on the residual profit method, courts have determined the baseline by critically assessing the royalty rates claimed by the parties, *Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 386 (2014), or by simply averaging the rates claimed by the parties. *Wright v. United States*, 53 Fed. Cl. 466, 475 (2002). In one modern case, despite finding no evidence of past royalties, the Court of Claims forewent the baseline determination, and instead calculated a royalty rate directly using the multi-factor *Georgia-Pacific* test. *Gargoyles, Inc. v. United States*, 37 Fed. Cl. 95, 108 (1997), *aff'd*, 113 F.3d 1572 (Fed. Cir. 1997).
- ¹⁸⁹ *Tektronix*, 552 F.2d at 350-51 (applying this method to reach a residual share of 4.6%, and increasing this to 10% after considering other factors); *Honeywell*, 107 Fed. Cl. at 693 (applying this method to reach a residual share of 4.2%, and adopting this as the reasonable royalty).
- ¹⁹⁰ *Honeywell*, 107 Fed. Cl. at 693 (citing *Tektronix*, 552 F.2d at 350); see also *Decca Ltd. v. United States*, 640 F.2d 1156, 11811 (Ct. Cl. 1980) (noting that minimal investment in R&D will lower royalty rate).
- ¹⁹¹ CHISUM, *supra* note 175 § 20.03; see *Leesona*, 599 F.2d at 979 ("A floor on the royalty would be provided by the expense incurred by Le[e]sona in developing its invention, less any compensation received from defendant in its pre-1969 development contracts. The figure, with a reasonable profit, could be

burden on the patentee to provide the relevant facts for this analysis, concluding that “the party having the burden of proof must suffer if a scantiness of record fails to support a fully informed and reasoned determination.”¹⁹²

The best approach to compensation under § 1498, then, would begin with the “residual royalty” earned by the infringer. In the pharmaceutical context, this approach would typically set a very low baseline. In the HCV example, if a course of treatment that costs \$900 to manufacture sells for \$1000 and a court found that the infringer enjoys a 10% profit on other comparable products, the government would be liable for only \$90 per course in royalty payments.¹⁹³ Because generic medicines are often so relatively inexpensive, and because patent-holding firms will be able to claim that they paid for extensive R&D, these rates should be grossed up to ensure adequate incentives for innovation. This should result in a reasonable measure of “what the [patent] owner has lost.”¹⁹⁴ In other words, compensation should reflect the sunk costs of R&D, but not lost exclusivity, since exclusivity was never an entitlement.

As suggested in *Leesona*, courts can also factor into the award “reasonable” profits, perhaps keyed to approximate average industry returns.¹⁹⁵ Publicly available estimates suggest that a 10 to 30% bounty would approximate average profits in the pharmaceutical industry.¹⁹⁶ However, courts

amortized by the royalty attributable to the Eagle Picher procurement in the proportion such procurement bore to the anticipated sales of the invention during the patent life.”); *see also* *Penda Corp. v. United States*, 29 Fed. Cl. 533, 576 (1993) (questioning whether the patentee should recoup its entire development cost from the government based on a single case of infringement).

¹⁹² *Leesona*, 599 F.2d at 969.

¹⁹³ In this example, the gross profit is \$100. Following *Tektronix*, the infringer would receive its usual share of profit (\$10), while the remainder of the profit would serve as a royalty for the patentee (\$90). *Tektronix*, 552 F.2d at 351. The royalty for the patentee, as a percentage of the sale price, would be 9%.

¹⁹⁴ *Leesona*, 599 F.2d at 969.

¹⁹⁵ Notably, similar bounties have been deployed in eminent domain law. For example, the nineteenth century Mills Acts, which enabled private persons to invade the riparian rights of upstream property owners, required takers to pay property owners substantial bounties on top of market prices in order to deter overuse and ensure adequate compensation. *See, e.g.*, New Hampshire Mill Act, 1868 N.H. Laws, ch. 20, § 3 (setting compensation for private takings of riparian land at 150% of market value).

¹⁹⁶ *See* SPIRO ET AL., *supra* note 17, at 7; Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS, Nov. 6, 2014, <https://perma.cc/Z23H-B2A5> (finding that the world’s ten largest pharmaceutical companies have profit margins between 10% and 43%, with the majority making about 20% margins); *Trade, Foreign Policy, Diplomacy and Health: The Pharmaceutical Industry*, WORLD HEALTH ORG., <https://perma.cc/F6ZC-NYPC> (last visited Sept. 10, 2015) (estimating average

could fix the level of profit based on expert testimony and even incorporate an additional margin to compensate for the risk of error in their R&D assessments. Agencies would ideally also issue guidelines to help establish the premium to be awarded and diminish uncertainty associated with the reliance on courts. Such guidelines would apply to voluntary settlements in the shadow of § 1498 and perhaps also influence courts in their damages calculations.¹⁹⁷

Protecting incentives to innovate and reasonably compensating patentees, we think, also requires courts, where possible (*i.e.*, where the patentee is able to put forth credible evidence on the point) to compensate patentees not just for R&D expenditures but also the *risk* associated with those expenditures. This follows from the high-risk nature of pharmaceutical development. Before investing \$1, for example, a company will require a potential profit of \$2 if there is a 50% risk that the product it is developing will fail. Ideally, courts could follow an option pricing approach, and (with the aid of discovery and expert testimony) estimate R&D outlays and the risk of failure at each stage of investment in a compound. According to one recent estimate, the average probability that an investigational compound, *i.e.* a new drug, will advance from Phase I clinical testing to Phase II is about 60%.¹⁹⁸ The probability that the drug will advance from Phase II to III testing is about 20%.¹⁹⁹ And the overall probability that a drug that has entered clinical testing will be successful is about 10%.²⁰⁰ The most sophisticated approach to accounting for risk would factor in outlays and risks at these different stages, and use inputs specific to the drug or drug class in question.²⁰¹ In the absence of such evidence, courts might instead rely on evidence regarding average failure rates, or average failure

profit margins at 30%); Frederic M. Scherer, *Markets and Uncertainty in Pharmaceutical Development* 7 (Harvard KSG Fac. Res. Working Paper Series, Working Paper No. RWP07-039, Sept. 2007), *available at* <https://perma.cc/JG8T-942G> (arguing that pharmaceutical return on investment was closer to 10% with appropriate accounting adjustments).

¹⁹⁷ Congress could also pass an act to establish a damages formula. *See, e.g.*, S. Res. 15968, 114th Cong. § 7330B (2015) (Senator Bernie Sanders proposing a bill that sets out factors the Secretary of the Veterans Administration should consider when setting royalties for medications it provides under § 1498).

¹⁹⁸ *See* Joseph A. DiMasi, Henry G. Grabowski, & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 24 tbl.2 (2016); *see also* James Love, *The 2016 Tufts Estimates of the Risk Adjusted Out-of-Pocket Costs To Develop a New Drug*, KNOWLEDGE ECOLOGY INT'L (Apr. 12, 2016), <https://perma.cc/DT5N-JJN3>.

¹⁹⁹ DiMasi, Grabowski, & Hansen, *supra* note 198 at 24 tbl.2.

²⁰⁰ *Id.*

²⁰¹ Different types of drugs can have dramatically different levels of risk associated with their development. *See* Love, *supra* note 198.

rates at the later stages of development which are the most expensive.²⁰²

There is also a sound innovation policy argument for adjusting royalties to reflect the proportion of the worldwide market for the drug comprised by the government's anticipated use. If, for example, the government's § 1498 power is used only to supply federally sponsored insurance and healthcare programs, then damages might be pro-rated to reflect the proportion of the global market that these payors represent. One strength of using courts to effectively set an ex post prize here is their ability to examine evidence of market share, which may vary with the nature of the disease as well as over time.

While there are of course limits to the quality of government information about these inputs,²⁰³ courts in § 1498 cases are well-situated to undertake the relevant inquiries. As in *Leesona*, courts can impose the burden on the patentee—who ought to be the cheapest provider of such information—to produce information about R&D expenditures, risk, reasonable profits, and worldwide market share. Courts can also protect this information from broader disclosure through protective orders and *in camera* review. Courts also have the benefit of expert testimony and the flexibility under existing law to award either a lump-sum or an ongoing royalty.²⁰⁴

Even if courts may sometimes err in their calculations, it should be noted that the resulting efficiency case for § 1498 remains strong, particularly in cases such as HCV. This is because the efficiency gains from lower pricing are likely to be large, given the amount of associated deadweight loss. Consider the conventional deadweight loss graph in Figure One above (reproduced below). Lowering the price in the context of exclusive rights, from P_M to P' , both increases social welfare (by *Area B + C*) and decreases patent-holder profits (by *Area B - A*). As Ian Ayres and Paul Klemperer have shown, even small decreases in price under monopolistic conditions result in extensive welfare gains, because “[t]he last bit of monopoly pricing produces large amounts of deadweight loss for a relatively small amount of patentee profit.”²⁰⁵ As they put it, “allowing patentees to raise price all the way to the monopoly

²⁰² DiMasi, Grabowski, & Hansen, *supra* note 198 at 24 tbl.2.

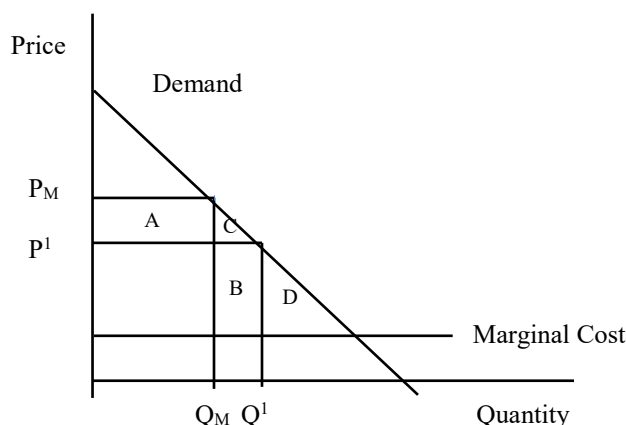
²⁰³ See Demsetz, *supra* note 113, at 11-13.

²⁰⁴ See *Virnetx, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed. Cir. 2014) (“A reasonable royalty may be a lump-sum payment not calculated on a per unit basis, but it may also be, and often is, a running payment that varies with the number of infringing units. In that event, it generally has two prongs: a royalty base and a royalty rate.”); *Liberty Ammunition, Inc. v. United States*, 119 Fed. Cl. 368, 402 (2014) (establishing an ongoing, forward-looking royalty rate in a § 1498 case).

²⁰⁵ Ayres & Klemperer, *supra* note 15, at 987.

level is a little like giving them a license to steal car radios – it produces social cost (to car owners) far greater than the private benefit.”²⁰⁶

Figure 1. Monopoly Pricing



While alternative approaches that would yield higher royalties are not definitively foreclosed by existing law, the approach we describe here has a sound basis in precedent, reflects the purpose of § 1498, and promotes social welfare and health. It also resonates with the academic literature on patent damages in recent years, which has urged courts to move away from the unpredictable 15-factor *Georgia-Pacific* test²⁰⁷ and to use damages law to promote welfare and prevent hold-out in other domains.²⁰⁸

²⁰⁶ *Id.*

²⁰⁷ J. Gregory Sidak, *Bargaining Power and Patent Damages*, 19 STAN. TECH. L. REV. 1, 3-4 (2015). Judge Richard Posner has asked, “could a judge or a jury really balance 15 or more factors and come up with anything resembling an objective assessment?” *Apple Inc. v. Motorola, Inc.*, 869 F. Supp. 2d 901, 911 (N.D. Ill. 2012), *aff’d in part, rev’d in part, vacated in part, and remanded*, 757 F.3d 1286 (Fed. Cir. 2014); David A. Haas, John R. Bone & Bruce W. Burton, *An Interview of Judge Richard A. Posner on Patent Litigation*, STOUT RISIUS ROSS (July 10, 2013), <https://perma.cc/JY65-2RKA> (“[T]he *Georgia-Pacific* test is baloney. Fifteen factors, that’s ridiculous.”).

²⁰⁸ See Jorge L. Contreras & Richard J. Gilbert, *A Unified Framework for Rand and Other Reasonable Royalties*, 30 BERKELEY TECH. L.J. 1451, 1456 (2015); Carl Shapiro, *Injunctions, Hold-Up, and Patent Royalties*, 12 AM. L. & ECON. REV. 280, 308 (2010); Daralyn J. Durie & Mark A. Lemley, *A Structured Approach To Calculating Reasonable Royalties*, 14 LEWIS & CLARK L. REV. 627 (2010); Thomas F. Cotter, *Patent Holdup, Patent Remedies, and Antitrust Responses*, 34 J. CORP. L. 1151, 1152-53 (2009); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1994 (2007).

B. When and How Should § 1498 Be Invoked?

If the static benefits of government use are large enough, they will offset any dynamic losses imposed by error from royalties set under § 1498. Partly for this reason, we suggest that the government only invoke its § 1498 power where drug pricing has created sizeable deadweight loss, as with the new HCV medications. By focusing on these cases, the government will ensure that social gains are substantial. As with eminent domain, where the government often purchases land on the private market despite having the power to take it, so too should government use of patents be invoked in the exceptional rather than routine case.²⁰⁹

When deciding whether to invoke § 1498, the federal government should consider two primary factors. The first factor is the likelihood that firms command rents in excess of risk-adjusted R&D costs plus a reasonable profit. Given our compensation methodology, the government would have no incentive to use the power where a drug's price was closely tied to risk-adjusted R&D expenditures. It should be noted that high drug prices may not always be a proxy for inefficiency. In the context of rare diseases, for example, high prices may be justifiable because firms must spread R&D costs over a much smaller patient population. Such claims, of course, would need to be carefully scrutinized on a case-by-case basis given the potential for abuse.²¹⁰ The second factor is the magnitude of potential public health gain. If such gains are minimal, then the benefits of invoking the mechanism might be too small to justify the intervention.²¹¹ Conversely, the presence of

²⁰⁹ See generally DANA & MERRILL, *supra* note 163. As we will describe, this likely reflects the political pressures to avoid eminent domain, which would also play a role in the patent context.

