

**PRIZING INSURANCE: PRESCRIPTION DRUG INSURANCE  
AS INNOVATION INCENTIVE**

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## I. INTRODUCTION

Over the last hundred years, the development of new pharmaceuticals has revolutionized the practice of medicine and turned many horrific conditions into problems of the past. Innovations as diverse as penicillin, insulin, and the smallpox vaccine have saved the lives of countless people. But there are still entire classes of disease for which no effective treatments exist.

Most notably, much of the world's population is still imperiled by a range of communicable diseases. The World Health Organization's seventeen Neglected Tropical Diseases affect more than one billion people worldwide, with billions more living in countries in which these diseases are endemic.<sup>1</sup> By any measure, these diseases impose enormous costs, not only on the people who suffer from them and those developing countries in which they are most prevalent, but also on the global economy. Many of these conditions are present in increasingly high rates even within the United States. For instance, roughly 300,000 people in the United States suffer from Chagas disease,<sup>2</sup> which is responsible for nearly \$900 million in costs in the United States alone, including treatment expenditures and lost income.<sup>3</sup> Dengue fever is now endemic to Florida.<sup>4</sup> In 2014, forty-six states reported 2,811 cases of chikungunya, at least some of which were acquired in the United States rather than by travel abroad.<sup>5</sup> The

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1. WORLD HEALTH ORG., NEGLECTED TROPICAL DISEASES (2015), [http://www.who.int/neglected\\_diseases/diseases/en/](http://www.who.int/neglected_diseases/diseases/en/) [<https://perma.cc/D29L-C4V7>]. This list does not include HIV/AIDS, malaria, or tuberculosis, for which R&D investments are healthy by comparison.

2. Peter J. Hotez et al., *Chagas Disease: "The New HIV/AIDS of the Americas"*, 6 PLOS NEGLECTED TROPICAL DISEASES 1, 1 (2012); Caryn Bern & Susan P. Montgomery, *An Estimate of the Burden of Chagas Disease in the United States*, 49 CLINICAL INFECTIOUS DISEASES e52, e52 (2009).

3. Bruce Y. Lee et al., *Global Economic Burden of Chagas Disease: A Computational Simulation Model*, 13 LANCET INFECTIOUS DISEASES 342, 345 (2013).

4. Dongyoung Shin et al., ASTMH 2012 Conference Poster Presentation: Evidence of a New Distinct Strain of Dengue Virus 1 Isolated in Key West, Florida (Nov. 14, 2012), <http://www.abstractsonline.com/Plan/ViewAbstract.aspx?sKey=cd94979d-5d70-43f4-bcc3-3e6d52c8cf33&cKey=4113489c-a312-4ed7-b0b4-31e7b811f965&mKey=%7BC0DC51D1-29D3-44C6-BC0E-2069047A3801%7D> [<https://perma.cc/BD5A-5JJE>]; Maryn McKenna, *Dengue, aka "Breakbone Fever," Is Back*, SLATE (Dec. 21, 2012), [http://www.slate.com/articles/health\\_and\\_science/pandemics/2012/12/dengue\\_fever\\_in\\_unit\\_ed\\_states\\_breakbone\\_fever\\_outbreaks\\_florida\\_texas\\_and\\_single.html](http://www.slate.com/articles/health_and_science/pandemics/2012/12/dengue_fever_in_unit_ed_states_breakbone_fever_outbreaks_florida_texas_and_single.html) [<https://perma.cc/35FM-TDD5>]; see also Peter J. Hotez, *Tropical Diseases: The New Plague of Poverty*, N.Y. TIMES (Aug. 18, 2012), [http://www.nytimes.com/2012/08/19/opinion/sunday/tropical-diseases-the-new-plague-of-poverty.html?\\_r=0](http://www.nytimes.com/2012/08/19/opinion/sunday/tropical-diseases-the-new-plague-of-poverty.html?_r=0) (last visited Dec. 15, 2016).

5. CTRS. FOR DISEASE CONTROL, CHIKUNGUNYA VIRUS IN THE UNITED STATES (2015), <http://www.cdc.gov/chikungunya/geo/united-states.html> [<https://perma.cc/9M96-JHUA>]; CTRS. FOR DISEASE CONTROL, CHIKUNGUNYA VIRUS: 2014 FINAL DATA FOR THE UNITED

species of mosquitoes capable of transmitting dengue, chikungunya, and yellow fever are spreading rapidly across California.<sup>6</sup> And these diseases are only growing in prevalence in the United States.<sup>7</sup>

At the same time, mental health and other neuropsychiatric disorders are now responsible for the loss of more disability-adjusted life years worldwide than any other set of conditions.<sup>8</sup> The global costs attributable to these diseases, already extremely high at \$2.5 trillion annually, are likely to grow as high as \$6 trillion annually by 2030, given current treatment capabilities.<sup>9</sup> Mental health disorders are responsible for at least \$300 billion in costs annually in the United States alone, including both direct health care expenditures and the (far larger) related lost income and disability expenses.<sup>10</sup> Much of this cost is traceable to major depression, which affects 16 million Americans, but other large portions are borne by the 2.4 million Americans with schizophrenia, the 6.1 million with bipolar disorder, and the 42 million with a diagnosed anxiety disorder.<sup>11</sup>

These two classes of diseases differ in a host of ways. Yet they share one key characteristic: we lack effective pharmaceutical treatments for most of them. Consider Chagas Disease. In addition to being one of the abovementioned Neglected Tropical Diseases, the Centers for Disease Control and Prevention (“CDC”) has named Chagas as one of its five Neglected Parasitic Infections, so named not only because they affect large numbers of people with severe illnesses, but

STATES (2015), <http://www.cdc.gov/chikungunya/geo/united-states-2014.html> [https://perma.cc/UP5X-FU5F].

6. Soumya Karlamangla, *Aggressive Nonnative Mosquitoes Spreading Across State Carry Disease Risk*, L.A. TIMES (Oct. 24, 2015), <http://www.latimes.com/local/california/la-me-disease-mosquitoes-20151025-story.html> [https://perma.cc/4WNY-YCFU].

7. Although there were 2,811 reported cases of chikungunya in 2014, CTRS. FOR DISEASE CONTROL AND PREVENTION, CHIKUNGUNYA VIRUS: 2014 FINAL DATA FOR THE UNITED STATES (2015), <http://www.cdc.gov/chikungunya/geo/united-states-2014.html> [https://perma.cc/UP5X-FU5F], from 2006 to 2013 an average of just 28 cases per year were reported, CTRS. FOR DISEASE CONTROL AND PREVENTION, CHIKUNGUNYA VIRUS IN THE UNITED STATES (2015), <http://www.cdc.gov/chikungunya/geo/united-states.html> [https://perma.cc/9M96-JHUA].

8. See WORLD ECON. F., THE GLOBAL ECONOMIC BURDEN OF NON-COMMUNICABLE DISEASES 26 (2011), [http://www3.weforum.org/docs/WEF\\_Harvard\\_HE\\_GlobalEconomicBurdenNonCommunicableDiseases\\_2011.pdf](http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf) [https://perma.cc/85Q5-S7Q5]; see also Thomas R. Insel & Story C. Landis, *Twenty-Five Years of Progress: The View from NIMH and NINDS*, 80 NEURON 561, 563 (2013); Steven E. Hyman, *The Unconscionable Gap Between What We Know and What We Do*, 6 SCI. TRANSLATIONAL MED. 1, 1 (2014).

9. WORLD ECON. F., *supra* note 8, at 27.

10. Thomas R. Insel, *Assessing the Economic Costs of Serious Mental Illness*, 165 AM. J. PSYCHIATRY 663, 664 (2008).

11. NAT’L ALL. ON MENTAL ILLNESS, MENTAL ILLNESS FACTS AND NUMBERS 1 (2013), <http://www.nami.org/NAMI/media/NAMI-Media/Infographics/GeneralMHFacts.pdf> [https://perma.cc/MVE4-5K43].

also because we lack the ability to prevent and treat them.<sup>12</sup> If not caught within two months after infection (during which there are often no symptoms),<sup>13</sup> Chagas will progress to the chronic stage, which often leads to heart failure and requires a heart transplant.<sup>14</sup> Even beyond any concerns we might have about the health of Chagas patients simply due to their status as members of society, the special solicitude reserved for health conditions that impinge on our scarce supply of organs should cause particular concern. Yet Chagas cannot be effectively treated once it reaches the chronic stage.<sup>15</sup>

In the mental health context, consider depression. To date, no clinical trial has demonstrated success in the treatment of mild depression.<sup>16</sup> Likewise, meta-analyses of clinical trials performed on individuals with severe depression typically show clinically significant efficacy only for patients at the upper end of the very severely depressed category.<sup>17</sup> Worse yet, the mean treatment effect demonstrated in clinical trials has decreased over the past few decades.<sup>18</sup> The Director of the National Institute of Mental Health has argued that the new generation of antidepressants is no more effective than the medications available in the 1980s.<sup>19</sup>

There are a host of reasons why effective pharmaceutical treatments for these disparate diseases have not been developed, even as the societal burden of disease grows ever larger. One major issue is scientific. In the case of mental health conditions,<sup>20</sup> scientists lack an

12. CTRS. FOR DISEASE CONTROL, NEGLECTED PARASITIC INFECTIONS IN THE UNITED STATES (2015), <http://www.cdc.gov/parasites/npi/> [<https://perma.cc/R2Z2-V4TB>].