²¹⁰ See Garret Kent Fellows & Aidan Hollis, *Funding Innovation for Treatment for Rare Diseases: Adopting a Cost-Based Yardstick Approach*, 8 ORPHANET J. RARE DISEASES 1, 1 (2013) (noting the blockbuster success of some rare disease treatments and calling for a cost-based approach to rare disease drug pricing).

²¹¹ Nevertheless, an interesting case could be made for the use of § 1498 in situations where medications present little to no public health benefit, but produce massive new drug markets. For example, in 1989, AstraZeneca, introduced a new type of gastroesophageal reflux disease medication called omeprazole. See FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS 314 (2015). More commonly known by its brand name (Prilosec) this medication was the world's top selling drug by 2000, earning over \$6 billion per year in the United States. See Walid F. Gellad et al., *Assessing the Chiral Switch: Approval and Use of Single-Enantiomer Drugs, 2001 to 2011*, 20 AM. J. MANAGED CARE e90, e90 (2014). Faced with omeprazole's patent expiration in 2001, *id.* at e90, AstraZeneca began promoting a "new" version of the drug: esomeprazole, branded as Nexium. *Id.* at e92. But the functional distinction between the two drugs is

significant population-wide benefits, for example where treatment also acts as a form of prevention, should counsel in favor of using § 1498.

We imagine that government agencies would go beyond our two-factor analysis to define the conditions for use of § 1498 more granularly and incorporate the input of experts. Such definition would minimize the uncertainty companies face, thereby protecting their incentives to invest. Even without more fine-tuned analysis and elaboration, however, it is clear that new HCV treatments satisfy both factors and are a prime candidate for government use. Other candidates for § 1498 use would become more apparent with more publically available information about drug R&D costs. Fortunately, the lack of transparency around drug development costs has spurred calls for R&D disclosure requirements, with several state legislators introducing bills to that effect.²¹² Government agencies or Congress, using their subpoena powers, may also be able to gather the information needed to establish the set of drugs suitable for § 1498 use.

extremely limited. *Id.* at e94. Prilosec (omeprazole) is a mixture of the active and inactive enantiomers of the chiral drug omeprazole, whereas Nexium (esomeprazole) is only the active enantiomer of the same chiral drug. *Id.* at e90 (“A chiral drug is a single molecule product that exists in 2 mirror image forms, called enantiomers.”). Nevertheless, AstraZeneca obtained patent protection on esomeprazole—the active enantiomer of the drug—and priced it accordingly. Through a highly successful marketing campaign, AstraZeneca then managed to convince prescribers and patients to prescribe and buy esomeprazole, instead of the substantially cheaper generic versions of omeprazole that came onto the market when the drug’s patent expired. Between 2001 and 2011, Medicaid programs spent \$3.5 billion on esomeprazole. *Id.* at e92. In 2014 alone, Medicare spent \$2.66 billion on esomeprazole—its second highest expenditure on any drug, bested only by sofosbuvir. *See Medicare Drug Spending Dashboard*, CENTER FOR MEDICARE AND MEDICAID SERVICES, <https://perma.cc/9ELX-ETPD>.

Although Nexium does not offer much by way of public health gain, the drug may still present an interesting case for § 1498 use. Astrazeneca’s ability to charge such a high price for Nexium results from a market failure: asymmetrical information about the true benefits of esomeprazole over omeprazole. The government could threaten use of § 1498 in this case as a means of reducing the financial burden on consumers and the government, and reducing incentives for this kind of market manipulation. It is perhaps unlikely, however, that the government would prioritize such a case, since the medicine in question is not a health priority.

²¹² Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES, July 23, 2015, <https://perma.cc/397Z-6KKY> (noting that pharmaceutical transparency bills have been introduced in six state legislatures to stiff opposition). The Presidential Advisory Council for HIV/AIDS has also called for mandatory disclosure of R&D costs. Letter from Nancy Mahon, Chair, Presidential Advisory Council for HIV/AIDS, to U.S. Dep’t of Health and Human Services Sec’y Sylvia Burwell (June 9, 2015), available at <https://perma.cc/73VL-6DZK>.

Reliance on § 1498 will be the exception rather than the rule, in part because the government's mere invocation of its government use power in a single pharmaceutical patent case will immediately impact prices in other cases. Companies can be expected to price in a way that reduces the risk that the government will invoke its power under § 1498. This effect will apply with equal force to later generations of new therapies. As the Senate Report on Sovaldi reflects, a prominent consideration for Gilead was the likelihood of government reaction to its launch price.²¹³

Finally, governments and companies would likely negotiate in the shadow of any serious attempt to procure generic medicines through § 1498. Such negotiations could reduce uncertainty, advantaging all parties.²¹⁴ As we discuss in Part V.A, the statutory limits of § 1498 imply that, without Congressional intervention, the government's immunity may extend only to federal programs and state correctional facilities. Through negotiations, however, the government could explore the possibility of paying a lump sum to the patent holder in exchange for non-exclusivity in all U.S. markets. In other words, the government could use § 1498 as a tool to bring a company into negotiations for a patent buyout. Such a buyout would leverage the power inherent in § 1498 to generate a more comprehensive approach, with greater health implications, that allows all private and public payors to access generic versions of the medication in question.

C. Addressing Objections

There are several possible objections to our approach that should be countered before we move on. Four, in particular, merit discussion. First, some may fear that our proposal, despite the safeguards we propose, will under-compensate innovators and thus undermine pharmaceutical firms' incentives to innovate. We indeed expect our approach to diminish industry profits, both in the specific cases where the power is invoked and in other cases where dynamic effects from

²¹³ Gilead did not envision the use of § 1498. Rather, it considered government reactions in the form of prescribing restrictions and Congressional hearings. STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 30.

²¹⁴ Similarly, federal officials have previously credited the mere threat of using the Bayh-Dole march-in authority for giving the government leverage in licensing negotiations with contractors. U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-742 FEDERAL RESEARCH: INFORMATION ON THE GOVERNMENT'S RIGHT TO ASSERT OWNERSHIP CONTROL OVER FEDERALLY FUNDED INVENTIONS 11-12 (2009), <https://perma.cc/A39A-XNFM>; *see also* Austin Frakt, *Even Talking About Reducing Drug Prices Can Reduce Drug Prices*, N.Y. TIMES, Jan. 18, 2016, <https://perma.cc/EX9J-M68K> (discussing research that shows political pressure can limit drug price growth).

use of the power will influence drug prices. For example, if the government invoked § 1498 over the new HCV drugs, patent-holding companies might lose a substantial portion of the approximately \$10 billion in annual sales²¹⁵ to the federal government.²¹⁶ This, however, is precisely the point: these profits create substantial deadweight loss and cannot plausibly be considered necessary to induce research. The knock-on effects on profits in cases where drugs are not directly subject to government use will be smaller, but for the reasons described by Ayres and Klemperer above, those too should yield disproportionate welfare gains.

A related concern might be raised to our reliance on average industry profits in a context where profits tend to be skewed. In the pharmaceutical industry, a small number of blockbusters generate a significant share of returns.²¹⁷ If we award firms the mean share of profits, we will reduce returns on certain extremely lucrative drugs and also reduce the internal capital that firms have available to invest in R&D. But the result is not necessarily a less efficient system of drug development and distribution. The effects on innovation may be small, for example, if the central constraint in R&D is the supply of innovations or if the elasticity of innovation with respect to expected profits is relatively low. Reducing the profits available for blockbusters could even increase dynamic efficiency, because outsized rewards can induce wasteful racing wherein parties expend more effort to be first to obtain a reward (e.g., patents related to a potential new drugs) than society gains from their race.²¹⁸ Providing large rewards to those who win encourages duplicative efforts, with entrants dissipating resources along the way.²¹⁹ Finally, even assuming that incentives for innovation are reduced somewhat, the net effects in efficiency terms—or, more simply, for health—can still be strongly positive. This is because allowing inventors to recover vastly more than their risk-adjusted R&D costs itself yields inefficiencies. The primary inefficiency is deadweight loss: namely, the restriction of supply associated with supra-marginal cost pricing and the general taxation needed for the

²¹⁵ *Trade, Foreign Policy*, WORLD HEALTH ORG., *supra* note 196.

²¹⁶ *See infra* Part IV.D.

²¹⁷ Henry Grabowski et al., *Returns on Research and Development for 1990s New Drug Introductions*, 20 PHARMAECONOMICS 11, 27 (2002).

²¹⁸ *See* Partha Dasgupta & Joseph Stiglitz, *Uncertainty, Industrial Structure, and the Speed of R&D*, 11 BELL J. ECON. 1, 12-15 (1980); Glenn C. Loury, *Market Structure and Innovation*, 93 Q. J. ECON. 395, 405-08 (1979); Yoram Barzel, *Optimal Timing of Innovations*, 50 REV. ECON. & STAT. 348, 348 (1968).

²¹⁹ Anupam B. Jena & Tomas J. Philipson, *Cost-Effectiveness Analysis and Innovation*, 27 J. HEALTH ECON. 1224, 1229 (2008).

government to pay for medicines.²²⁰ Put simply, small reductions in incentives for R&D may still be efficient if the gains in terms of access are large.

A second objection might be raised to our reliance on risk-adjusted R&D costs as a baseline for compensation, rather than on a measure of social welfare itself, such as disability-adjusted life years (DALYs) or quality-adjusted life years (QALYs).²²¹ Many recent proposals for prizes and systems of government price control rely on this metric, assuming that the government should pay directly for the desired outcome of the years of life or disability that are averted.²²²

The difficulty with this approach comes from the arbitrary nature of DALYs and QALYs themselves. Both concepts have been developed in the context of cost-effectiveness studies. Such studies widely adopt \$50,000 to \$100,000 per QALY as the appropriate social valuation, and imply that interventions that cost less than that per QALY are cost-effective and should be purchased.²²³ DALYs and QALYs are also a commonly used policy tool. For example, the United Kingdom's National Institute for Clinical Excellence (NICE), which makes pharmaceutical coverage decisions for the U.K.'s National Health Service, currently uses a cost-effectiveness threshold of about \$28,000 to \$42,000 per QALY.²²⁴

²²⁰ Private insurers estimate that spending on new HCV drugs will result in a five cent-per-hour tax on every single paycheck. N.L., *Crippling*, THE ECONOMIST, June 4, 2015, <https://perma.cc/XJ9F-YR32>.

²²¹ The quality-adjusted life year (QALY) measures the extent of health gain from a healthcare intervention. It is calculated by multiplying the additional life expectancy attributable to an intervention by the quality of that extended life expectancy. One QALY reflects one year in perfect health. *See, e.g.*, Luis Prieto & José A. Sacristán, *Problems and Solutions in Calculating Quality-Adjusted Life Years (QALYs)*, 1 HEALTH & QUALITY OF LIFE OUTCOMES 80, 81 (2003). Conversely, the disability-adjusted life year (DALY) measures the extent of health loss from a disease. It is calculated by adding the sum of years of life lost due to premature mortality and years lived in disability or disease. One DALY reflects the loss of one year of a healthy life. *See* Health Statistics & Information Systems, *Metrics: Disability-Adjusted Life Year (DALY)*, WORLD HEALTH ORG., <https://perma.cc/Y9SS-CYV2> (last visited Feb. 25, 2015).

²²² *See, e.g.*, Danzon et al., *supra* note 167, at 3; James Love & Tim Hubbard, *Prizes for Innovation of New Medicines and Vaccines*, 18 ANNALS OF HEALTH L. 155, 159-60 (2009); Aidan Hollis, *An Efficient Reward System for Pharmaceutical Innovation 2* (Working Paper, June 2004), available at <https://perma.cc/KM33-MB93>.

²²³ *See, e.g.*, Peter A. Ubel et al., *What is the Price of Life and Why Doesn't it Increase at the Rate of Inflation?*, 163 ARCHIVE INTERNAL MED. 1637, 1637 (2003).

²²⁴ *See* Claxton, *supra* note 222, at xxix. Empirical work based on NICE expenditures suggests that the central or "best" threshold would be closer to \$18,000 per QALY. *See id.* at xxx.

However, such cost-effectiveness thresholds have not been systematically derived.²²⁵ For example, the lower bound commonly used in the U.S. (\$50,000 per QALY) was apparently drawn from the price paid for renal dialysis by Medicare at the time the threshold was accepted.²²⁶ As critics have pointed out, “[t]here may be many [programs] that meet this critical ratio, but to fund them all would imply that the opportunity cost of healthcare resources was constant over whatever range of expenditures are required to support all these programs.”²²⁷ This approach thus does not confront the problem of limited resources. If a new invention were developed tomorrow that saved one QALY for half of all Americans—150 million people—a \$50,000 threshold would suggest that the appropriate price would be \$7.5 trillion dollars. That is more than twice the entire U.S. federal budget in 2015. Yet the intervention may have been developed for far less, for example for the \$2.6 billion that represents the very high end of estimates of the cost of developing a new drug.²²⁸ Fixed thresholds for cost-effectiveness therefore encourage industry to raise the cost of interventions far beyond the prices needed to induce them, and far beyond prices that are affordable from a budgetary perspective. HCV drug pricing offers a good example of this problem in practice.

A variant of this objection might suggest that our approach will encourage companies to invest more heavily in less socially valuable drugs. But our approach is designed to compensate for risk and error, as well as to target medicines on the basis of rent-seeking *and* health benefits, rather than health benefits alone. In addition, our scheme envisions significant returns, in addition to compensation, keyed to the industry average. It would create a significant dynamic effect only if there is both intense scarcity of investment dollars and a

²²⁵ They also differ in important ways from the kind of cost-benefit approach more familiar in economics. For a summary, see Alan M. Garber & Charles E. Phelps, *Economic Foundations of Cost-Effectiveness Analysis*, 16 J. HEALTH ECON. 1 (1997). That approach itself is, of course, subject to deep critique, for example, based on the limits of our empiricism as well as the political implications of the technical nature of its claims.

²²⁶ Amiram Gafni & Stephen Birch, *Incremental Cost-Effectiveness Ratios (ICERs): The Silence of the Lambda*, 62 SOC. SCI. & MED. 2091, 2093 (2006).

²²⁷ *Id.* at 2094.

²²⁸ *How the Tufts Center for the Study of Drug Development Pegged the Cost of a New Drug at \$2.6 Billion*, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT (Nov. 18, 2014), available at <https://perma.cc/V9GQ-GU5P>. This inflated figure has been heavily criticized in the literature. See, e.g., Jerry Avorn, *The \$2.6 Billion Pill — Methodologic and Policy Considerations*, 372 NEW ENG. J. MED. 1877 (2015). In 2001, Tufts estimated the cost to be \$800 million—about \$1 billion in 2013 dollars. See Aaron E. Carroll, *\$2.6 Billion To Develop a Drug? New Estimates Make Questionable Assumptions*, N.Y. TIMES, Nov. 18, 2014, <https://perma.cc/VL98-5D72>.

large surplus of scientific opportunities for lucrative investment.²²⁹ There is little reason, however, to think that either circumstance prevails in the industry. The latest and most robust empirical assessments of the pharmaceutical industry suggest that it has a relatively low elasticity of innovation of approximately 0.25; “when a market increases in potential size by 10%, that stimulates a 2.5% increase in the number of treatments to serve that market.”²³⁰ While it is not surprising that greater potential market returns yield more investment, the relationship is far from proportionate. It may be due to “decreasing margins as competition intensifies,” increasing likelihood of duplicate efforts “as more firms are attracted into a market,” and the fact that “if there is a limited amount of ‘low-hanging fruit’ to be plucked, then the more research teams are seeking to enter a market, the lower will be the average productivity of each.”²³¹

As work on racing problems suggests, the innovation foregone when returns are reduced can also have positive welfare implications that arise from preventing duplicative work or overinvestment in speed. Again, even assuming static net losses to innovation, our approach will have net positive welfare effects as long as the dynamic gains—sure to be very large in cases like HCV—are larger than those losses. We note, moreover, that the federal government can account for all of these concerns when calculating adequate returns for the industry under § 1498. Using experts and agencies, the government can also develop a more sophisticated compensation approach than the one we employ here, with more precise estimates of deadweight losses, innovation elasticities, and profits needed to induce investment.

A third objection to § 1498 is potential overuse by the federal government. Here, the eminent domain literature is again helpful. As scholars have pointed out, the assumption that the government will abuse its eminent domain power conflicts with public choice insights about the relationship between concentrated interests and political action.²³² Takings will tend to produce diffuse social benefits and acute costs.

²²⁹ See, e.g., Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT’L J. TECH. MGMT. 98, 101-02 (2000) (noting that imperfect capital markets and limited external funds may mean that current revenue has an impact on firm investments in R&D).

²³⁰ Pierre Dubois, Olivier de Mouzon, Fiona Scott-Morton, & Paul Seabright, *Market Size and Pharmaceutical Innovation*, 46 RAND J. ECON. 844, 845 (2015). Earlier estimates tended to put the figure higher, for example around 0.5. *Id.*

²³¹ Dubois et al., *supra* note 230, at 848.

²³² Steven Shavell, *Economic Analysis of Property Law*, Working Paper No. 9695, NAT’L BUREAU OF ECON. RES. 88-89 (May 2003), <https://perma.cc/P9XQ-PQWN>.

Therefore, we should perhaps worry about *underuse*, rather than overuse, of the power. The history of § 1498 in the pharmaceutical context supports the public choice point. Despite its availability, the statute has not been used by the government to procure medications in decades. The patent-based pharmaceutical industry's notorious lobbying power²³³ suggests that underuse is indeed a greater risk than is overuse.

Finally, some may see our proposal as giving too much responsibility and discretion to courts to make decisions with important effects on innovation policy. We see the risk, but note that courts regularly—and inevitably—adjudicate disputes and assess damages in cases with very significant innovation policy effects. Our recommended approach to damages responds to the criticisms levied at the conventional approach to damages in this context—the “simple” application of the *Georgia-Pacific* factors, which have long been criticized as leading to inappropriate and inconsistent damages awards.²³⁴ Courts will play a significant role in setting damages, but this is the structure that Congress demanded when it passed § 1498. As with eminent domain, if the government is to have a right to a liability rather than a property rule, courts must play a role in setting damages. That role might, however, be merely a backstop. Agencies can establish guidelines that will shape any bargaining around the courts' powers, thereby influencing courts' calculations and reducing uncertainty about how courts would assess damages.

Notably, the government and patent holders can minimize compensation uncertainty by negotiating voluntary licenses as previously described. Should courts rely on our damages methodology, the government and patent holders could come to voluntary agreements, based on the knowledge that court-ordered damages awards would be keyed to risk-adjusted R&D costs.

D. Application of the R&D-Based Compensation Methodology to the HCV Context

²³³ The pharmaceutical and health products industry has spent more each year on federal lobbying than any other industry since 1999. *See Influence and Lobbying: Top Industry*, OPENSECRETS.ORG, <https://perma.cc/SKY5-E6Q3> (last visited Feb. 28, 2016). The pharmaceutical industry's influence over Congress has been documented on numerous instances, including in passing the Medicare Modernization Act of 2003 (which established the Part D program) and the Affordable Care Act. *See* Andrea Seabrook, *Drug Firms Pour \$40 Million into Health Care Debate*, NAT'L PUB. RADIO (July 23, 2009), <https://perma.cc/J3E2-PE48>; Michelle Singer, *Under the Influence*, 60 MINUTES (Mar. 29, 2007 <https://perma.cc/34NN-9TRY>).

²³⁴ *See supra* note 207-208.

In the HCV context, we have a considerable amount of information relevant to our proposed compensation methodology. Given the availability of data surrounding Gilead's drugs, including approximate costs of developing its sofosbuvir-based products, we use government procurement of these drugs under § 1498 to illustrate how our approach to damages would work in practice.

Sofosbuvir was initially developed by a now-defunct company named Pharmasset.²³⁵ In its earliest phases, sofosbuvir was supported by government funding, including grants to put the drug through early clinical trials.²³⁶ These initial years, from 2008-2011, cost Pharmasset \$62.4 million.²³⁷ By 2012, the drug's promise was clear, and Gilead purchased the compound (and Pharmasset itself) for \$11.2 billion.²³⁸ This purchase price was extraordinary, given Pharmasset's level of investment to that point.²³⁹ Indeed, the price is suggestive of the racing described above: Gilead paid a sum radically disproportionate to investment in the drug because of the drug's promise and Gilead's ability to unilaterally set the drug's launch price.²⁴⁰

After its purchase, the company reported \$880 million in R&D spending on all sofosbuvir-containing regimens, which in addition to sofosbuvir (Sovaldi) and its follow-on combination drug, sofosbuvir/ledipasvir (Harvoni), includes two other compounds.²⁴¹ For the sake of convenience—and we stress that with more data, this estimate could be much more precise—we generously assume Gilead's R&D investment in sofosbuvir and sofosbuvir/ledipasvir was \$800 million, yielding total R&D costs of under \$870 million (Gilead's \$800 million plus Pharmasset's \$62.4 million).

²³⁵ See Troyen Brennan & William Shrank, *New Expensive Treatments for Hepatitis C Infection*, 312 J. AM. MED. ASS'N 593, 593 (2014).

²³⁶ Jeffery Sachs, *The Drug that is Bankrupting America*, HUFFINGTON POST (Feb. 16, 2015, 11:01 AM), <https://perma.cc/F6ZG-KHGS>.

²³⁷ STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 13. Pharmasset moved the drug through phase II trials and had initiated phase III clinical trials. See Sachs, *supra* note 236.

²³⁸ See John Carroll, *Pharmasset science founder lands a fortune from \$11B Gilead buyout*, FIERCEBIOTECH (Nov. 23, 2011), <https://perma.cc/V87Q-63FZ>.

²³⁹ See *id.* A Gilead executive nonetheless described the acquisition later as a "bargain." STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 17.

²⁴⁰ Significantly underestimating this power, Pharmasset originally planned to sell a course of treatment at \$36,000. Gilead's price tag for Sovaldi in 2013 was more than double Pharmasset's projected price for the drug in 2011. STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 17. Racing was also present as "Gilead was not only concerned about ensuring it could acquire Pharmasset's promising molecule, [but] it was [also] aware that it could move too slowly and miss the chance to purchase the company in a highly competitive industry." *Id.* at 14.

²⁴¹ See STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 22 n.111, 23.

In less than two and a half years, Gilead has made about \$36 billion on its sofosbuvir-based drugs, Sovaldi and Harvoni.²⁴² Gilead has not only recouped nearly three times the \$11 billion purchase price of Pharmasset, but has also likely already earned around *forty times* the cost of developing the drugs. Such a return on investment is surely adequate to induce this type of investment. Even adjusting for risk, and factoring in reasonable profit, society has already vastly overpaid for the drugs, particularly considering how little treatment the \$36 billion expenditure has purchased.

Under our proposed compensation method, the government would be able to procure enough of the new medicines to treat all of those with HCV for a far smaller sum. Assume, for example, that the government sought to procure generic sofosbuvir/ledipasvir for all those living with HCV in the US.²⁴³ In the absence of appropriate benchmark licenses, the first step in determining damages involves establishing a baseline royalty, using the residual profit method described in *Tektronix*.²⁴⁴ Assume a generic price of \$500 (similar to the current price of generic treatment available in other countries),²⁴⁵ a manufacturing cost of \$100,²⁴⁶ and an average infringer profit rate of 10%. The \$400 profit margin on sofosbuvir/ledipasvir would translate into a baseline royalty of \$360 per course of treatment for Gilead.

Courts would then consider whether the royalty should be adjusted to compensate for R&D costs and risks and add a premium for profits.²⁴⁷ Assume a total \$870 million R&D cost

²⁴² See *Gilead's 4th-qtr Sales and Earnings Beat Expectations, as Harvoni Soars*, THEPHARMALETTER (Mar. 2, 2016), <https://perma.cc/PVK8-MLTD>. In 2015, Gilead's sales of sofosbuvir/ledipasvir reached \$13.86 billion and sales of sofosbuvir were \$5.28 billion. In 2014, Gilead's sales of sofosbuvir/ledipasvir were \$2.13 billion and sales of sofosbuvir were \$10.28 billion. In the first quarter of 2016, Gilead's sales of sofosbuvir/ledipasvir and sofosbuvir totaled \$4.29 billion. Press Release, Gilead Sciences, Gilead Sciences Announces First Quarter 2016 Financial Results (Apr. 28, 2016, 4:04PM), *available at* <https://perma.cc/3LQK-U8UR>.

²⁴³ The calculation is intended as illustrative only: our figures are rough estimates, and reaching everyone with HCV may require Congressional action. See *infra* Part V.A (discussing the scope of government use under § 1498).

²⁴⁴ See *Tektronix*, 552 F.2d at 349; see also *Honeywell*, 107 Fed. Cl. at 693; *Standard Mfg.*, 42 Fed. Cl. at 766.

²⁴⁵ Hill, *supra* note 13, at 30; HEPATITIS C IN ASIA, *supra* note 13.

²⁴⁶ This is the estimated cost of manufacturing of sofosbuvir. Hill, *supra* note 13, at 30.

²⁴⁷ See *Leesona*, 599 F.2d at 978 ("A floor on the royalty would be provided by the expense incurred by Le[es]ona in developing its invention, less any compensation received from defendant in its pre-1969 development contracts. The figure, with a reasonable profit, could be amortized by the royalty attributable to the Eagle Picher procurement in the proportion such

(again, likely an overestimate).²⁴⁸ We lack specific information on risk of failure for these drugs, so assume a 10 to 20% chance of success (with the lower bound of 10% representing the general likelihood a drug that begins trials succeeds, and the upper bound of 20% representing the general rate of success in Phase III trial, when the majority of expenditures occur).²⁴⁹ Add a 30% profit premium, which is our rough estimate of average industry profit rates, and the resulting compensation award would be between \$5.65 and \$11.3 billion.²⁵⁰

This is a broad range, based on rough estimates; a court could be far more precise, because it could require that Gilead produce evidence, and also admit expert testimony. Our rough calculation, however, makes two important points. First, payments for innovative companies under government use can easily reach billions of dollars, and protect incentives to invest. Prospectively, companies should be happy to invest \$870 million for a 10% chance of \$11.3 billion, for example. Second, in this case, no upwards adjustment on the baseline royalty would be justified, because Gilead has already earned more than three times the largest estimate from sales of its sofosbuvir-based regimens. This highlights just how extreme the rent seeking in this case has been.²⁵¹

Using our method of compensation, the government could thus provide sofosbuvir/ledipasvir treatments at only the baseline royalty rate. The total cost per treatment would be an estimated \$860 per course of treatment (with \$500 paid to the generic supplier and \$360 paid as a royalty to Gilead). The current best-reported prices of sofosbuvir-based drugs are about \$45,000,²⁵² and some payers are still paying more for the

procurement bore to the anticipated sales of the invention during the patent life.”).