13. WORLD HEALTH ORG., CHAGAS DISEASE (AMERICAN TRYPANOSOMIASIS) (2015), <http://www.who.int/mediacentre/factsheets/fs340/en/> [<https://perma.cc/NEU9-ERDB>].

14. Valeria B. deCarvalho et al., *Heart Transplantation in Chagas' Disease: 10 Years After the Initial Experience*, 94 CIRCULATION 1815, 1815 (1996). There have also been cases of Chagas transmission through organ transplant. CTRS. FOR DISEASE CONTROL AND PREVENTION, *Chagas Disease After Organ Transplantation—Los Angeles, California, 2006*, 55 MORBIDITY AND MORTALITY WKLY. REP. 798, 798 (2006).

15. WORLD HEALTH ORG., *supra* note 13.

16. Silvana Borges et al., *Review of Maintenance Trials for Major Depressive Disorder: A 25-Year Perspective from the U.S. Food and Drug Administration*, 75 J. CLIN. PSYCHIATRY 205, 205 (2014).

17. See, e.g., Ni A. Khin et al., *Exploratory Analyses of Efficacy Data from Major Depressive Disorder Trials Submitted to the U.S. Food and Drug Administration in Support of New Drug Applications*, 72 J. CLIN. PSYCHIATRY 464, 469–70 (2011); cf. Jay C. Fournier et al., *Antidepressant Drug Effects and Depression Severity: A Patient-Level Meta-Analysis*, 303 J. AM. MED. ASS'N 47, 51 (2010); Irving Kirsch et al., *Initial Severity and Antidepressant Benefits: A Meta-Analysis of Data Submitted to the Food and Drug Administration*, 5 PLOS MED. 260, 261 (2008).

18. Khin, *supra* note 17, at 465.

19. Insel & Landis, *supra* note 8, at 564.

20. There are, of course, other problems that are unique to mental health, such as stigmatization. Hyman, *supra* note 8, at 3.

understanding of neurobiology that can be translated into effective treatments.<sup>21</sup> These scientific difficulties have even led many large pharmaceutical companies to shutter their neuroscience divisions entirely.<sup>22</sup> Recently, the National Institute of Mental Health has reoriented its clinical trial funding to focus on the underlying biological mechanisms of mental health disorders, in an effort to decrease the high failure rates of existing clinical trials.<sup>23</sup>

Another issue is financial. In the case of the Neglected Tropical Diseases, the inability of most of the patients who suffer from these diseases to pay for expensive drugs means that companies cannot be assured of a market for their products. As a result, few companies have chosen to invest in treatments for these conditions.<sup>24</sup> If private companies are the only source of innovation in this area, such therapies will be chronically underproduced.

But a more fundamental problem for the development of treatments for these disparate diseases is legal. The primary laws that are set up expressly to incentivize innovation into pharmaceuticals — the patent system and features of the Food and Drug Administration (“FDA”) regulatory system — are structured in a way that encourages companies to invest in the development of certain types of drugs to the exclusion of others. However, the therapies incentivized by our current laws do not necessarily address the diseases with the greatest burden on society. There is a mismatch between the drugs our health system most urgently needs and those it is structured to produce.

Other scholars and policymakers who have identified unmet health needs of this type have proposed various compensatory schemes in an effort to encourage pharmaceutical companies to invest in neglected areas. One such group of proposals is targeted toward increasing the duration or scope of patent rights.<sup>25</sup> Another group would provide additional incentives through the FDA regulatory pro-

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21. *Id.*; see also Nicholas Kozauer & Russell Katz, *Regulatory Innovation and Drug Development for Early-Stage Alzheimer’s Disease*, 368 *NEW ENG. J. MED.* 1169, 1170 (2013).

22. See generally Greg Miller, *Is Pharma Running Out of Brainy Ideas?*, 329 *SCIENCE* 502, 502 (2010); see also Dennis W. Choi et al., *Medicines for the Mind: Policy-Based “Pull” Incentives for Creating Breakthrough CNS Drugs*, 84 *NEURON* 554, 554 (2014).

23. Sara Reardon, *NIH Rethinks Psychiatry Trials*, 507 *NATURE* 288, 288 (2014).

24. Michael Kremer, *Pharmaceuticals and the Developing World*, 16 *J. ECON. PERSP.* 67, 75 (2002).

25. See generally Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 *UCLA L. REV.* 672 (2014); Michael Abramowicz, *Orphan Business Models: Toward a New Form of Intellectual Property*, 124 *HARV. L. REV.* 1362 (2011). Scholars of patent law and innovation policy have long confronted questions about how to optimize the patent system to best promote progress. See, e.g., SUZANNE SCOTCHMER, *INNOVATION AND INCENTIVES* (2004); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 *VA. L. REV.* 1575 (2003); Julie E. Cohen & Mark A. Lemley, *Patent Scope and Innovation in the Software Industry*, 89 *CAL. L. REV.* 1, 39 (2001).

cess, either by lengthening the period of exclusivity provided when a new drug is approved or by awarding some sort of other in-kind benefit, such as a tax credit or fast-track approval voucher.<sup>26</sup>

More recently, though, some scholars have taken a broader view of potential legal solutions to innovation problems. A burgeoning strand of scholarship has considered the potential of alternative legal mechanisms such as prizes or government grants to incentivize innovation.<sup>27</sup> Yet these scholars have thus far largely overlooked the potential of a different legal lever — prescription drug insurance — to perform these very same functions.<sup>28</sup>

This Article will consider the potential for prescription drug insurance to remedy the distortions in the patent system that have led to the underdevelopment of drugs for mental health conditions and the Neglected Tropical Diseases alike. Prescription drug insurance has largely been studied in the context of health law as a means to pro-

26. See generally Choi et al., *supra* note 22; Arti K. Rai, *Building a Better Innovation System: Combining Facially Neutral Patent Standards With Therapeutics Regulation*, 45 HOUS. L. REV. 1037 (2008); Henry G. Grabowski et al., *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFF. 2157 (2011).

27. This strand of the literature, explored more fully in Section III.B *infra*, might most helpfully be called “Innovation Law Beyond IP,” after conferences by that name at Yale Law School in 2014 and 2015 designed to showcase work in this field. See, e.g., Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 352 (2007); Nancy Gallini & Suzanne Scotchmer, *Intellectual Property: When Is It the Best Incentive System?*, in 2 INNOVATION POLICY AND THE ECONOMY 51, 54–55 (Adam B. Jaffe et al. eds., 2002); Yaniv Heled, *Patents vs. Statutory Exclusivities in Biological Pharmaceuticals—Do We Really Need Both?*, 18 MICH. TELECOMM. TECH. L. REV. 419, 424 (2012); Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 303 (2013); Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1952 (2013); Lisa Larrimore Ouellette, *Patentable Subject Matter and Non-Patent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1115 (2015); Brett Frischmann & Mark P. McKenna, *Comparative Analysis of (Innovation) Failures and Institutions in Context* (September 1, 2014) (unpublished manuscript) (draft on file with author). In this way, it deserves to be contrasted with a strand of literature that explores the way in which community norms (rather than other legal levers) may function as an alternative to patent or copyright law. This literature presents case studies of groups including stand-up comedians, tattoo artists, magicians, chefs, and roller derby players, who innovate and create without resorting to formal legal systems. See, e.g., David Fagundes, *Talk Derby to Me: Intellectual Property Norms Governing Roller Derby Pseudonyms*, 90 TEX. L. REV. 1094, 1144–46 (2012); Dotan Oliar & Christopher Sprigman, *There’s No Free Laugh (Anymore): The Emergence of Intellectual Property Norms and the Transformation of Stand-Up Comedy*, 94 VA. L. REV. 1787 (2008); Aaron Perzanowski, *Tattoos & IP Norms*, 98 MINN. L. REV. 511 (2013). This strand of the literature is most useful when examining industries in which the costs to develop an innovation (such as a new recipe) are relatively low, which is not the case for a typical innovation in the medical field.