²⁴⁸ We do not use Pharmasset’s \$11.2 billion purchase price as a proxy for R&D costs because reliance on this figure might further encourage the inefficient racing that led Gilead to agree to this purchase price in the first place.

²⁴⁹ DiMasi et al., *supra* note 198, at 24 tbl.2; *see supra* Part IV.A.

²⁵⁰ $(\$870 \text{ million} \times 5) + ((\$870 \text{ million} \times 5) \times 0.30) = \5.65 billion ; $(\$870 \text{ million} \times 10) + ((\$870 \text{ million} \times 10) \times 0.30) = \11.3 billion . This could additionally be adjusted downward to account for the share of U.S. government use in the worldwide market for the drug, if evidence on this were available to the court. Ideally, the U.S. government should only compensate patent holders for part of their R&D costs, because the U.S. government is only responsible for part of the patent holders’ revenue. *See Penda Corp. v. United States*, 29 Fed. Cl. 533, 576 (1993) (questioning whether the patentee should recoup its entire development cost from the government based on a single case of infringement).

²⁵¹ *See* STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 2.

²⁵² Gilead has reported that it offers average discounts of 46%, but many government payors do not have access to discounts this steep. *See infra* note 76-88 and accompanying text.

drugs.²⁵³ It would cost at least \$234 billion to treat all 5.2 million Americans with HCV at \$45,000 per patient,²⁵⁴ while our approach would cost \$4.47 billion. Recall, too, that the U.S. government market is only a portion of the global market, so the gross returns to the company would be greater still.

Our approach could thus save hundreds of billions of dollars, enable rapid scale up in the health benefits associated with these medicines, and leave companies assured of a reward sizeable enough to attract future investment. Scaling up now would also generate positive externalities for decades to come by preventing new infections.

V. ADDITIONAL CONSIDERATIONS FOR INVOKING § 1498 IN THE U.S. HEALTHCARE SYSTEM

Using § 1498 to infringe drug patents presents two unique difficulties that the existing literature has not addressed. Both issues arise out of interactions between the government use power and the complexity of the U.S. healthcare system.

First, § 1498 may only be invoked when a patented invention “is used or manufactured by or for the United States.”²⁵⁵ The phrase “for the United States” includes and indemnifies infringement by contractors, subcontractors, or other persons, firms, or corporations acting “for the Government and with the authorization or consent of the Government.”²⁵⁶ Below we explore when procurement of generics by a variety of health providers fulfills this condition.

Second, under the Food Drug & Cosmetics Act (FDCA), pharmaceutical companies must submit safety and efficacy data to the FDA before this agency will approve their drugs and allow them to sell those medicines in the United States.²⁵⁷ As a reward for producing this data, the FDCA prohibits other pharmaceutical manufacturers from relying on the data to gain approval for their own drugs for a five-year period.²⁵⁸ This

²⁵³ See Am. Ass’n for the Study of Liver Diseases & Infectious Diseases Soc. of Am., *supra* note 101.

²⁵⁴ See *supra* note 9.

²⁵⁵ 28 U.S.C. § 1498(a) (2012).

²⁵⁶ *Id.*

²⁵⁷ 21 U.S.C. § 355(a) & (b) (2012).

²⁵⁸ See *Id.* § 355(c)(3)(ii-iv); see also JOHN R. THOMAS, CONG. RES. SERV., R42890, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN PHARMACEUTICAL INNOVATION 4-7 (Jan. 7, 2013). Data exclusivity for Sovaldi (sofosbuvir), Harvoni (ledipasvir/sofosbuvir), and Viekira Pak (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir) expire on December 6, 2018, October 10, 2019, and December 19, 2019, respectively. See Press Release, FDA Approves Sovaldi for Chronic Hepatitis C, Food & Drug Admin. (Dec. 6, 2013), available at <https://perma.cc/CG7T-6V4Q>; Press Release, FDA Approves First

period of exclusivity is generally known as data exclusivity. We discuss the applicability of data exclusivity laws to § 1498, as well as two possible methods of obtaining FDA approval for generic drugs procured under § 1498.

A. “Government Use” and Public-Private Divisions in Healthcare

In Part IV, we discussed the circumstances that justify using § 1498 to acquire generic medicines. Here, we consider the statutory language limiting the scope of § 1498 to determine which sectors of the healthcare system may access generic medicines procured under § 1498. As we explained above, the provision applies under two scenarios: first, when the United States uses or manufactures a patented product without a license; and second, when a third party, such as a government contractor, infringes *for* the United States. In the first scenario, the federal government accepts liability when it directly infringes the patent; in the second, the federal government assumes liability for third-party infringements on its behalf.²⁵⁹ The scope of any action to procure and distribute generic medicines under § 1498 will turn on the breadth of the statute’s shield for various parties.

The federal government’s involvement in the use of prescription drugs can be divided into three tiers. It is most directly involved in federally run healthcare programs, where federal officers procure medicines directly from drug manufacturers. Examples of such programs include the Veterans Health Administration, Department of Defense, Indian Health Service, and Federal Bureau of Prisons.²⁶⁰ At the next level are federally sponsored health insurance programs, notably Medicare and Medicaid. Under these programs, the federal government pays for the majority of healthcare costs, but relies on states and private entities to procure and distribute prescription drugs.²⁶¹ Furthest removed are state-sponsored healthcare programs and private health insurance

Combination Pill to Treat Hepatitis C, Food & Drug Admin. (Oct. 10, 2014), *available at* <https://perma.cc/RXM2-LMJ8>; Press Release, FDA Approves Viekira Pak to Treat Hepatitis C, Food & Drug Admin. (Dec. 19, 2014), *available at* <https://perma.cc/62CG-FPMP>.

²⁵⁹ *Madey v. Duke Univ.*, 307 F.3d 1351, 1359 (Fed. Cir. 2002) (“In general, there are two important features of § 1498(a). It relieves a third party from patent infringement liability, and it acts as a waiver of sovereign immunity and consent to liability by the United States.”).

²⁶⁰ GRETCHEN A. JACOBSON ET AL., CONG. RESEARCH SERV., RL33802, PHARMACEUTICAL COSTS: A COMPARISON OF DEPARTMENT OF VETERANS AFFAIRS (VA), MEDICAID, AND MEDICARE POLICIES 8-11 (2007).

²⁶¹ *See id.* at 3-5, 13-15 (describing prescription drug coverage under Medicare and Medicaid).

plans. The federal government regulates and subsidizes such plans through the tax system to varying extents, but plays no role in their drug purchasing processes.²⁶² With respect to state correctional facilities, the federal government's regulatory authority includes ensuring that conditions of confinement are consistent with the U.S. Constitution,²⁶³ including the Eighth Amendment's prohibition on "deliberate indifference to serious medical needs of prisoners."²⁶⁴ This section addresses the extent to which § 1498 allows the federal government to assume liability for patent infringement within and across these tiers.

Section 1498 is an assumption of *federal liability* under a theory of sovereign immunity. As such, when the procurer of the infringing product is not the government itself, the statute imposes two requirements: the use of the patented invention by a third party must be (1) "*for* the Government"; and (2) "*with the authorization or consent* of the Government."²⁶⁵ If a use is not *for* the government, then the logic of sovereign immunity does not apply: private parties, not sovereigns, would be immunized. If a use is not with the *authorization or consent* of the government, then the government has not agreed to waive its sovereign immunity and is not liable for damages. We refer to these two requirements collectively as § 1498's "government use" test.

Courts have treated the second requirement—whether the government has authorized use—expansively to accommodate *express* and *implied* as well as *ex ante* and *ex post* consent.²⁶⁶ This flexibility equally accommodates situations where the government knows in advance that third parties will

²⁶² See BERNADETTE FERNANDEZ & NAMRATA K. UBEROI, CONG. RESEARCH SERV., RL32237, HEALTH INSURANCE: A PRIMER 7-8 (Jan. 8, 2015) (discussing the regulation of private health insurance, including tax provisions to expand health insurance coverage); Mary V. Muse, *Regulations, Standards and Policies*, NATIONAL COMM'N ON CORRECTIONAL HEALTH CARE, <https://perma.cc/PG9R-5MW3> (last visited Sept. 13, 2015) (describing the mix of state, federal, and private regulations that apply to correctional health systems).

²⁶³ Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 *et seq.* (2012) (authorizing the United States to enforce the rights of incarcerated individuals).

²⁶⁴ *Estelle v. Gamble*, 429 U.S. 97, 104 (1976).

²⁶⁵ 28 U.S.C. § 1498(a) (2012) (emphasis added).

²⁶⁶ *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976) ("'[A]uthorization or consent' on the part of the Government may be given in many ways other than by letter or other direct form of communication" [sic]—e.g., by contracting officer instructions, by specifications or drawings which impliedly sanction and necessitate infringement, by post hoc intervention of the Government in pending infringement litigation against individual contractors.").

infringe patents on its behalf²⁶⁷ and where the government learns, after the fact, that its demands of third parties have necessitated infringement (for example, where a contractor must infringe a patent to fulfill the terms of its contract with the government, but the government is not aware of this issue until after the infringement has occurred).²⁶⁸ As we will describe below, consent also may be found if entities are infringing to fulfill obligations under federal law.²⁶⁹ This approach makes sense: as the Federal Circuit has explained, “The coverage of § 1498 should be broad so as not to limit the Government’s freedom in procurement by considerations of private patent infringement.”²⁷⁰

With respect to the first requirement, in cases where the infringing party has shown that they are acting pursuant to a contract with the federal government, courts typically assume use “for” the government without further inquiry.²⁷¹ The harder cases arise when no contract exists. In such instances, courts have interpreted use “for” the government to mean that the infringement must benefit the government in some non-incidental way.²⁷² But the line between sufficient and insufficient government benefit is not entirely defined.²⁷³ The

²⁶⁷ See, e.g., *Sevenson Env’tl Servs., Inc. v. Shaw Env’tl, Inc.*, 477 F.3d 1361, 1366-67 (Fed. Cir. 2007) (finding that the contract included an express authorization clause).

²⁶⁸ See, e.g., *TVI Energy Corp. v. Blane*, 806 F.2d 1057, 1060 (1986) (finding that government bidding requirements can imply authorization to infringe).

²⁶⁹ See, e.g., *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014) (“In this case, the government has clearly provided its authorization or consent because—as the parties and the United States agree—JAL cannot comply with its legal obligations without engaging in the allegedly infringing activities.”); cf. *Larson v. United States*, 26 Cl. Ct. 365, 371 (1992) (“[B]ecause there is no orthotic procedure recognized by Medicare as ‘necessary’ that requires the use of plaintiffs’ patents, the Medicare Act provides no basis to find implied consent to any provider’s alleged infringement.”).

²⁷⁰ *TVI Energy Corp.*, 806 F.2d at 1060.

²⁷¹ *Sevenson Env’tl Servs., Inc.*, 477 F.3d at 1366 (“[W]here infringing activity has been performed by a government contractor pursuant to a government contract and for the benefit of the government, courts have all but bypassed a separate inquiry into whether infringing activity was performed ‘for the Government.’”).

²⁷² *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1378 (Fed. Cir. 2009); see also *Sheridan v. United States*, 120 Fed. Cl. 127, 131 (2015) (“Where benefits to the Government are merely an incidental effect of private conduct, they do not constitute ‘use or manufacture for the Government’ within the meaning of § 1498.” (quoting *Advanced Software*, 583 F.3d at 1379)). Use “for” the government can be present even where the “primary” beneficiary is a private party. See *Advanced Software*, 583 F.3d at 1378 (finding government use, despite the fact that the primary benefits accrued to private banks, because the use also served national interests such as the interest in “averting fraud in Treasury checks”).

²⁷³ For example, in *Larson v. United States*, the Court of Claims (the predecessor court of the Federal Circuit) held that the tangential monetary benefit that

Federal Circuit tends to align itself with the government's position, whether the government argues that it benefits from infringing conduct or not.²⁷⁴

Applying these two conditions to our fragmented healthcare system will raise novel fact patterns that courts have yet to consider, especially where the federal government does not have any direct role in drug procurement. But the federal government's role as insurer of last resort, coupled with its responsibility for enforcing many statutory and constitutional obligations that affect state and even private actors, creates a plausible case that § 1498 can apply to providing generic drugs, including HCV treatments, across the healthcare system.

Starting with the simplest case, for programs the federal government controls directly, such as the Veterans Health Administration, the federal use requirement is easily

accrued to the government when Medicare reimbursed providers for cheaper, infringing splints was inadequate, on its own, to constitute use "for the Government." *Larson*, 26 Cl. Ct. at 369 ("Medical care is provided for the benefit of the patient, not the government. . . . The fact that the government has an interest in the program generally, or funds or reimburses all or part of its costs, is too remote to make the government the program's beneficiary for the purposes underlying § 1498." (citations omitted)). In contrast, in *IRIS Corp. v. Japan Airlines Corp.*, the Federal Circuit found that the government benefitted from a Japanese airline's scanning of electronic passports made according to a patented process, finding that the infringing conduct "directly enhance[d] border security and improve[d] the government's ability to monitor the flow of people into and out of the country." 769 F.3d 1359, 1362 (Fed. Cir. 2014). The government did not expressly authorize the infringing conduct in either case; however, in *IRIS*, the Federal Circuit found such authorization was implied.

²⁷⁴ Compare *id.* at 1363 ("We also note that the United States has unequivocally stated its position that suit under § 1498(a) is appropriate here. . . . Although the government's statement is not dispositive, it reinforces our conclusion that the United States has waived sovereign immunity in this case and, therefore, that IRIS's exclusive remedy is suit for recovery against the United States under § 1498(a)."), and *Advanced Software*, 583 F.3d at 1376 ("The communications from the United States to the Federal Reserve Banks, reinforced by the request by the United States to intervene in the district court and its representations to this court that the accused activities are 'for the United States' and with its authorization or consent, established the applicability of § 1498(a)."), with *Larson v. United States*, 26 Cl. Ct. 365 (1992) (the United States successfully opposed the plaintiff's attempt to hold it liable for the infringement of patents by healthcare providers reimbursed by Medicare and other public insurance programs). This deferential approach appears to track how federal courts approach the "public use" requirement in eminent domain proceedings. As Thomas Merrill has observed, "courts have become increasingly uncomfortable in defining the correct or 'natural' ends of government. Not surprisingly, therefore, courts have adopted a hands-off posture regarding questions of public use." Merrill, *supra* note 166, at 64. The courts' approach to the public use requirement in eminent domain cases is informative due to the similarities between § 1498 and eminent domain.

met.²⁷⁵ If the government directed its contractors to procure generic HCV medicines and agreed to assume liability on their behalf, it would satisfy the government benefit requirement.²⁷⁶ These contractors would also have little difficulty demonstrating that their procurement of generic HCV treatments benefits the federal government, should a court inquire further. As we discussed in Part II, public programs have struggled to afford treatment for just a fraction of HCV-infected enrollees.²⁷⁷ While the Veterans Health Administration removed its access restrictions following public and Congressional criticism,²⁷⁸ the Indian Health Service does not even offer the new HCV treatments on its formulary.²⁷⁹ Procurement of generic HCV drugs would enable these programs to make treatment available to all enrollees at significantly lower cost. The monetary savings that would result from generic use would not be “incidental” to private interests, but rather the antecedent to achievement of the central goals of these federal programs.

Although the application of § 1498 to the Medicare and Medicaid programs is slightly more complex, the outcome should be the same. Under Medicaid, the federal government enters into agreements with drug manufacturers to set the terms of their participation in the program,²⁸⁰ but an array of state (rather than federal) contractors are responsible for procuring and distributing covered drugs.²⁸¹ For Medicare, the federal government contracts with private health insurance

²⁷⁵ See *supra* note 260 and accompanying text (describing how certain federal agencies purchase drugs directly from manufacturers). Procurement agents are required to review bids without regard to patent status, see *supra* note 138, and Federal Acquisition Regulations (FAR) establish standardized procedures and language for granting authorization and consent to use or manufacture a patented invention in federal contracts. See FAR 27.201-2 & 52.227-1 (2013).

²⁷⁶ The Federal Circuit has observed that government benefit can be assumed when the infringer is a government contractor acting pursuant to its contract or where the infringement is related to “a ‘governmental function’ that the government had sought or required the [infringer] to carry out.” *Sevenson Env'tl Servs., Inc. v. Shaw Env'tl, Inc.*, 477 F.3d 1361, 1366 (Fed. Cir. 2007); see also JACOBSON, *supra* note 260, at 8-11 (describing how the federal government contracts with drug manufacturers and other businesses to facilitate the ordering, payment, and physical shipment of drugs).

²⁷⁷ See *supra* Part II.B.

²⁷⁸ Patricia Kime, *VA Expands Hepatitis C treatment to All Patients with the Virus*, MILITARY TIMES, Mar. 10, 2016, <https://perma.cc/8RFQ-SA3J>.

²⁷⁹ See IHS NATIONAL PHARMACY & THERAPEUTICS COMMITTEE, NATIONAL CORE FORMULARY (May 25, 2015), available at <https://perma.cc/C8R4-PCND>.

²⁸⁰ See 42 U.S.C. § 1396r-8(a)(1) (2012).

²⁸¹ For a general overview of how prescription drug coverage is provided in Medicaid, see DEP'T OF HEALTH & HUMAN SERVS., OFF. OF INSPECTOR GEN., OEI-03-11-00480, COLLECTION OF REBATES FOR DRUGS PAID THROUGH MEDICAID MCOS 1-5 (Sept. 2012), available at <https://perma.cc/X6XW-UTK6>.

plans to provide drug coverage, rather than directly dealing with the drug manufacturers or distributors.²⁸² Thus, to the extent that entities involved in Medicaid and Medicare drug procurement do not contract with the federal government directly, the federal government could issue letters consenting to infringement and assuming liability for any subsequent claims related to the provision of generic HCV medicines.²⁸³ It could then make a similar argument for governmental benefit here as it would for direct federal purchasers: the federal government pays the majority of drug costs for both Medicare and Medicaid,²⁸⁴ and therefore stands to save substantially from the switch to generic HCV treatment. Such a change would also substantially increase access to treatment.

Private health insurance coverage and state-run healthcare programs represent more novel circumstances and

²⁸² For the same with respect to Medicare, see U.S. GOV'T ACCOUNTABILITY OFF., GAO-09-819T, OVERVIEW OF APPROACHES TO CONTROL PRESCRIPTION DRUG SPENDING IN FEDERAL PROGRAMS 7-8 (2009), *available at* <https://perma.cc/P5ZW-N69F>.

²⁸³ Section 1498 is clear that the government need not have a direct contractual relationship with a third-party to shield it from liability, so long as that party is acting with the consent and on behalf of the government. 28 U.S.C. § 1498(a) (2012) (“For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States” (emphasis added)); *see also* *Sheridan v. United States*, 120 Fed. Cl. 127, 130-32 (2015) *aff’d*, No. 2015-5073, 2015 WL 5845301 (Fed. Cir. 2015) (“While neither a contractual nor an agency relationship is necessary for the Government to accept infringement liability for actions of private parties, Plaintiff must demonstrate that the ‘activities by ‘any person, firm, or corporation’ [are] for the benefit of the government.’” (quoting *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1378-79 (Fed. Cir. 2009))). The courts have recognized that in such scenarios, “‘authorization or consent’ on the part of the Government may be given in many ways other than by letter or other direct form of communication[]—e.g., by contracting officer instructions, by specifications or drawings which impliedly sanction and necessitate infringement, by post hoc intervention of the Government in pending infringement litigation against individual contractors.” *Hughes Aircraft Co. v. United States*, 534 F.2d 889, 901 (Ct. Cl. 1976) (internal citation omitted); *see also* *Advanced Software*, 583 F.3d at 1377-78 (finding authorization and consent from correspondence from a government agency to the infringer and from statements of the government acting as *amicus curiae*).

²⁸⁴ *See* Henry J. Kaiser Family Found., *The Medicare Part D Prescription Drug Benefit Fact Sheet* (Oct. 13, 2015), <https://perma.cc/B8TZ-DEH2> (“Financing for Part D comes from general [federal] revenues (73%), beneficiary premiums (14%), and state contributions (13%)”); HENRY J. KAISER FAMILY FOUND., MEDICAID FINANCING: AN OVERVIEW OF THE FEDERAL MEDICAID MATCHING RATE (FMAP) 1-5 (Sept. 2012), *available at* <https://perma.cc/94NJ-JZQH> (describing the federal government’s contribution to the cost of Medicaid services across states and eligibility groups).

could push the boundaries of the “government use” test. Whereas federal officials have broad implementation authority over Medicare, Medicaid, and direct federal purchasing programs, the federal government’s involvement with private and state insurers is more circumscribed.²⁸⁵ Section 1498 does not overtly limit who may give the government’s consent to assume liability or under what circumstances such consent can be given. Can any government official commit the government to assuming liability for a private or state party’s patent infringement so long as that official makes a plausible argument that the federal government would benefit in some way? Presumably some limits exist, but the existing case law—focused primarily on infringement by parties operating under contracts or grants that were presumably congressionally authorized—does not clearly define these limits.

It does however show that consent may be established via federal legal mandates. In *IRIS Corp. v. Japan Airlines Corp.*, for example, IRIS sued JAL for examining electronic passports that were made with a method claimed in a patent owned by IRIS. The court found that JAL was shielded by § 1498 even though the government had no contract or other formal relationship with the infringing airline.²⁸⁶ It found that consent was present because the airline could not “comply with its legal obligations [to examine passengers’ passports] without engaging in the allegedly infringing activities.”²⁸⁷

The logic here is extremely expansive, and for example could lead to a finding of consent to infringe for state correctional facilities that purchase generic HCV medications to fulfill their constitutional obligation to provide healthcare. Researchers estimate that one in every six inmates is infected and that nearly one-third of HCV-positive Americans cycle through prison or jail each year.²⁸⁸ But few HCV-infected prisoners are receiving treatment due to the high drug

²⁸⁵ For example, the McCarran-Ferguson Act establishes the presumption that the “business of insurance” is to be regulated at the state-level unless Congress explicitly authorizes federal action. 15 U.S.C. § 1012 (2012).

²⁸⁶ 769 F.3d 1359 (Fed. Cir. 2014). The plaintiff’s theory was that the examination of the passports involved an infringing “use” of a product made by a patented process, under 35 U.S.C. § 271(g).

²⁸⁷ *Id.* at 1362. A similar comparison may be drawn with *Advanced Software*. Here, even though it was not a party to any of the relevant contracts, the U.S. Treasury was intimately involved in the banks’ processes for validating checks, including printing checks with encoded seals that required use of the patented technology to decode. *Advanced Software Design Corp. v. Fed. Reserve Bank of St. Louis*, 583 F.3d 1371, 1373-74 (Fed. Cir. 2009).

²⁸⁸ Josiah D. Rich et al., *Responding to Hepatitis C through the Criminal Justice System*, 370 NEW ENG. J. MED. 1871, 1872 (2014).

prices.²⁸⁹ To address this issue, inmates who have been denied HCV treatment in three different state prison systems have filed suit in federal court, alleging that the states are violating the Eighth Amendment in their deliberate indifference towards inmates' medical needs.²⁹⁰ State officials might in turn argue that their constitutional obligations to provide HCV treatment—coupled with the practical reality of limited state budgets—establish consent to infringe.²⁹¹ Alternatively, the U.S. Department of Justice (DOJ) could step in to issue express consent. Federal law authorizes DOJ to bring its own lawsuit

²⁸⁹ State prisons are typically unable to secure significant discounts on prescription drugs. See Am. Ass'n for the Study of Liver Diseases & Infectious Diseases Soc. of Am., *supra* note 101. At sofosbuvir's \$84,000 sticker price, state prisons collectively would need to pay Gilead \$33 billion to treat all HCV-infected inmates. This amount is four times greater than what state prisons currently pay in total for healthcare. Anna Maria Barry-Jester, *Eliminating Hepatitis C Means Treating Prisoners*, FIFTYTHREE (Aug. 31, 2015), <https://perma.cc/CL94-3PST>. Because of the high cost of treatment relative to their healthcare budgets, most states have been forced to greatly restrict access to treatment. Peter Loftus, *New Hepatitis Drugs Vex Prisons*, WALL ST. J. (Apr. 24, 2014, 5:23 PM), <https://perma.cc/G9SV-VHQL>; see also Beth Schwartzappel, *Why Some Prisons are Spending Millions on a Pricey New Drug*, THE MARSHALL PROJECT (Feb. 22, 2015), <https://perma.cc/8DKV-N5E8> (highlighting California and New York's recent increases in spending on HCV treatments for prisoners, while noting that the majority of state prisons continue to limit treatment access).

²⁹⁰ *Chimenti v. Pennsylvania Dep't of Corr.*, No. CV 15-3333, 2016 WL 1125580 (E.D. Pa. Mar. 21, 2016); *Paszko v. O'Brien*, No. 1:15-cv-12298-NMG (D. Mass. filed June 10, 2015); *Ligons v. Minn. Dep't of Correction*, No. 0:15-cv-02210-PJS-BRT (D. Minn. filed May 1, 2015). Individual actions have also been brought in at least three other instances: *Abu-Jamal v. Kerestes*, No. 3:15-cv-00967-RDM-KM (M.D. Penn. 2015); *Harvey v. Neb. Dep't of Correctional Services*, No. 8:15-cv-00102-RJK-PRSE (D. Neb. Filed Mar. 20, 2015); *Harrell v. Cal. Forensic Med. Group, Inc.*, No. 2:15-cv-00579-KJN (E.D. Cal. filed Mar. 21, 2015).

²⁹¹ The ability of a state prison to bring an implied consent claim will, however, depend on FDA-approval of a generic option which the state could then procure. In addition, we caution that in *Carrier Corp. v. United States*, the Court of Federal Claims declined to find that the government had authorized infringement by a contractor in the absence of express written authorization when non-infringing equipment was generally available and could have been used to perform the work required. 534 F.2d 244, 247-49 (Ct. Cl. 1976). The success of an implied authorization argument in the situation we propose may turn on whether a court is convinced by a state prison that brand-name HCV treatments are practically unavailable at the scale required under the Constitution in light of real budget restraints. We recognize that this line of argument may be subject to abuse. If accepted here, could a factory argue that it should be shielded from liability if it infringed a patent to comply with an environmental statute if paying royalties to use the required technologies would have put it out of business? But we believe the state prison system should be distinguishable. First, state prison obligations are absolute and unavoidable: unlike a private company, a state cannot close all of its prisons or choose to pay fines in lieu of compliance. State prisons also do not control their own budgets, and often operate under block grants from state legislatures.

against state prisons to enforce the constitutional rights of inmates,²⁹² and to file statements of interest in existing litigation.²⁹³ DOJ could give state prisons explicit authorization to procure and distribute generic HCV treatments as part of a settlement agreement or in a statement of interest.