28. See *infra* Section III.B for a more complete discussion of the ways in which this topic has been raised in the legal literature to date.

mote access to medicines presently in existence.<sup>29</sup> Yet it has several economic and institutional features that make it ideally suited not only to promote access to existing therapies, but also to provide targeted incentives for innovation into humanity's most significant unmet health needs.

Part II of this Article considers the existing patent and FDA regulatory systems and describes the ways in which these legal structures systematically incentivize drugs with certain characteristics, to the exclusion of medications with other features. Part II first explains the puzzle presented by the two classes of diseases considered here. These classes of diseases are vastly different in their etiology, prevalence, and natural history. Yet they share a key feature: the lack of effective pharmaceutical treatments for nearly all of them. In many ways, this outcome is traceable to the structure of the law. Part II next maps the way in which specific design choices made in the construction of patent laws — those dealing with duration and scope, and with the market-based attributes of the system — systematically bias innovation not only away from certain types of drugs, but also away from certain types of diseases, particularly those primarily affecting the poor.

Part III outlines existing scholarly and legislative proposals for addressing particular unmet health needs. It begins by demonstrating that most current proposals to tailor the patent and FDA exclusivity systems to fill these innovation distortions are at best unresponsive and at worst actively harmful. As a result, Part III goes on to situate this Article within an emerging line of scholarship exploring alternative innovation mechanisms. However, current academic consideration of alternative innovation levers has largely ignored the role of prescription drug insurance, typically understood as an access mechanism, to serve innovative ends.

Part IV provides an in-depth theoretical exploration of the ways in which prescription drug insurance can incentivize innovation. It begins by exploring the principal economic and institutional features of prescription drug insurance as practiced both in the United States and other countries and then moves on to consider the ways in which this traditional access lever strongly resembles a prize system. Part IV then considers the potential for prescription drug insurance to remedy the innovation distortions identified in Part II, concluding that, as typically practiced, it is naturally suited to compensate for the market-related difficulties identified there.

Part V considers a specific instance of insurance's innovation potential: prescription drug insurance through Medicaid in the United

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29. See, e.g., Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?* 27 HEALTH AFF. 33 (2008).

States. Medicaid is expressly designed to promote access to care for the neediest Americans. However, it might perversely decrease incentives for innovation in drugs that would primarily be prescribed for low-income Americans — like those for many mental health disorders or communicable diseases. Part V details specific aspects of Medicaid drug reimbursement and how they embody this tradeoff. Part V then proposes altering Medicaid's prescription drug rebate system to reward innovators who bring drugs for diseases primarily affecting low-income populations to market, improving incentives for innovation related to those specific diseases. Part VI concludes.

## II. INNOVATION DISTORTIONS IN THE CURRENT PATENT AND FDA LANDSCAPE

The patent system is intended to encourage the creation and development of all types of technologies, and several features of the FDA regulatory system are intended to bolster the patent system's incentives as they relate to pharmaceuticals. Most notably, a number of statutes empower the FDA to award periods of regulatory exclusivity for approved drugs.<sup>30</sup> But too often, these two systems fail to encourage the production of important, socially valuable pharmaceutical interventions. These invisible interventions are often difficult to spot — by definition, they are missing precisely because the current innovation ecosystem has distorted inventive behavior away from what might be socially optimal.

Existing scholarship has identified unmet health needs for which treatments could be, but have not been, developed — including mental health and other neuropsychiatric disorders and the Neglected Tropical Diseases.<sup>31</sup> As discussed in the Introduction, the literature convincingly argues that healthcare technologies affecting particular diseases are being underproduced relative to standard metrics of social value for a variety of reasons.<sup>32</sup>

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30. See, e.g., Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(F)(ii) (2012) (conferring a five-year period of exclusivity for small-molecule drugs); Orphan Drug Act, 21 U.S.C. § 360cc(a) (2012) (conferring seven years of market exclusivity); Biologics Price Competition and Innovation Act, 42 U.S.C. § 262(k)(7)(A) (2012) (conferring twelve years of data exclusivity).

31. Choi et al., *supra* note 22, at 555; Pierre Chirac & Els Torreele, *Global Framework on Essential Health R&D*, 367 LANCET 1560, 1560–61 (2006).

32. See, e.g., Insel & Landis, *supra* note 8, at 564 (explaining the scientific barriers involved in developing drugs for mental health conditions); Kevin Outterson et al., *Repairing the Broken Market for Antibiotic Innovation*, 34 HEALTH AFF. 277, 278 (2015) (discussing the market-based concerns blocking the development of new antibiotics); Peter Hotez, et al., *Rescuing the Bottom Billion Through Control of Neglected Tropical Diseases*, 373 LANCET 1570, 1570–75 (2009) (discussing the financial concerns involved in the development of new drugs for neglected tropical diseases).



This Part focuses not on the unmet health needs themselves, but on the innovation distortions in the existing legal system that underlie those unmet health needs. It explores the ways in which deliberate design choices made in constructing the patent system and FDA regulatory regime bias incentives to invent toward particular therapeutic areas or types of technology and away from others. In practice, this often means that innovation is also biased away from entire classes of diseases, including many with the largest societal impacts.

This Part begins by organizing its analysis around the key factors at the heart of any exclusive rights regime: the duration and scope of the rights it awards. These two variables encourage innovation into certain types of drugs by pushing development funding toward drugs with shorter development times and toward new drugs rather than new information about old drugs. This Part then considers the way in which the structure of these rights interfaces with the market for drugs to illuminate another class of missing drugs: those whose product characteristics or whose patient populations render them unprofitable. Taken together, these innovation distortions provide a unifying explanation for society's failure to develop a range of therapies, including those for the treatment of both mental health conditions and neglected tropical diseases.

#### *A. Innovation Distortions Created by the Duration and Scope of Rights*

The exclusive rights awarded by the patent system and the FDA regulatory regime incorporate deliberate choices about the duration and scope of the rights involved. These choices implicate competing policy tradeoffs. The longer a patent or FDA exclusivity period lasts or the broader the scope of that right, in general the more profits a company can expect to recoup and thus the greater its incentive to develop the drug in question. However, the longer a patent or FDA right lasts or the broader its scope, the larger the social costs accompanying it.<sup>33</sup> Many more patients who value the drug in question at more than its marginal cost but at less than its monopoly price will be unable to access needed therapies. In the context of pharmaceuticals, patients' lives may be at stake.

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33. This tradeoff is well-known. *See, e.g.,* SCOTCHMER, *supra* note 25, at 58. Scholars have argued that the best policy may be to provide some level of protection less than exclusivity but for a longer period. *See generally* 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 (1999). The analysis here takes as given the current form of patent law, if not its specifics.

The way we initialize these variables not only impacts the balance between incentives and access, it also distorts drug development in certain directions. With respect to duration, an early-starting patent clock drives firms to invest in drugs requiring shorter clinical trials, namely those using surrogate endpoints and those designed to treat, rather than prevent, disease. With respect to scope, problems of non-excludability discourage investment in discovering new information about old drugs, whether positive or negative.

### 1. Duration

To maximize social benefits, policymakers should theoretically set the length of an exclusivity term to be equal to the minimum amount of time needed to incentivize the development of the good in question.<sup>34</sup> Although this time is likely to be field- and even invention-specific, patent law is essentially uniform on this front,<sup>35</sup> setting the term of patent protection for all inventions at twenty years from the date on which the patent application was filed.<sup>36</sup> This means that inventions in fields like software, where product lifecycles are typically just a few years,<sup>37</sup> receive roughly the same term of patent protection as pharmaceuticals, where product lifecycles are far longer. In reality, though, pharmaceuticals typically experience a much shorter *effective* patent life than other fields, because patents on drug compounds must be applied for before a drug begins the FDA review process.<sup>38</sup> The average effective patent life remaining after a drug receives FDA approval is roughly twelve years,<sup>39</sup> compared to the nearly eighteen<sup>40</sup> enjoyed on average in other fields. This is true even though industry surveys reveal that patents are far more important to

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34. See, e.g., STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 145 (2004); cf. SCOTCHMER, *supra* note 25, at 59.

35. For a more general treatment of this issue, see Michael W. Carroll, *One for All: The Problem of Uniformity Cost in Intellectual Property Law*, 55 AM. U. L. REV. 845 (2006); see also Michael W. Carroll, *One Size Does Not Fit All: A Framework for Tailoring Intellectual Property Rights*, 70 OHIO ST. L.J. 1361 (2009).

36. 35 U.S.C. § 154(a)(2) (2012).

37. Burk & Lemley, *supra* note 25, at 1622; see also Cohen & Lemley, *supra* note 25, at 46.

38. See Rebecca S. Eisenberg, *The Problem of New Uses*, 5 YALE J. HEALTH POL'Y L. & ETHICS 717, 722 (2005).

39. Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. TECH. L. REV. 345, 352 (2007); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 (2012).

40. See U.S. PATENT & TRADEMARK OFFICE, PERFORMANCE & ACCOUNTABILITY REPORT 2014, at 17 (2014) (listing the average total pendency of an application at 27.4 months).

drug manufacturers than to any other area of industry.<sup>41</sup> The duration of exclusivity periods awarded by the FDA is more granular, generally lasting either five, seven, or twelve years depending on the type of drug and indication.<sup>42</sup> These exclusivity periods begin running at the time the drug is approved, and therefore typically run concurrently for at least some period of time with the patents on the drug.<sup>43</sup>

These chosen durations — patent rights that last twenty years from filing, and concurrent FDA exclusivity periods that last either five, seven, or twelve years from FDA approval — affect the incentives for pharmaceutical companies to develop drugs with certain characteristics. Most importantly, pharmaceutical companies are encouraged to invest in drugs with comparatively short development times, all else being equal.<sup>44</sup> The shorter the time-to-market, the longer the time remaining before the patent expires and the longer the manufacturer can maintain their monopoly. Relatedly, if a particularly lengthy development process has consumed most of the original patent, it is unlikely that a given drug will be able to recoup its costs, which can run into the billions of dollars.<sup>45</sup>

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41. See, e.g., Wesley Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (Or Not)* 2, 12 (Nat'l Bureau of Econ. Research, Working Paper No. 7552, 2000).

42. The Orphan Drug Act awards seven years of marketing exclusivity to FDA-designated orphan drugs, which treat a “rare disease or condition.” 21 U.S.C. § 360cc(a) (2012). New small-molecule drugs (those that, like aspirin, can be manufactured using standard chemical techniques) receive five years of exclusivity under the Hatch-Waxman Act. 21 U.S.C. § 355(c)(3)(E)(ii) (2012). New biologic drugs (pharmaceuticals made in living cells) receive twelve years of exclusivity under the Biologics Price Competition and Innovation Act, enacted as part of the Affordable Care Act. 42 U.S.C. § 262(k)(7)(A) (2012). In reality, this twelve-year term is far longer, as biosimilars are much more difficult and expensive to develop than are small-molecule generics. Henry Grabowski et al., *Does Generic Entry Always Increase Consumer Welfare?*, 67 FOOD & DRUG L.J. 373, 390 (2012) (estimating the approval costs of biosimilars at \$200 million, and the approval costs of small-molecule generic drugs at \$2 million).

43. Heled, *supra* note 27, at 422–24.

44. This has been studied both theoretically and empirically. See, e.g., Eric Budish et al., *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials* (Nat'l Bureau of Econ. Research, Working Paper No. 19430, 2013).

45. The typical cost of developing a new drug is hotly contested. Doctor Joseph A. DiMasi recently estimated the per-drug cost of drug development at \$2.6 billion, a significant increase from his 2003 estimate of \$802 million. See Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 20 (2016) (estimating pre-approval costs to be \$2.558 billion); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003) (estimating preapproval costs to be \$802 million). Another consulting group roughly contemporaneously estimated the cost at \$1.5 billion. OFF. HEALTH ECON., THE R&D COST OF A NEW MEDICINE (2013), <http://www.slideshare.net/OHENews/rd-cost-of-a-new-medicine-mestre-ferrandiz-19-jan2013> [https://perma.cc/9XFM-Y2UA]. Studies like these have been heavily criticized by public interest advocates, who report far lower numbers. See, e.g., Donald W. Light & Rebecca Warburton, *Demythologizing the High Costs of Pharmaceutical Research*, 6 BIOSOCIETIES 34, 46–47 (2011) (\$43.4 million). For my pur-

This distortion encourages companies to invest in certain types of drugs for certain types of diseases. Because clinical trials are generally the longest, most expensive portion of the drug development process, companies will prefer to invest in drugs for which they can predict that the clinical trial<sup>46</sup> process will be relatively short (and, by extension, cheaper).<sup>47</sup> This is likely to bias incentives in two ways.<sup>48</sup>

First, it favors interventions whose effect can be measured using surrogate endpoints rather than true endpoints. A surrogate endpoint is a “laboratory measurement or a physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions, or survives.”<sup>49</sup> A classic example is cholesterol. Drugs may be tested based on their ability to lower a patient’s level of cholesterol, a surrogate endpoint, rather than on their ability to decrease the risk of death from heart disease, the true endpoint. Clinical trials of interventions whose efficacy can be tested using a surrogate endpoint tend to be shorter and to require fewer patients than those using a true endpoint, each of which decreases the costs of clinical trials.<sup>50</sup>

Second, within the class of interventions that must be evaluated using true endpoints, therapeutic interventions are favored over preventive interventions. This is because clinical trials for therapeutic interventions also have these same two advantages over trials involving preventive interventions. The clinical trials are typically shorter for therapeutic interventions, as they assess improvement in a condition that is already present rather than waiting for an absent condition to develop. They are also likely to involve fewer patients, as the statistical power needed to detect a therapeutic effect will generally be

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poses, though, there is sufficient agreement that drugs are among the most costly technological goods to develop. See Cynthia M. Ho, *Drugged Out: How Cognitive Bias Hurts Drug Innovation*, 51 *SAN DIEGO L. REV.* 419, 426, 448–57 (2014).

46. This is likely to concern only Phase II and III trials, which test a drug’s effectiveness. There is no particular reason to suppose that Phase I trials, which measure safety, would differ between two therapeutic drugs, one planning to use a surrogate endpoint in later trials and one planning to use a true endpoint. However, there might be a difference between a preventive intervention and a therapeutic one, in the sense that the FDA will likely set the permitted balance of side effects and efficacy at a different level where patients are currently asymptomatic.

47. Shorter clinical trials are cheaper in the absolute sense — they are less expensive to conduct — and also in the sense that they allow a drug to be approved with more time remaining in its patent term.

48. The relationship between these two biases is likely additive, rather than synergistic. Surrogate endpoints are not more likely to be available for a therapy than for a preventive intervention.

49. ROBERT J. TEMPLE, *A Regulatory Authority’s Opinion About Surrogate Endpoints*, in *CLINICAL MEASUREMENT IN DRUG EVALUATION* 4 (Nimmo ed., 1995); see also 21 C.F.R. § 314.510 (1992).

50. See, e.g., Thomas R. Fleming, *Surrogate Endpoints and FDA’s Accelerated Approval Process*, 24 *HEALTH AFF.* 67, 67 (2005).

smaller than that needed in the preventive context.<sup>51</sup> Sometimes these disparities in patient numbers may be quite stark, differing by a factor of ten or even a hundred. For instance, antibiotics are often approved on the basis of trials involving just two or three hundred patients,<sup>52</sup> while an ongoing trial evaluating a prospective Ebola vaccine hopes to enroll more than 27,000 patients.<sup>53</sup>

Problematically, these features of interventions map to certain types of diseases. Surrogate endpoints are generally only available when a disease is extremely well understood biologically. Yet scientists lack sufficient understanding of most neurological diseases — including mental health conditions like depression and diseases like Alzheimer’s or amyotrophic lateral sclerosis (“ALS”) — to study interventions using scientifically validated surrogate endpoints.<sup>54</sup> Within this group of conditions, therefore, investment will be biased toward therapeutic, rather than preventive interventions. But this may be problematic, as preventing conditions like Alzheimer’s or Parkinson’s may be more valuable than simply delaying their progression once the underlying pathology manifests symptomatically.

## 2. Scope

Policy choices on the subject of scope also affect incentives. Here, I do not use the term “scope” to refer to the breadth of any individual right. That is, I put aside the types of questions that typically arise under patent law doctrines like enablement, in which courts consider whether a patent identifying a particular technology encom-

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51. Importantly, they are also likely to be shorter *because* they involve fewer patients. For many clinical trials, recruitment difficulties are a limiting factor in abbreviating the length of the trial. See *Clinical Trial Delays: America’s Patient Recruitment Dilemma*, DRUG DEVELOPMENT TECH. (July 19, 2012), <http://www.drugdevelopmenttechnology.com/features/featureclinical-trial-patient-recruitment/> [https://perma.cc/MN5U-5X9L].