When consent is created by an existing legal obligation, the presence of that legal obligation itself may also be enough to establish the second “government use” requirement: governmental benefit. In *IRIS*, for example, the court found that the requirement that the airline check passports enhanced border security by detecting fraudulent passports, while reducing reliance on government resources.²⁹⁴ The court went on to observe that “[w]hen the government requires private parties to perform quasi-governmental functions, such as this one, there can be no question that those actions are undertaken ‘for the benefit of the government.’”²⁹⁵ By that logic, enabling a state to fulfill its constitutional obligations to provide adequate medical treatment to prisoners should certainly be seen as producing a governmental benefit.

It is possible that federal officials could leverage other constitutional or statutory authorities to justify granting either express or implied consent to private insurers as well. If private insurers are not seen as performing “quasi-governmental functions,” however, the government would still need to independently demonstrate to a court that any infringement is for its benefit. The arguments supporting governmental benefit from infringement by private insurers may be more tenuous than those discussed for the federal healthcare and insurance programs. Nonetheless, they still

²⁹² 42 U.S.C. § 1997(a) (2012) (permitting the U.S. Attorney General to bring a civil action against a State or local government that, pursuant to a pattern or practice, is subjecting incarcerated individuals “to egregious or flagrant conditions which deprive such persons of any rights, privileges, or immunities secured or protected by the Constitution or laws of the United States causing such persons to suffer grievous harm”).

²⁹³ See 28 U.S.C. § 517 (2012) (“The Solicitor General, or any officer of the Department of Justice, may be sent by the Attorney General to any State or district in the United States to attend to the interests of the United States in a suit pending in a court of the United States, or in a court of a State, or to attend to any other interest of the United States.”). For example, in 2015 the Department of Justice filed a statement of interest in a case against the Georgia Department of Corrections for failure to provide a transgender prisoner with adequate care for her gender dysphoria. In its statement, DOJ took the position that the “Eighth Amendment mandates individualized assessment and care for gender dysphoria.” Press Release, Off. of Pub. Aff., Dep’t of Just., Justice Department Files Brief to Address Health Care for Prisoners Suffering from Gender Dysphoria (Apr. 3, 2015), *available at* <https://perma.cc/PDW7-GVVH>.

²⁹⁴ *IRIS Corp. v. Japan Airlines Corp.*, 769 F.3d 1359, 1362 (Fed. Cir. 2014).

²⁹⁵ *Id.*

merit. The federal government's financial stake in private spending is indirect—primarily composed of tax-funded subsidies to certain types of private insurance²⁹⁶—so a court might dismiss any financial savings that pass through to the federal government as incidental. However, the federal government clearly has a long-term financial interest in reducing the number of future Medicare and Medicaid beneficiaries that have HCV. Because the full effects of HCV can take decades to manifest, many patients insured in the private sector will end up on public insurance (*i.e.*, Medicare). The government will be left with the bill for treatment of not only HCV, but any secondary health problems that resulted from delayed HCV treatment as well.²⁹⁷ Use of § 1498 in select circumstances would also advance the federal government's interest in safeguarding the health of its population and reducing the spread of infectious disease, much as the use of electronic passports in *IRIS* supported the federal government's interest in border security.²⁹⁸ If private and state insurers could procure generic HCV treatments, elimination of HCV in the United States could become a real possibility.²⁹⁹

B. Facilitating FDA Approval and Registration

To be sold in or imported into the United States legally, all medicines, including generic medicines, must be approved by the FDA. The FDA has the discretion, in some instances, to permit importation of unapproved medicines.³⁰⁰ But purchasers

²⁹⁶ See, e.g., *Options for Reducing the Deficit: 2014-2023: Reduce Tax Preferences for Employment-Based Health Insurance*, CONG. BUDGET OFF. (Nov. 13, 2013), <https://perma.cc/SE6H-33PW> (describing how the “federal tax system subsidize[s] employment-based health insurance”).

²⁹⁷ This argument would also be even stronger with respect to state prisons as a recent study estimated that wide-scale screening and treatment in prison settings could provide substantial health and economic benefits to the general population over a thirty-year period. See Tianhua He et al., *Responding to Hepatitis C through the Criminal Justice System*, 164 ANNALS OF INTERNAL MED. 84, 85 (2016).

²⁹⁸ *IRIS Corp.*, 769 F.3d at 1362.

²⁹⁹ See *supra* note 8 and accompanying text. Cf. Ctr. For Disease Control and Prevention, *HIV/AIDS: Prevention Benefits of HIV Treatment* (Feb. 9, 2016), <https://perma.cc/7WDB-S8HJ>.

³⁰⁰ For example, the FDA relies on this discretion to permit individuals to import a limited supply of medicines for personal use. See 9-2 – *Coverage of Personal Importations*, U.S. FOOD & DRUG ADMIN., <https://perma.cc/L8CT-KXMZ> (last visited May 23, 2016). In the late 1980s, AIDS advocacy organizations pointed to this policy to import cheaper, but unapproved versions of a drug called pentamidine. See Gina Kolata, *Group Plans to Import an AIDS Drug*, N.Y. TIMES, Sept. 25, 1989, <https://perma.cc/R59S-DHAZ>. The drug was protected by orphan drug exclusivity and priced out of reach of many AIDS patients in the United States. *Id.* A recent D.C. Circuit decision related to the importation of unapproved lethal injection drugs identifies certain limits on

undoubtedly prefer to purchase FDA-approved drugs and may be required to do so by agency or company rules. Successful invocation of government patent use thus implicates a second novel legal issue: What are the mechanisms through which the FDA can approve generic medicines intended for use under § 1498?³⁰¹

For non-biological drugs, the FDCA establishes three principal pathways to drug approval.³⁰² First, any drug manufacturer may file a New Drug Application (NDA) to obtain FDA permission to market its medicine.³⁰³ This route is normally used for active ingredients or formulations never before approved in the United States and requires companies to prove to the agency that their drugs are both safe and efficacious. Manufacturers must submit full reports of the investigations they have undertaken to assess the safety and efficacy of their drugs.³⁰⁴ The FDA may reject any NDA that fails to present “substantial evidence that the drug will have the effect it purports or is represented to have.”³⁰⁵ The FDCA defines such “substantial evidence” as “evidence consisting of adequate and well-controlled investigations, including clinical investigations.”³⁰⁶ The FDCA further specifies that the FDA may approve a NDA on the basis of “data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation)”³⁰⁷ if the FDA is satisfied that this trial proves efficacy.

However, generic drug companies usually take advantage of a shortened, second approval pathway known as the Abbreviated New Drug Application (ANDA). Formalized as part of the Hatch-Waxman Act of 1984, this approval pathway permits generic manufacturers to rely on the safety and efficacy data of the original NDA applicant (the “reference product”) to obtain FDA approval, rather than produce their own such studies.³⁰⁸ ANDA applicants must only show that

the FDA’s enforcement discretion, but precisely how the FDA understands these limits is not yet clear. *See* *Cook v. Food & Drug Admin.*, 733 F.3d 1 (D.C. Cir. 2013).

³⁰¹ As discussed above, existing evidence of the use of § 1498 to procure generic medicines pre-dated modern FDA regulatory law. It appears as though the emergence of drug data exclusivity laws disrupted what was once settled practice. *See supra* Part III.B.

³⁰² 21 U.S.C. § 355(b)(1), (b)(2), & (j) (2012).

³⁰³ *Id.* § 355(b)(1).

³⁰⁴ *Id.* § 355(b)(1)(A).

³⁰⁵ *Id.* § 355(d)(5).

³⁰⁶ *Id.* § 355(d).

³⁰⁷ *Id.*

³⁰⁸ *Id.* § 355(j)(2)(A)(i).

their products are chemically equivalent and bioequivalent to their reference products.³⁰⁹

To achieve registration under this pathway while the reference product is still under patent protection,³¹⁰ a generic company must certify that its product either does not infringe the reference product's patents or that those patents are invalid.³¹¹ If a generic manufacturer submits such a certification, the patent holder may challenge it through what is known as a "Paragraph IV challenge." The Paragraph IV challenge effects a thirty-month stay of the generic company's ANDA application pending resolution of the dispute.³¹²

Importantly, ANDA applicants are also forbidden from relying on a reference product's safety and efficacy data for five years after the reference product's NDA approval, a period often called the "data exclusivity" period.³¹³ The term lasts five years, but generic manufacturers may submit an ANDA after only four years if they submit the requisite patent non-infringement or invalidity certifications described above.³¹⁴

If the government seeks to provide, under § 1498, a slight variation on an existing, effective medication, a third approval route is available: a 505(b)(2) application.³¹⁵ This pathway is appropriate for a new dosage form of a previously-approved drug (e.g., solid oral dosage to transdermal patch).³¹⁶ Like ANDAs, 505(b)(2) applications permit manufacturers to rely on the studies that other NDA applicants have conducted to obtain FDA approval.³¹⁷ 505(b)(2) applicants can also rely on published literature to support their applications.³¹⁸ This approval pathway cannot, however, be used for drugs that are duplicates of existing, listed drugs.³¹⁹ It is also subject to the same data exclusivity provisions as ANDA applications.³²⁰

³⁰⁹ *Id.* § 355(j)(2)(A)(ii)-(v).

³¹⁰ The patents the brand-name drug relies on must be listed in the FDA's Orange Book. *See Orange Book Preface*, FOOD AND DRUG ADMIN., *available at* <https://perma.cc/6EYV-UFJV> (last visited June 12, 2016).

³¹¹ 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

³¹² *Id.* § 355(j)(5)(B)(iii).

³¹³ *Id.* § 355(j)(5)(F)(ii)

³¹⁴ *Id.*

³¹⁵ *Id.* § 355(b)(2); *see* FOOD AND DRUG ADMIN., GUIDANCE FOR INDUSTRY: APPLICATIONS COVERED BY SECTION 505(B)(2) 4 (1999), *available at* <https://perma.cc/X3NQ-N4XS>.

³¹⁶ APPLICATIONS COVERED BY SECTION 505(B)(2), *supra* note 315, at 4

³¹⁷ 21 U.S.C. § 355(b)(2) (2012).

³¹⁸ *See* 21 C.F.R. 314.54; APPLICATIONS COVERED BY SECTION 505(B)(2), *supra* note 315, at 2.

³¹⁹ *See* APPLICATIONS COVERED BY SECTION 505(B)(2), *supra* note 315, at 6.

³²⁰ *See Small Business Assistance: Frequently Asked Questions for New Drug Product Exclusivity*, FOOD AND DRUG ADMIN., <https://perma.cc/EWP5-SV63> (last visited June 12, 2016).

In the § 1498 context, the appropriate route for approval of the relevant medicines will vary depending on the circumstances. If the generic drug the government seeks to use is an exact copy of a registered medicine, and the five-year data exclusivity period has lapsed, a generic drug manufacturer can simply use the ANDA process. The generic firm will be able to certify under Paragraph IV that its product is non-infringing because the medicine is intended only for government use pursuant to § 1498. Under the plain text of § 1498, any use of a patent “by or for” the federal government only has one available remedy: an action in the Court of Federal Claims for reasonable compensation.³²¹ The Federal Circuit has repeatedly affirmed that courts may not issue injunctions that have the effect of preventing a private entity from supplying the government under § 1498, even in cases where the government is not a party.³²² Thus, a generic drug company should be able to prevail quickly in any Paragraph IV challenge and register its drug under an ANDA solely for supply under § 1498. Similarly, if the government seeks to use a drug that is a slight variation of a registered medicine, and data exclusivity does not apply, the 505(b)(2) application will be the appropriate route. Under this route, the generic drug company would submit the same Paragraph IV certification of non-infringement.

Nevertheless, during the data exclusivity period, the only route for registration of either a generic drug or a slightly modified form of an approved drug would appear to be through the NDA pathway. This route is usually significantly more expensive than the alternatives, and the applicant drug company and FDA would have to be attentive to ethical

³²¹ 28 U.S.C. § 1498(a) (2012).

³²² See, e.g., *Trojan, Inc. v. Shat-R-Shield, Inc.*, 885 F.2d 854, 856 (Fed. Cir. 1989) (“Section 1498(a) would be emasculated if a patent holder could enjoin bidding to supply infringing products. . . . [A] patent owner may not use its patent to cut the government off from sources of supply, either at the bid stage or during performance of a government contract.”); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1283 (Fed. Cir. 1988) (holding that § 1498 “automatically” protects the government and its suppliers from interference via injunctions. Also stating that “[t]he patentee takes his patent from the United States subject to the government’s eminent domain rights to obtain what it needs from manufacturers and to use the same. The government has graciously consented, in the same statute, to be sued in the Claims Court for reasonable and entire compensation, for what would be infringement if by a private person. The same principles apply to injunctions which are nothing more than the giving of the aid of the courts to the enforcement of the patentee’s right to exclude.”); see also *Zoltek Corp. v. United States*, 672 F.3d 1309, 1318 (Fed. Cir. 2012) (“[T]he right to use is a comprehensive term and embraces within its meaning the right to put into service any given invention.” (quoting *Bauer & Cie v. O’Donnell*, 229 U.S. 1, 10 (1913)); *Lipson*, *supra* note 179, at 249.

problems associated with replicating studies with known results.³²³ Nonetheless, the FDA has displayed flexibility with respect to what investigations it considers sufficient to meet NDA requirements, “broadly interpreting the statutory requirements to the extent possible where the data on a particular drug were convincing.”³²⁴ For example, the FDA sometimes approves NDAs on the basis of a single adequate and well-controlled efficacy study³²⁵ and has, in some instances, not required that trials be randomized.³²⁶ The FDA has also approved well-known but previously unapproved drugs, such as colchicine, on the basis of data from public studies accompanied by limited clinical safety information.³²⁷ Similarly, if a generic firm sought to register equivalent forms of the new HCV drugs under an NDA, the FDA would have the discretion to determine that appropriate studies would be of shorter duration and smaller size because the drugs’ side effects and efficacy are already well characterized, including in the published literature. The FDA could also opt to accept trials

³²³ Because of these ethical concerns, and the expense, full NDAs have long been considered an impractical means of avoiding the consequences of data exclusivity. But this may be case specific, and depend on the degree of evidence the FDA is willing to accept.