52. See, e.g., FDA, LABELING INFORMATION: AVYCAZ 7 (Feb. 2015), [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2015/206494lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206494lbl.pdf) [https://perma.cc/CA8W-D8JN].

53. U.S. NAT’L INSTS. OF HEALTH, PARTNERSHIP FOR RESEARCH ON EBOLA VACCINES IN LIBERIA (PREVAIL) TRIAL (2015), <https://clinicaltrials.gov/ct2/show/study/NCT02344407?term=NCT02344407&rank=1> [https://perma.cc/6KUF-YWHL].

54. N. Coley et al., *Biomarkers in Alzheimer’s Disease: Not Yet Surrogate Endpoints*, 1180 ANN. N.Y. ACAD. SCI. 119, 123 (2009); see also *ALS Drug Development Gets FDA Hearing, Could See Push For Surrogate Markers*, ALS ASS’N (Feb. 1, 2013), <http://www.alsa.org/news/archive/drug-development-fda-hearing.html> (last visited Dec. 15, 2016); Monica Uddin, *Blood-Based Biomarkers in Depression: Emerging Themes in Clinical Research*, 18 MOL. DIAGNOSIS & THERAPY 469, 469 (2014); see generally Russell Katz, *Biomarkers and Surrogate Markers: An FDA Perspective*, 1 NEURORX 189 (2004). But see Callie L. McGrath et al., *Toward a Neuroimaging Treatment Selection Biomarker for Major Depressive Disorder*, 70 JAMA PSYCHIATRY 821, 821 (2013).

passes closely related technologies.<sup>55</sup> Rather, I mean “scope” to refer to the breadth of the rights system as a whole. Patent law and FDA exclusivity protect only certain types of inventions. Sometimes this is true de jure — the FDA is empowered to grant exclusivity only to drugs, and not to medical devices or diagnostics.<sup>56</sup> But other times this is true only de facto, in a way that biases the innovation process.

Specifically, where the patent and FDA systems provide superior ways to protect particular innovations, incentives will be distorted accordingly. Professors Amy Kapczynski and Talha Syed have argued convincingly that patents suffer from a “problem of nonexcludability,”<sup>57</sup> under which patent rights will “predictably and systematically distort private investment decisions . . . by overstating the value of highly excludable information goods and understating the value of highly nonexcludable ones.”<sup>58</sup> Although a complete explanation of the way in which this theory applies to the healthcare context is beyond the scope of this Article, it is important to consider its application to pharmaceuticals.<sup>59</sup>

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55. *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200 (Fed. Cir. 1991) is a representative example in the pharmaceutical context. Amgen had applied for and received a patent covering not only erythropoietin, which Amgen had brought to market, but also any “purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence *sufficiently duplicative* of that of erythropoietin.” *Id.* at 1204 (emphasis added). Although Amgen could patent erythropoietin itself, the Federal Circuit held that Amgen was not entitled to claim all “sufficiently duplicative” DNA sequences due to Amgen’s failure to “enable” those sequences under 35 U.S.C. § 112. *Id.* at 1213–14; 35 U.S.C. § 112(a). In other words, the remaining DNA sequences did not fall within the scope of the patent. See also Arti K. Rai, *Fostering Cumulative Innovation in the Biopharmaceutical Industry: The Role of Patents and Antitrust*, 16 BERKELEY TECH. L.J. 813, 840 n.113, 853 (2001).

56. See *supra* note 42.

57. Kapczynski & Syed, *supra* note 27, at 1905.

58. *Id.* at 1907.

59. As such, for now I put aside examples of other healthcare innovations toward the nonexcludable end of the continuum, particularly those relying on behavioral or social intervention. These interventions may be as or even more important than pharmaceutical interventions in the mental health context. Consider talk therapy, which may be prescribed for the treatment of a broad range of mental health conditions. Few rigorous clinical trials have examined the practice, including the ways in which it might be optimized for particular maladies. See, e.g., McGrath et al., *supra* note 54; Charles B. Nemeroff et al., *Differential Responses to Psychotherapy Versus Pharmacotherapy in Patients with Chronic Forms of Major Depression and Childhood Trauma*, 100 PNAS 14293 (2003); see also Richard A. Friedman, *To Treat Depression, Drugs or Therapy?*, N.Y. TIMES (Jan. 8, 2015), <http://well.blogs.nytimes.com/2015/01/08/to-treat-depression-drugs-or-therapy/> [<https://perma.cc/MWM8-V83J>]. Even further along the continuum of nonexcludability, consider that studies have demonstrated the efficacy of exercise for the treatment of moderate depression, finding it as or more effective than existing pharmacological interventions. See, e.g., Leandro Z. Agudelo et al., *Skeletal Muscle PGC-1 $\alpha$ 1 Modulates Kynurenine Metabolism and Mediates Resilience to Stress-Induced Depression*, 159 CELL 33, 33 (2014); Madhukar H. Trivedi et al., *Exercise as an Augmentation Treatment for Nonremitted Major Depressive Disorder: A Randomized, Parallel Dose Comparison*, 72 J. CLIN. PSYCHIATRY 677, 677 (2011).

In general, pharmaceuticals are highly excludable in the economic sense, meaning that it is possible to prevent consumers from accessing drugs they have not paid for. However, the information leading to their development is often nonexcludable,<sup>60</sup> since it is far more difficult to prevent its consumption once it exists in public.<sup>61</sup> The result is to bias innovative activity away from the collection of information about existing drugs, discouraging the production of both positive and negative information.

Scholars including Professors Rebecca Eisenberg and Benjamin Roin have focused on the underproduction of positive information, arguing that pharmaceutical companies lack sufficient motivation to study their existing drugs for new uses.<sup>62</sup> Critically, in their view this problem is directly traceable to the structure of the existing patent and FDA regulatory systems. Patents on new uses and additional FDA exclusivity periods for new uses may both be awarded, but because these rights are limited to the new use, they are difficult to enforce and “provide little protection from generic competition once the term of protection has expired for an older use of the same product.”<sup>63</sup> Physicians may prescribe existing drugs for off-label uses, and holders of new use patents find it both undesirable and difficult to detect prescriptions for new uses and enforce their patents against such behavior. As such, discoveries of secondary or other uses for existing drugs are typically serendipitous rather than the result of careful study and investigation.<sup>64</sup>

Professors Kapczynski and Syed also focus on the even more difficult problem of the underproduction of socially valuable negative information about drugs.<sup>65</sup> Innovative activity will be directed away from the production of information that existing drugs either are not safe and effective, or are less safe and effective than other alternatives.<sup>66</sup> This is not merely because pharmaceutical companies lack financial incentives to provide negative information about their own

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60. See, e.g., Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 200 n.28 (2005). This is true for small molecule drugs, but is less true for biologics. W. Nicholson Price & Arti K. Rai, *Are Trade Secrets Delaying Biosimilars?*, 348 SCIENCE 188, 188 (2015).

61. See Kapczynski & Syed, *supra* note 27, at 1922.

62. See generally Eisenberg, *supra* note 38; see also Benjamin N. Roin, *Solving the Problem of New Uses by Creating Incentives for Private Industry to Repurpose Off-Patent Drugs* 12 (Sept. 15, 2014) (unpublished manuscript), [http://petrieflom.law.harvard.edu/assets/publications/Roin\\_Solving\\_the\\_Problem\\_of\\_New\\_Uses.pdf](http://petrieflom.law.harvard.edu/assets/publications/Roin_Solving_the_Problem_of_New_Uses.pdf) [<https://perma.cc/U9KA-CAZP>].

63. Eisenberg, *supra* note 38, at 720.

64. For examples, see text accompanying notes 69–71, *infra*.

65. Kapczynski & Syed, *supra* note 27, at 1926.

66. See *id.* at 1924.

products or because competitors would have similarly weak incentives to produce such information.<sup>67</sup> It is also because the holder of a patent on such negative information would find it nearly impossible to enforce such a patent, as enforcement would require the tracking of “either thoughts or abstention from purchasing.”<sup>68</sup>

Similar to the duration distortion, the scope distortion in the patent and FDA systems threatens not only to skew innovation toward particular types of drugs and away from others, but also away from certain types of diseases more generally. In particular, in the few instances where effective treatments for Neglected Tropical Diseases do exist, those treatments were generally developed by serendipitously discovering new indications for old products, relying on profits recouped for other indications in wealthier markets. For instance, eflornithine is startlingly effective not only as a cure for Human African Trypanosomiasis (also known as sleeping sickness), but also for its cosmetic ability to prevent the growth of facial hair in women under the brand name Vaniqa.<sup>69</sup> Merck’s Mectizan Donation Program has made great strides fighting onchocerciasis in both African and South American countries,<sup>70</sup> with the company’s charitable efforts made possible at least in part by the drug’s profitability as a deworming agent in veterinary medicine — pet owners might know the medication better as Heartgard.<sup>71</sup>

### *B. Innovation Distortions Created by the Role of the Market*

Both patent law and FDA exclusivity periods are market-based reward systems in the sense that the reward obtained by an innovator depends on how well the invention performs in the market.<sup>72</sup> Put another way, the existence of a patent or an FDA-approved treatment does not guarantee a profitable market for that treatment. Where the general population’s willingness and ability to pay for a particular drug track the social value it contributes, patents are thought to pro-

67. *See id.*

68. *Id.* at 1926.

69. Donald G. McNeil, *Cosmetic Saves a Cure for Sleeping Sickness*, N.Y. TIMES (Feb. 9, 2001), <http://www.nytimes.com/2001/02/09/world/cosmetic-saves-a-cure-for-sleeping-sickness.html> (last visited Dec. 15, 2016).

70. *See, e.g., 25 Years: The Mectizan Donation Program*, MERCK, <http://www.merck.com/about/featured-stories/mectizan.html> [https://perma.cc/5FDW-LW8F] (discussing the donation of more than 2 billion treatments in the first 25 years of the Program).

71. *See* Donald G. McNeil, *Beyond Swollen Limbs, a Disease’s Hidden Agony*, N.Y. TIMES (Apr. 9, 2006), <http://www.nytimes.com/2006/04/09/world/americas/beyond-swollen-limbs-a-diseases-hidden-agony.html> (last visited Dec. 15, 2016).

72. These systems can be contrasted with government-based systems such as grants and prizes, to be considered in more detail in Part IV, *infra*.



vide a relatively efficient way of incentivizing the development of socially valuable drugs. But each of these factors — willingness to pay and ability to pay — presents a well-known bias, through which innovation incentives will be directed away from certain types of treatments or diseases with high social salience.<sup>73</sup>

### 1. Willingness to Pay

Consumers' willingness to pay for any particular product depends on its value to them. However, the social value of a drug is often poorly measured by the sum of its value to each individual consumer. There are often significant externalities associated with medical innovations that redound to the benefit of society, rather than the consumer, and are therefore not incorporated into individual willingness to pay.<sup>74</sup> The positive externalities associated with vaccines and herd immunity are particularly well-known, as vaccines protect not only the people receiving them, but also other members of society who have not been vaccinated.<sup>75</sup> The social value associated with a vaccine for a communicable disease may be higher than the social value associated with a drug treating the same condition, given the positive externalities particular to the former. However, a drug company's ability to recoup only a fraction of the vaccine's social value suggests that it will be systematically underproduced.

Even putting social value concerns aside, there are behavioral reasons why consumers' willingness to pay will undervalue particular types of medical innovations. Professor Cass Sunstein has noted that the unrealistic optimism which afflicts most people may distort their willingness to pay.<sup>76</sup> As such, individuals who misperceive their risk of developing virtually any condition will undervalue a preventive

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73. I assume here that the producer lacks the ability to price discriminate perfectly. If the producer could engage in perfect price discrimination, in which each consumer who valued a given invention above marginal cost would be charged a price equal to their maximum willingness to pay, there would be no remaining consumer surplus, and there would also be no deadweight loss. Perfect price discrimination requires perfect information, however, a condition that is essentially never met in practice. In at least the United States, though, the producer has some ability to set several different prices, compare Brian Galle, *In Praise of Ex Ante Regulation*, 68 VAND. L. REV. 1715, 1730 (2015); with Outterson, *supra* note 60, at 205, a condition that I discuss *infra* as in some ways exacerbating the situation.

74. Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1030 (2014).

75. Aylin Sertkaya et al., Analytical Framework for Examining the Value of Antibacterial Products (Apr. 14, 2014) (unpublished manuscript), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2641820](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2641820) [<https://perma.cc/24XG-K5ZW>].

76. Cass R. Sunstein, *Willingness to Pay vs. Welfare*, 1 HARV. L. & POL'Y REV. 303, 325 (2007).

intervention.<sup>77</sup> The well-known difficulty of valuing cures as compared to treatments is another related problem. Present bias may cause individuals to balk at paying (for instance) \$10,000 this year to cure a given condition, rather than paying an equivalent amount over a period of years to treat but not cure the same condition, even when the cure would provide greater value both to the patient and the healthcare system.<sup>78</sup>

## 2. Ability to Pay

The innovation-related problems arising where the primary patient population for a given disease lacks the ability to pay for treatments are well-documented in the global health literature.<sup>79</sup> By almost any measure — lives, quality-adjusted life years (“QALYs”), or systemic burden — the seventeen Neglected Tropical Diseases prevalent in developing countries impose enormous costs not only on the people who suffer from them and their home countries, but also on the global economy.<sup>80</sup> Yet the precarious financial position of most of the patients who suffer from these diseases, and their concomitant inability to pay for expensive drugs, means that therapies for these conditions will be chronically underproduced if private companies are the only source of innovation in this area.<sup>81</sup>

These insights from the global health literature have not yet been translated to the context of developed countries with relatively wealthy economies, but they apply similarly to the uninsured or underinsured populations of nations like the United States. Even in the U.S., if the prevalence of a disease is heavily concentrated among populations with little ability to pay, the presence of a small high-income market may be insufficient to incentivize the development of particular healthcare interventions, even when they would be highly socially valuable.

Both classes of diseases considered previously in this Part fit this pattern. For both the Neglected Tropical Diseases and mental health conditions in the United States, their prevalence is far higher among the lowest-income groups of society than among the highest-income

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77. Insurers might refuse to cover a preventive intervention on similar grounds. The problem is one of fragmentation: even if an intervention will save the system money in the long run, an employer or insurer who foresees that the consumer is likely to belong to another insurance plan at the time the savings accrue may refuse to cover it.

78. See, e.g., Margot Sanger-Katz, *\$1,000 Hepatitis Pill Shows Why Fixing Health Care Costs Is So Hard*, N.Y. TIMES (Aug. 2, 2014), [http://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html?\\_r=0](http://www.nytimes.com/2014/08/03/upshot/is-a-1000-pill-really-too-much.html?_r=0) (last visited Dec. 15, 2016).

79. Kremer, *supra* note 24, at 75.

80. WORLD HEALTH ORG., *supra* note 1.

81. See *id.* at 82.

groups, which should cause us to worry about incentives for drug development. Among all age groups, the prevalence of major depression is five times as high for those living below the poverty line as compared to those living above 400% of the poverty line.<sup>82</sup> Similarly, the 300,000 Americans with Chagas, 2.8 million Americans with toxocarriasis, and many with other parasitic conditions are disproportionately likely to live in poverty.<sup>83</sup>

Thus far, this Part has argued that the primary laws that are set up for the express purpose of incentivizing innovation into pharmaceuticals — the patent system generally, and features of the FDA regulatory system more specifically — encourage companies to invest in the development of certain types of drugs to the exclusion of others. However, the incentivized therapies are not necessarily those that would have the greatest social value, or those that would address the diseases with the greatest burden on society.<sup>84</sup> In particular, we can expect treatments or preventive interventions for at least two seemingly disparate classes of diseases — Neglected Tropical Diseases and mental health conditions — to be underproduced.

There is a mismatch between the drugs our health system most urgently needs, and those we have set ourselves up to get. The next logical question is how we might spur innovation into these kinds of interventions.

### III. DISCOVERING NOVEL POLICY LEVERS

When scholars and policymakers encounter innovation distortions of the kind examined in Part II, a common response is to view the distortion as a deficiency or bug in the patent or FDA system that is solvable by reference to the same tools that created it in the first place.<sup>85</sup> Recent legislative attempts to extend the patent term for pharmaceuticals or to provide additional market exclusivity for par-

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82. NAT'L CTR. FOR HEALTH STATISTICS, HEALTH, UNITED STATES, 2011 60 (2012), <http://www.cdc.gov/nchs/data/hus/11.pdf> [<https://perma.cc/E8RV-PNS8>]. One poll of Medicaid recipients found that 22% of them have been diagnosed with depression, as compared to 7% of those with employer-sponsored health insurance. Elizabeth Mendes, *Preventable Chronic Conditions Plague Medicaid Population*, GALLUP (Apr. 4, 2013), <http://www.gallup.com/poll/161615/preventable-chronic-conditions-plague-medicaid-population.aspx> (last visited Dec. 15, 2016).