³²⁴ FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS FOR HUMAN DRUG AND BIOLOGICAL PRODUCTS 3 (1998), available at <https://perma.cc/TE5T-JY4F>; see also 21 C.F.R. § 314.105(c) (“[The] FDA is required to exercise its scientific judgment to determine the kind and quantity of data and information an applicant is required to provide for a particular drug to meet the statutory standards.”).

³²⁵ See Nicholas S. Downing et al., *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012*, 311 J. AM. MED. ASS’N 368, 371 (2014) (finding that 37% of approvals were based on a single trial); PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS, *supra* note 324, at 3 (such single studies are, generally, only accepted “in cases in which a single multicenter study of excellent design provided highly reliable and statistically strong evidence of an important clinical benefit, such as an effect on survival, and a confirmatory study would have been difficult to conduct on ethical grounds”).

³²⁶ See Downing et al., *supra* note 325, at 372-73 (FDA “approvals can be made without requiring costly and time-consuming randomized, double-blinded, controlled trials, although these trials are regarded as the gold standard for evaluation”).

³²⁷ Aaron Kesselheim & Daniel Solomon, *Incentives for Drug Development—The Curious Case of Colchicine*, 362 N. ENG. J. MED. 2045, 2046 (2010). Colchicine is a well-known drug, first used by the ancient Greeks to treat gout. For years, this medicine was unapproved but prescribed in the United States. But in 2007, URL Pharma sought FDA approval for its version of the drug through an NDA. On the basis of one randomized, controlled trial involving 185 patients, the FDA approved this medication for the treatment of gout. The FDA also approved this drug for a different indication: to treat familial Mediterranean fever (FMF), a rare genetic disorder that affects 100,000 patients worldwide. The FDA approved the drug for treatment of FMF based on previously collected data along with additional limited safety information from the 185 patient clinical trial. *Id.* at 2045-46.

that demonstrate the generic drug is not inferior to an existing reference product rather than make a full showing of superiority over placebo or existing treatments.³²⁸

In the case of sofosbuvir, Gilead's term of NDA-based data exclusivity has almost run. Generic manufacturers would be able to file Paragraph IV challenges, seeking FDA approval through an ANDA, in December 2017. Harvoni exclusivity does not expire until October 2018.³²⁹ This could make it worthwhile to try the NDA route instead, particularly because there are ongoing trials of DAAs that might be a source of data.³³⁰ The federal government might also explore whether an Executive Order might bolster the case for the exercise of FDA enforcement discretion for supply by validated and high quality suppliers.³³¹

Finally, it worth noting that § 1498 was enacted and used for pharmaceutical products long before the current FDA approval framework was put into place. This regulatory framework could better facilitate government use under § 1498 with explicit amendment. For example, Congress might make an exception to data exclusivity where ANDAs are intended only to supply for government use under § 1498. Congress could also clarify that the FDA has enforcement discretion or other accelerated routes for approval with respect to drugs produced pursuant to § 1498.

VI. FROM THEORY TO PRACTICE: GOVERNMENT USE OF § 1498 TO PROCURE GENERICS

So far, we have provided theoretical and legal arguments for why the federal government can and should invoke § 1498 to facilitate access to generic versions of prescription drugs when brand-name prices result in significant deadweight loss. This Part describes how § 1498 can

³²⁸ A non-inferiority study, simply attempts to show the tested drug is not *inferior* to a known effective treatment. FOOD AND DRUG ADMINISTRATION, GUIDANCE FOR INDUSTRY: NON-INFERIORITY CLINICAL TRIALS 2 (2010), available at <https://perma.cc/5ZXC-CJW3>. Non-inferiority study designs are often used where superiority trial designs would be inappropriate due to ethical concerns. *Id.* at 6. Non-inferiority trial designs may be particularly appropriate in the § 1498 context, where the government is simply attempting to copy a known effective treatment.

³²⁹ See *supra* note 258.

³³⁰ See, e.g., *Reviewing DAA Efficacy Managing Patient Treatment in Online Neighbourhoods (REDEMPTION)*, CLINICALTRIALS.GOV, <https://perma.cc/3Y9C-BNYX> (last visited June 12, 2016).

³³¹ See, e.g., *id.*; see generally Andrew Hill et al., *Minimum Costs for Producing Hepatitis C Direct-Acting Antivirals for Use in Large-Scale treatment Access Programs in Developing Countries*, 58 CLINICAL INFECTIOUS DISEASES 928 (2014).

and should be used to expand access to HCV treatment. Specifically, we identify four possible implementation options of varying scope and complexity. Invoked narrowly, § 1498 could immediately expand access to treatment to hundreds of thousands of individuals with HCV, including some groups most affected by the disease. Invoked broadly, § 1498 could provide universal access to generic drugs and permit elimination of HCV in the United States. The effectiveness of our strategy will turn on the administrative and, potentially, congressional will to cross these barriers.

There are certain steps common to all options of our § 1498 strategy.³³² First, the government should announce legal justification for the action and identify which drug(s) it plans to cover. We recommend that the government choose sofosbuvir/ledipasvir (brand name Harvoni) because, as previously discussed, this drug appears to be the safest, most effective, and widely prescribed treatment currently available. It should then encourage generic companies to register their drugs via the NDA or ANDA routes discussed above, and encourage procurement officers for the various payors described below to contract directly with the companies, with the federal government assuming liability for the royalties owed to Gilead in any ensuing litigation.

A. Option One: Providing Generic Access to Direct Federal Purchasers

Direct federal purchasing programs, including the Veterans Health Administration, Indian Health Service, and Federal Bureau of Prisons, present the most straightforward application of § 1498. The Veterans Health Administration—which regularly handles the procurement and distribution of drugs for itself and other direct federal purchasing programs and which has used the provision in the past³³³—could solicit bids for FDA-approved generic sofosbuvir/ledipasvir and include authorization and consent clauses in its solicitation and contracts with manufacturers.³³⁴ It could also amend its

³³² Efforts to scale up HCV treatment would need to be accompanied by stronger efforts to screen people for the disease. Many people remain unaware of their infection. *See supra* note 70.

³³³ JACOBSON, *supra* note 260, at 8-11 (describing the Veterans Administration's role negotiating drug contracts for itself and other federal agencies through the Federal Supply Schedule and national standardization contracts).

³³⁴ Federal Acquisition Regulations (FAR) provide that when the government expressly authorizes and consents to use or manufacture of a patented invention it may require a contractor to reimburse it for liability for patent infringement. FAR 27.201-1(d). In some contracts, the contracting officer is required to include an indemnity clause, FAR 27.201-2(c); in other cases, the contracting officer may include an indemnity clause "if it is in the

distribution contracts, as needed, to assume liability on behalf of private parties across the supply chain.

The agency should then offer to compensate Gilead according to the methodology discussed in Part IV.A (i.e., offer modest or nominal compensation, such as a royalty on the generic procurement price). If Gilead is dissatisfied with this compensation, it could bring an administrative claim against the applicable federal agency³³⁵ or bring suit against the government in the Court of Federal Claims.³³⁶ Because using direct federal purchasing programs to provide generic HCV medications most closely resembles existing uses of § 1498, it should be legally uncontroversial and can be quickly implemented. (The most time-consuming aspect would likely be the registration of the generic products, as per the discussion above.) Although relatively few people are covered by direct federal purchasing programs compared to the general

Government's interest to do so." FAR 27.201-2(f). Even when an indemnity clause is normally required, however, the relevant agency head can choose to waive indemnity for specific U.S. patents. FAR 27.201-2(e). Thus, to the extent that any relevant contracts for drugs fall within the scope of FAR 27.201-2(c), the relevant agency head should authorize inclusion of a Waiver of Indemnity to protect the contractors from responsibility for damages. See FAR 52.227-5. Cf. *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 91st Cong. 7,587 (1970) (statement of Rear Admiral. H.S. Etter, Med. Corps, U.S. Navy, Chairman, Def. Med. Material Bd.) (noting that the Department of Defense "assumes the full financial responsibility for patent infringement by deleting the indemnity provisions from the solicitation where this would result in a lower overall cost to the Government").

³³⁵ Richard J. McGrath, *The Unauthorized Use of Patents by the United States Government or its Contractors*, 18 AIPLA Q. J. 349, 355-56 (1991) (providing an in-depth discussion of administrative claims for compensation, which must be filed with the agency and include: "(1) an allegation of infringement; (2) a request for compensation, either expressed or implied; (3) a citation of the patent or patents alleged to be infringed; (4) a sufficient designation of the allegedly infringing item; and (5) a designation of at least one claim of each patent alleged to be infringed" (citing 48 C.F.R. § 227.7004)).

³³⁶ 28 U.S.C. § 1498; see McGrath, *supra* note 335, at 357; Matthew J. Brophy, *It's Better to Ask for Forgiveness Than Permission: How Patent Infringers Can Invoke the Government Contractor Defense Post Hoc*, 40 AIPLA Q.J. 135, 142-43 (2012). The forum in which infringement claims are filed determines which part of the government bears the cost of infringement. "If an administrative claim for patent infringement relates to an ongoing contract for procurement of an infringing item, the agency must pay the administrative claim out of the agency's current funds." McGrath, *supra* note 335, at 356 (citing 48 C.F.R. § 227.7006(i)) (emphasis added). In contrast, patent infringement claims brought in the Claims Court would be paid out of the Department of Treasury's general Judgment Fund. See *id.* at 362 (describing the judgment fund); see also 31 U.S.C. § 1304 (2012) (explaining judgment fund payments and regulations).

population,³³⁷ many of these programs serve populations that face disproportionately high rates of HCV, including veterans, American Indians/Alaskan Natives, and federal prisoners.³³⁸ While reliable data on the number of people with HCV by payor is limited, and many of the numbers that do exist are widely accepted to be underestimates,³³⁹ these three programs alone could currently treat at least 350,000 people if the federal government invoked § 1498 for their benefit.³⁴⁰

³³⁷ Jessica C. Smith & Carla Medalia, *Health Insurance Coverage in the United States: 2014*, U.S. CENSUS BUREAU 5 tbl.5 (2015), available at <https://perma.cc/2P94-AHGA>.

³³⁸ *Epidemiology of Hepatitis C - Viral Hepatitis*, DEP'T OF VETERANS AFF. (Dec. 9, 2013), <https://perma.cc/U43M-HNEW>; Julia D. Rempel & Julia Uhanova, *Hepatitis C Virus in American Indian/Alaskan Native and Aboriginal Peoples of North America*, 4 VIRUSES 3912, 3916 (2012), available at <https://perma.cc/8DNA-2REZ>; Aidan K. Varan et al., *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High but Declining*, 129 PUB. HEALTH REP. 187, 188 (2014), available at <https://perma.cc/T8NW-MA9S>.

³³⁹ See, e.g., Chak et al., *supra* note 7, at 1090.

³⁴⁰ A 2013 report estimated that the number of HCV-positive individuals covered by the VA or other military health programs was 312,000. Kathryn Fitch et al., HEALTH CARE REFORM AND HEPATITIS C: A CONVERGENCE OF RISK AND OPPORTUNITY, MILLIMAN INC. 8 fig.5 (Dec. 10, 2013), available at <https://perma.cc/2J7X-JMJ5>. The BOP likely accounts for more than 35,000 individuals with HCV, given its coverage of nearly 200,000 people, STATISTICS, FED. BUREAU OF PRISONS (Mar. 24, 2016), available at <https://perma.cc/8FG6-VX4R> (identifying 196,144 total federal inmates), and the HCV prevalence rate among prison inmates is estimated to be around 17.4%. *Treatment of Hepatitis C in a Correctional Setting*, HEPATITIS C ONLINE, <https://perma.cc/5Q4C-MAEU> (last visited Mar. 31, 2016). We acknowledge that this is a rough estimate. The December 2015 Senate Finance Committee report on Sovaldi noted that “As of November 5, 2015, the BOP reported that 9,216 of the system’s 198,953 inmates have been diagnosed with HCV.” STAFF OF S. COMM. ON FINANCE, *supra* note 11, at 93. The differences in this number and our estimate is likely due in part to the previously discussed discrepancy between the number of people infected with HCV and the actual number of people *diagnosed* with HCV. Finally, the Indian Health Service (IHS) provides healthcare to approximately 2.2 million American Indians/Alaskan Natives. U.S. DEP'T OF HEALTH & HUMAN SERVS., INDIAN HEALTH SERVS., JUSTIFICATION OF ESTIMATES FOR APPROPRIATIONS COMMITTEES FY2016 at CJ-1 (2015), available at <https://perma.cc/V282-P69V>. While nationwide prevalence rates for this population are unavailable, applying the HCV prevalence rate for the general U.S. population—2%—would account for another 44,000 HCV-positive individuals. See, e.g., Chak, *supra* note 7, at 1097. Of course, a portion of the population has already received treatment. As of 2015, approximately 25,000 veterans, Letter from Carol E. Farer, Veterans Health Administration FOIA Office, to Hannah Brennan, Public Citizen Attorney (Aug. 21, 2015) (on file with authors), and 405 federal prisoners, STAFF OF S. COMM. ON FIN., *supra* note 11, at 93 tbl. 4 (for fiscal years 2014-2015), had received treatment. However, the VA has since expanded access, based upon increased congressional appropriations and additional price discounts. Press Release, VA Expands Hepatitis C Drug Treatment, U.S. Dep't Veterans Aff. (Mar. 9, 2016), available at <https://perma.cc/UAX3-3DQ9>.