83. Hotez, *supra* note 4.

84. Importantly, this method of analysis replicates the unmet needs already identified in the literature. As discussed above, scholars have expressed particular concern about antibiotic resistance, disorders of the nervous system, and neglected tropical diseases. Each of these areas can be subsumed within the paradigm presented here.

85. Kapczynski & Syed, *supra* note 27, at 1943 (recognizing that this is the “standard ‘optimizing’ response”).

ticular classes of drugs fall into this category.<sup>86</sup> Similarly, scholars have generated a vast number of proposals to alter the patent system in ways that would not only distinguish between different types of technology, but that could also make even finer distinctions within particular technological areas.<sup>87</sup>

This Part argues that patent law and FDA regulations are generally not well-suited to remedying their own innovation distortions, which is why many current proposals aiming to do so fall short. However, this conclusion should not lead to despair about the future of pharmaceutical innovation. Rather, this Part draws inspiration from an emerging line of scholarship that explores alternative innovation mechanisms beyond the standard intellectual property levers. Thinking creatively beyond those two areas for novel, alternative mechanisms to incentivize the development of new drugs reveals a potential new tool for encouraging innovation: prescription drug insurance.

#### *A. Internal Solutions Are Unresponsive and Counterproductive*

Many current proposals aiming to satisfy unmet health needs of the type articulated in the previous Part advocate looking internally for solutions by attempting to use the patent and FDA exclusivity systems to solve their own problems. However, considering both the unmet health needs and the innovation distortions that lead to them, it becomes clear that in the majority of cases these proposed solutions are at best unresponsive to the problems at hand and at worst would be actively harmful. That is, these proposals will either fail to address the relevant concerns or will only further distort the kinds of biases considered above. Even if some inventions that would not otherwise have occurred are incentivized, they will either not be of the kind the

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86. See, e.g., DISCUSSION DOCUMENT: 21ST CENTURY CURES ACT (Jan. 26, 2015), <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/Cures/20150127-Cures-Discussion-Document.pdf> [https://perma.cc/HVM6-NDWC]; MODERN Cures Act of 2013, H.R. 3116, 113th Cong., <https://www.congress.gov/bill/113th-congress/house-bill/3116/text> [https://perma.cc/F7LK-ESP2].

87. See, e.g., Karen I. Boyd, *Nonobviousness and the Biotechnology Industry: A Proposal for a Doctrine of Economic Nonobviousness*, 12 BERKELEY TECH. L.J. 311, 313 (1997); Robert A. Hodges, *Black Box Biotech Inventions: When a "Mere Wish or Plan" Should Be Considered an Adequate Description of the Invention*, 17 GA. ST. U. L. REV. 831, 833 (2001); John C. Phillips, *Sui Generis Intellectual Property Protection for Computer Software*, 60 GEO. WASH. L. REV. 997 (1992); Roin, *supra* note 25, at 672–73; Neel U. Sukhatme, *Regulatory Monopoly and Differential Pricing in the Market for Patents*, 71 WASH. & LEE L. REV. 1855, 1855 (2014); see also Burk & Lemley, *supra* note 25, at 1631–33 (cataloging many such proposals).

law was designed to address or will be overshadowed by the social costs of the increase in exclusivity.<sup>88</sup>

Proposals to alter patent or FDA law that are designed to remedy the innovation distortion caused primarily by the market-based nature of patents aim to incentivize drugs for the most neglected diseases. Yet these proposals are frequently unresponsive to those concerns, and therefore are ineffective. These interventions are likely to be more effective at the margins, where return-on-investment calculations are roughly comparable. But lengthening patent rights or exclusivity periods simply does not create a market where none exists. Where the relevant market for a drug is essentially absent, there is no reason to think that such solutions would be particularly effective.

The FDA's Priority Review Voucher ("PRV") is an example of this misguided approach. A company receiving FDA approval for a treatment for any Neglected Tropical Disease receives a transferable voucher, which when presented at the FDA entitles its bearer to a shortened review process for a different product.<sup>89</sup> The shortened review process allows that drug to spend more time on the market while under patent protection. Yet the structure of the law does not require that a company create a *new* product, it merely requires that the company shepherd a compound through the FDA approval process. As such, the recent grant of a voucher to Knight Pharmaceuticals for its approval of miltefosine for the treatment of leishmaniasis came under fire from the access-to-medicines community.<sup>90</sup> The drug's utility in treating leishmaniasis had been studied in clinical trials as early as the 1990s, and Knight spent just \$10 million to complete the clinical trial process with the FDA in 2014.<sup>91</sup> It then sold the voucher for \$125 million.<sup>92</sup> As a result, Knight not only did not develop a new drug or provide access to the drug, but also did not even add measurably to the information already known about miltefosine.<sup>93</sup>

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88. Kapczynski & Syed, *supra* note 27, at 1943.

89. 21 U.S.C.A. § 360n (2012). The primary value of the voucher comes not necessarily from its benefits to the organization receiving it, but from its transferability. Note that the voucher does not apply only to the Neglected Tropical Diseases as defined by the WHO. It also applies to malaria and tuberculosis, *id.* at (a)(3)(A)–(B), and in 2014, it was updated to include filoviruses, a class that includes Ebola, *id.* at (a)(3)(Q); *see also* Pub. L. 113-233, § 2, 128 Stat. 2127 (2014).

90. Bernard Pécoul & Manica Balasegaram, *FDA Voucher for Leishmaniasis Treatment: Can Both Patients and Companies Win?*, PLOS BLOGS (Jan. 20, 2015), <http://blogs.plos.org/speakingofmedicine/2015/01/20/fda-voucher-leishmaniasis-treatment-can-patients-companies-win/> (last visited Dec. 15, 2016).

91. *Id.*

92. Ed Silverman, *How Much? Gilead Pays \$125M for an FDA Priority Review Voucher*, WALL ST. J. (Nov. 19, 2014), <http://blogs.wsj.com/pharmalot/2014/11/19/how-much-gilead-pays-125m-for-an-fda-priority-review-voucher/> [<https://perma.cc/L8SJ-TTA3>].

93. Advocates have also expressed concern about the voucher granted for Coartem, an anti-malarial drug. *See* Pécoul & Balasegaram, *supra* note 90.

The Priority Review Voucher may be unhelpful, but it is not generally viewed as actively harmful.<sup>94</sup> Unfortunately, other proposals may be. Recent Congressional proposals to give 15 years of marketing exclusivity to new drugs that “address one or more unmet medical needs”<sup>95</sup> are examples of this phenomenon. Even today, most drugs approved by the FDA address “unmet medical needs.”<sup>96</sup> The primary effect of this provision would be to give 15 years of exclusivity to treatments which would have otherwise received 5, 7, or 12 years. Of course, there will likely be some innovation into therapies that would not otherwise have occurred. However, the enormous social costs incurred by the doubling or tripling of otherwise-granted exclusivity periods make this provision a highly inefficient way to incentivize the development of those therapies.<sup>97</sup>

The distortions caused by the scope of patent and FDA protection are similarly difficult to remedy by reference to these same systems. The problem of incentivizing the development of information (either positive or negative) about existing drugs is not that patents cannot be obtained, but instead that the information is nonexcludable. The rewards for developing the information will not redound primarily to the benefit of the developer, and therefore extending the patent or FDA exclusivity period is in some sense orthogonal to the problem at hand.<sup>98</sup> The classic economic response for the market’s failure to appropriately produce public goods of this type is not to ramp up private incentives to do so, but rather to empower the government to fund the development of the information itself.<sup>99</sup>

The distortions caused by differences in duration, though, are potentially addressable at least in part with highly specified solutions. For instance, Professor Benjamin Roin has argued that patent rewards ought to be tailored to an invention’s time-to-market.<sup>100</sup> Essentially, he argues that because “certain types of inventions take much longer to develop than others, and a lengthier time-to-market strongly corre-

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94. *But see* Daniel Carpenter et al., *Drug-Review Deadlines and Safety Problems*, 358 *NEW ENGL. J. MED.* 1354, 1354 (2008).

95. DISCUSSION DOCUMENT: 21ST CENTURY CURES ACT, *supra* note 86.

96. Alexander Gaffney, *Regulatory Explainer: The 21st Century Cures Act*, REGULATORY AFFAIRS PROFESSIONALS SOCIETY (Jan. 28, 2015), <http://www.raps.org/Regulatory-Focus/21st-Century-Cures-Act/> [<https://perma.cc/H5N4-E96P>].

97. *See, e.g.*, Louis Kaplow, *The Patent-Antitrust Intersection: A Reappraisal*, 97 *HARV. L. REV.* 1813, 1829–30 (1984). Incidentally, though, this proposal would redress the duration bias, just in a socially harmful way.