B. Option Two: Expanding Generics to Medicare & Medicaid

The federal government would need a different approach to use § 1498 to extend generic HCV treatments to Medicare and Medicaid enrollees than for direct federal purchasing programs. However, we believe it is equally feasible and it would more than double the impact of action.

With respect to Medicaid, the federal government, operating through the Centers for Medicare & Medicaid Services (CMS), first would enter into a rebate agreement with the FDA-approved generic manufacturer. This agreement sets a national floor for the percent of sales that manufacturers must repay to the Medicaid program and is a pre-condition for Medicaid reimbursement of a drug.³⁴¹ In this case, this agreement would also include an express authorization or consent clause. Because of the complex web of third parties subsequently involved in the procurement and distribution of drugs—including state Medicaid agencies, managed care organizations, wholesalers, pharmacy benefit managers, and pharmacies³⁴²—the federal government should issue public statements that explicitly authorize the provision of generic sofosbuvir/ledipasvir to Medicaid beneficiaries and assume liability for the resulting infringement. These statements could take the form of Dear State Medicaid Director Letters and other Informational Bulletins frequently issued by CMS.³⁴³

In contrast to Medicaid, CMS is statutorily prohibited from directly negotiating prices with drug manufacturers for Medicare.³⁴⁴ Instead, Medicare relies on private health plans (known as Part D plans) to both negotiate for and distribute drugs.³⁴⁵ Also unlike Medicaid, where states must cover a drug once it has been approved by the FDA and the manufacturer has negotiated a rebate contract with the federal

³⁴¹ See 42 U.S.C. § 1396r-8(a)(1) (2012).

³⁴² See DEP'T OF HEALTH & HUMAN SERVS., *supra* note 281.

³⁴³ See Centers for Medicare & Medicaid Services, *Federal Policy Guidance*, <https://perma.cc/HD3S-29MW> (last visited Feb. 24, 2016).

³⁴⁴ Medicare Part D's noninterference requirement should not pose a barrier to our proposal. This provision states: "In order to promote competition under this part and in carrying out this part, the Secretary--(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i) (2012). Under our proposal, Part D plans would retain both the choice to cover or not cover generic drugs acquired under the authority of § 1498 and the responsibility for negotiating prices for said drugs with the generic manufacturer.

³⁴⁵ See U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 282.

government,³⁴⁶ Part D plans retain more flexibility over what drugs they choose to cover.³⁴⁷ In light of these complications, CMS should issue letters to FDA-approved generic manufacturers notifying them that it will assume liability for infringement claims related to the provision of generic sofosbuvir/ledipasvir to Medicare beneficiaries. In addition, CMS should amend its Part D plan contracts to include express authorization and consent clauses and issue policy statements encouraging Part D plans to add generic sofosbuvir/ledipasvir to their formularies.

With these authorizations in place, Gilead's sole cause of action would be against the federal government, rather than the private parties involved in manufacturing and distributing the drugs. As under Option One, the government could offer to compensate Gilead according to the methodology discussed in Part IV.A. However, if Gilead is dissatisfied with the compensation award, it could (again) file an administrative claim against CMS or bring suit in the Court of Federal Claims.

Authorizing Medicare and Medicaid to cover generic sofosbuvir/ledipasvir would more than double the health and financial impact of § 1498 over that of Option One.

Combining state estimates of the number of Medicaid enrollees with HCV (698,000)³⁴⁸ with researchers' predictions for the number of (non dual) Medicare beneficiaries with HCV in 2015 (192,790),³⁴⁹ we estimate that at least 890,000 individuals infected with HCV are enrolled in either program. The vast majority of these individuals continue to wait for treatment.³⁵⁰

³⁴⁶ 42 U.S.C. § 1396r-8(k)(2)(A)(i) (2012) (defining "covered outpatient drugs" to include all FDA-approved prescription drugs); 42 U.S.C. § 1396r-8(a)(i) (2012) (requiring manufacturers of covered outpatient drugs to enter into a rebate agreement to receive payment under Medicaid).

³⁴⁷ MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL: CHAPTER 6 – PART D DRUGS AND FORMULARY REQUIREMENTS § 30.2.1 (2010), <https://perma.cc/2J85-J277> ("Formulary Categories and Classes").

³⁴⁸ STAFF OF S. COMM. ON FIN., *supra* note 11, at 82 n. 466 (698,000 is based on data reported by forty-three states and the District of Columbia; it excludes seven states that did not provide estimates to congressional staff).

³⁴⁹ Fitch, *supra* note 340, at 35 tbl. D-1 (assuming status quo treatment rates). This number is likely to grow significantly in the near future given the high HCV prevalence among Baby Boomers. For example, Fitch estimates that the number of (non-dual) Medicare beneficiaries with HCV could increase by anywhere between 92,000 to 209,000 lives from 2013 to 2020, depending on screening and treatment rates. *Id.* at 35-38 tbls. D-1, D-2, D-3, D-4.

³⁵⁰ See *Medicare Part D Hepatitis C Prescribing Data 2014*, PROPUBLICA (Mar. 2015), available at <https://perma.cc/9FRZ-7PAQ> (showing the number of Medicare beneficiaries that received sofosbuvir or sofosbuvir/ledipasvir by month in 2014); STAFF OF S. COMM. ON FIN., *supra* note 11, at 82 (reporting that only 16,281 Medicaid enrollees received sofosbuvir/ledipasvir in 2014).

C. Option Three: Covering State Correctional Facilities

In contrast to the programs described above, the federal government plays no active role in drug purchasing or procurement by state correctional facilities. Yet the Civil Rights of Institutionalized Persons Act (CRIPA) of 1980 gave DOJ power to enforce the rights of individuals incarcerated in state and local correctional facilities.³⁵¹ The federal government can and should rely on this authority to ensure states are providing HCV-positive inmates with the treatment they need.

Specifically, DOJ should commence investigations into existing allegations of Eighth Amendment violations based on the denial of HCV treatments by state correction facilities.³⁵² Assuming the federal government finds “reasonable cause to believe” that inmates are being deprived of their constitutional rights “pursuant to a pattern or practice,” the United States may intervene in one of the existing actions,³⁵³ or, if necessary, bring a new action.³⁵⁴ The United States could then give state officials express authorization to use FDA-approved generic sofosbuvir/ledipasvir to treat inmates with HCV as a part of or in connection with a settlement agreement. The states party to the settlement could then contract directly with a generic manufacturer without fear of liability or the threat of an injunction. More broadly, the Solicitor General or another DOJ official could file a Statement of Interest in one of the existing cases and take the position that the failure to provide treatment to HCV-positive inmates constitutes an Eighth Amendment violation.³⁵⁵ Then, based on the federal government’s interest in ensuring that the conditions of confinement in state correctional facilities comply with the Constitution, DOJ could issue a policy statement authorizing all state prison programs to access generic sofosbuvir/ledipasvir.³⁵⁶

As of December 2014, approximately 1.35 million people were held in state prisons.³⁵⁷ Assuming that number has held steady, with an estimated 17.4% of prisoners infected with

³⁵¹ Civil Rights of Institutionalized Persons Act, 42 U.S.C. § 1997 *et seq.*

³⁵² See 42 U.S.C. § 1997a-1(a) (2012).

³⁵³ 42 U.S.C. § 1997c(a)(1) (2012).

³⁵⁴ 42 U.S.C. § 1997a(a) (2012).

³⁵⁵ 28 U.S.C. § 517 (2012).

³⁵⁶ Alternatively, if the federal government invokes § 1498 for federal programs, but fails to affirmatively authorize generic use by state prisons, a state may procure generic drugs and defend itself against any infringement claims by arguing that consent is implied. See *infra* Part V.A.

³⁵⁷ E. Ann Carson *Prisoners in 2014*, U.S. DEP’T OF JUSTICE 2 tbl.1 (2015), available at <https://perma.cc/G9GB-LYUD>.

HCV,³⁵⁸ more than 235,000 inmates could gain access to treatment when such a policy goes into effect. With approximately 600,000 individuals transitioning in and out of state prisons each year,³⁵⁹ the long-term effect would be significantly greater.

D. Option Four: Reaching the Private Sector and the Uninsured

All three options discussed above involve using § 1498 to benefit individuals who are receiving healthcare sponsored, in some form, by federal or state government. Yet more than half of the U.S. population relies on private health insurance.³⁶⁰ Indeed, private insurance was predicted to cover an estimated 823,000 HCV-positive individuals in 2015, at status quo treatment rates.³⁶¹

We encourage the federal government to explore whether its existing regulatory authority could justify invoking § 1498 on behalf of some or all of private health insurance plans. Even in the absence of such authority, however, this sector need not be left without relief. For instance, Gilead could respond to the federal government's announcement that it plans to invoke § 1498 as Bayer did in 2001,³⁶² pre-emptively lowering its prices to more affordable levels. Unfortunately, it is impossible to predict whether Gilead would offer prices low enough to ensure widespread access to treatment. It is also unclear that Gilead would extend its discounts to sectors of the healthcare system that would not benefit from § 1498 under Options One, Two, and Three. Indeed, the federal government likely will need to make trade-offs between these interests if it pursues voluntary negotiations.

A superior version of this option is for Congress to create a new federal program modeled, in part, on the Ryan White HIV/AIDS Program.³⁶³ This program could be authorized to purchase generic sofosbuvir/ledipasvir and distribute it to individuals who cannot afford or otherwise access brand name drugs. Unlike voluntary negotiations, this surely would face numerous challenges, including strong political opposition from the pharmaceutical industry as well as the usual barriers inherent in the legislative process. But its benefits are two-fold: the government need not accept higher prices to expand access,

³⁵⁸ Varan, *supra* note 338, at 190.

³⁵⁹ Carson, *supra* note 357, at fig. 4.

³⁶⁰ Smith & Medalia, *supra* note 337, at 5.

³⁶¹ Fitch, *supra* note 340, at 35 tbl. D-1.

³⁶² See *supra* Part III.B, note 136 and accompanying text.

³⁶³ See HEALTH RESOURCES & SERVS. ADMIN., *About the Ryan White HIV/AIDS Program*, <https://perma.cc/M9UV-82WK> (last visited Sept. 13, 2015).

as it presumably would in a voluntary negotiation scenario, and uninsured HCV-positive individuals could receive treatment. While the Affordable Care Act has significantly reduced the number of uninsured by expanding access to Medicaid and private health insurance, more than 550,000 HCV-positive people were expected to still be uninsured in 2015.³⁶⁴ Thus, it is the only option that could ensure universal access to HCV treatment and make HCV elimination a real possibility.

VII. CONCLUSION

The costs associated with the new HCV medications have brought a pivotal problem with our healthcare system into stark relief: our existing innovation model invites hold-up pricing that harms public health. But this does not have to be the case. The government patent use power offers an important tool to combat high drug prices – a solution that was once used, and that can be used again without the need for Congressional action.

Section 1498's requirement of "reasonable" compensation provides a unique opportunity to think critically about compensation for innovation, especially for drugs with high social value. In line with the goals of § 1498 and patent protection more broadly, our proposed compensation methodology tethers patent compensation to the risk-adjusted costs of innovation. Such compensation enables the government to reduce the inefficiencies associated with patent monopoly. Effectively, § 1498 can operate as a kind of *ex post* prize mechanism, with all of the attendant benefits emphasized by the prize literature. By allowing the government to set an *ex post* price that it is willing to pay for innovation, § 1498 can reduce deadweight loss and increase the efficiency of investment in research. Government use can improve the health of millions by increasing access to lifesaving treatments while preserving long-term innovation incentives.

Without governmental action, the inefficiencies associated with drug pricing will only grow, as pharmaceutical companies increasingly price drugs based on what the market can bear, not the cost of R&D outlays (the industry's historical justification for its prices).³⁶⁵ Use of § 1498 provides an opportunity to re-align the price of innovation with its real risk-adjusted cost, and thereby re-align our innovation policy with our healthcare policy.

³⁶⁴ Fitch, *supra* note 340, at 135, tbl. D-1.

³⁶⁵ See Troyen Brennan & Willian Shrank, *New Expensive Treatments for Hepatitis C Infection*, 312 J. AM. MED. ASS'N 593, 593 (2014).

Accordingly, we propose that the federal government act to ensure all HCV-positive persons enrolled in a federally-run or sponsored program, as well as all HCV-positive inmates held by state correctional facilities, gain access to generic HCV medications. The government should procure generics for direct federal purchasing programs and consent to assume liability on behalf of manufacturers and distributors that provide drugs under Medicare and Medicaid, as well as state prisons. To make generics available to individuals receiving care outside of these programs, Congress should create a Ryan White-style program for HCV that procures and distributes generic HCV medicine to any population that the administration is otherwise unable to reach. The government should then provide compensation to Gilead based on the methodology we propose. If dissatisfied with this compensation, Gilead can litigate reasonable compensation in the Court of Federal Claims and then the Federal Circuit.

The HCV medications are only the first in a new line of extremely costly specialty medications. Recent reports have estimated that spending on specialty drugs could reach about \$400 billion by 2020.³⁶⁶ These trends illustrate the need for a tool that can help government provide maximal access to healthcare while also protecting investment in new drugs. Fortunately, the government already possesses such a tool. It is time that it again begins to use it.

³⁶⁶ SPECIALTY DRUGS AND HEALTH CARE COSTS, THE PEW CHARITABLE TRUSTS 2 (Nov. 2015), *available at* <https://perma.cc/Z2EU-LFDB>.