98. *See* Kapczynski & Syed, *supra* note 27, at 1943.

99. Gallini & Scotchmer, *supra* note 27, at 53–54.

100. *See generally* Roin, *supra* note 25; *cf.* Shamnad Basheer, *The Invention of an Investment Incentive for Pharmaceutical Innovation*, 15 *J. WORLD INTELL. PROP.* 1 (2012) (arguing a patent system which ensures recoupment of investments put into R&D would incentivize researchers to innovate).

lates with an increased need for patent protection, . . . [t]he government can use this relatively observable feature of inventions as the foundation for an objective and reasonably accurate system of tailored patent awards.”<sup>101</sup>

Roin and others are correct that the need for patent protection and thus the optimal duration (if any) of patent protection differs by industry. But as the previous Part explained, the need for and utility of patents differs even within an industry. If implemented industry-by-industry, Roin’s proposal would perpetuate the same kinds of problems created by recent Congressional initiatives.<sup>102</sup> If implemented on a highly specific, drug-by-drug basis, though, his proposal might ameliorate one of the distortions articulated above: the problem of underinvestment in pharmaceuticals which must undergo particularly lengthy clinical trials.

Regardless of whether specific interventions like these are ineffective or actively harmful, they certainly are not necessary. Rather than attempting to solve the innovation distortions in patent law and FDA regulation with the same tools that created them, it is more fruitful to view them as the direct result of design choices made in the construction of the patent and FDA systems. This does not mean that these distortions do not need to be addressed. Instead, it suggests that solutions external to the patent and FDA space might be better suited to these purposes.<sup>103</sup>

### *B. Searching for External Solutions*

A vibrant line of legal scholarship explores the potential of alternative innovation mechanisms beyond intellectual property. Scholars have long considered the role of prizes in the innovation ecosystem.<sup>104</sup> More recently, scholars have highlighted the potential of lesser-studied innovation mechanisms, including tax credits<sup>105</sup> and government grants.<sup>106</sup> Other scholars have constructed case studies exam-

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101. Roin, *supra* note 25, at 676.

102. *Id.* at 754–55.

103. Kapczynski & Syed, *supra* note 27, at 1951.

104. See, e.g., Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115 (2003); Michael Polanvyi, *Patent Reform*, 11 REV. ECON. STUD. 61 (1943); Brian D. Wright, *The Economics of Invention Incentives: Patents, Prizes, and Research Contracts*, 73 AM. ECON. REV. 691 (1983); see also Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 528 (2001) (cataloging the literature).

105. See Hemel & Ouellette, *supra* note 27, at 303.

106. Ouellette, *supra* note 27, at 1118; see also Bhaven N. Sampat, *Serendipity* (Jan. 5, 2015) (unpublished manuscript), [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2545515](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2545515) [<https://perma.cc/D9VV-LJWV>].

ining the role of alternative mechanisms in particular industries<sup>107</sup> and taking a deep look at particular instances of these alternative mechanisms.<sup>108</sup>

Despite its breadth, this literature has yet to consider the full potential of another legal lever to serve as an innovation incentive: prescription drug insurance. The economic literature, by contrast, has come to appreciate the fact that insurance (and the related phenomenon of procurement) has the potential not only to improve access to particular medicines, but also to create markets where none existed previously. The effect is to redirect innovative activities accordingly.<sup>109</sup>

Medicare Part D is the clearest example of this effect in the health insurance context. Although the broader Medicare program has existed since 1965, Medicare largely did not cover prescription drugs until 2006,<sup>110</sup> when Medicare Part D went into effect.<sup>111</sup> Medicare Part D provided a prescription drug benefit to Medicare enrollees, and as a result it both expanded the population of seniors with access to prescription drug coverage<sup>112</sup> and increased the prices pharmaceutical companies could expect to recoup for many drugs sold to senior citizens who had previously been eligible only for Medicaid.<sup>113</sup> The passage of Medicare Part D has been empirically associated with increased pharmaceutical investment into drug classes with higher consumption among the Medicare population.<sup>114</sup> Medicare Part D is not

107. See John M. Golden & Hannah Jacobs Wiseman, *The Fracking Revolution: Shale Gas as a Case Study in Innovation Policy*, 64 EMORY L.J. 955, 959 (2015).

108. See, e.g., Michael J. Burstein & Fiona E. Murray, *Innovation Prizes in Practice and Theory*, 29 HARV. J.L. & TECH. 401, 402–03 (2016); see also WILLIAM W. FISHER III, PROMISES TO KEEP 199–258 (2004); Shavell & Ypersele, *supra* note 104, at 534–41.

109. See, e.g., Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049 (2004); see also notes 114–15, *infra*.

110. Some drugs, such as anesthetics used in surgery, are covered under Medicare Parts A and B as incidental to hospital or physician services. See, e.g., *Anesthesia*, MEDICARE.GOV (Sept. 25, 2016), <http://www.medicare.gov/coverage/anesthesia.html> [https://perma.cc/XL2S-PVFK].

111. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 26 and 42 U.S.C.).

112. KAISER FAMILY FOUND., PRESCRIPTION DRUG TRENDS 2010 5 (May 2010) (“Prior to January 1, 2006, . . . about one-quarter (27%) of seniors age 65 and older, and one-third of poor (34%) and near-poor (33%) seniors, had no drug coverage.”); see also Dana Gelb Safran et al., *Prescription Drug Coverage and Seniors: Findings from a 2003 National Survey*, HEALTH AFF. W5-152, W5-160 (Apr. 19, 2005), <http://content.healthaffairs.org/content/early/2005/04/19/hlthaff.w5.152.citation> (last visited Dec. 15, 2016).

113. See Frank & Newhouse, *supra* note 29, at 34, 36–37.

114. See Margaret E. Blume-Kohout & Neeraj Sood, *The Impact of Medicare Part D on Pharmaceutical R&D* 12–13 (Nat’l Bureau of Econ. Research, Working Paper No. 13857, 2008). But see David Dranove et al., *Pharmaceutical Profits and the Social Value of Innovation* 6–7 (Nat’l Bureau of Econ. Research, Working Paper No. 20212, 2014) (qualifying



the only example of this phenomenon, with other analyses examining the effects of individual coverage mandates or population shifts.<sup>115</sup>

The Advance Market Commitment (“AMC”) for the development of a vaccine targeted at strains of pneumococcal disease that are more prevalent in developing countries<sup>116</sup> is a closely related example of procurement. Originally theorized by economist Michael Kremer, the essential idea is simple: sponsors “commit to purchase a specified number of doses at a specified price if a vaccine meeting certain specifications were developed.”<sup>117</sup> Such a commitment both encourages R&D investment and promotes access. The vaccines resulting from the AMC have already been administered to over forty-seven million children in developing countries, and administration is continuing to increase.<sup>118</sup> Although the AMC is not without its critics,<sup>119</sup> none of the objections to its structure or pricing target the underlying economic logic.

Within the legal literature, health insurance has been traditionally conceived of as a mechanism for promoting patients’ access to healthcare technologies. As such, its potential to impact innovation incentives has been vastly underexplored. Although scholars have recognized the “close structural and functional similarities between

the findings of Blume-Kohout and Sood by noting that truly innovative activity takes longer to emerge).

115. Professor Amy Finkelstein has discovered that several policies designed to increase the uptake of vaccines (including Medicare’s 1993 decision to cover the flu vaccine) resulted in an increase in clinical trials for new vaccines. Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 556–57 (2004); Acemoglu & Linn, *supra* note 109, at 1084 (“A 1 percent increase in the potential market size for a drug category leads to approximately a 4 percent growth in the entry of new nongeneric drugs and new molecular entities.”).

116. *Pilot AMC for Pneumococcal Disease*, GAVI (June 1, 2008), <http://www.gavi.org/library/news/amc-updates/pilot-amc-for-pneumococcal-disease/> [<https://perma.cc/6UGF-QPDM>].

117. Kremer, *supra* note 24, at 83.

118. *Pneumococcal Vaccine Support*, GAVI, <http://www.gavi.org/support/nvs/pneumococcal/> [<https://perma.cc/U7FE-5CYC>]; *GAVI, the Vaccine Alliance*, GLOBAL AFF. CANADA, (July 18, 2016), [http://www.international.gc.ca/development-developpement/partners-partenaires/key\\_partners-partenaires\\_cles/GAVI.aspx?lang=eng](http://www.international.gc.ca/development-developpement/partners-partenaires/key_partners-partenaires_cles/GAVI.aspx?lang=eng) [<https://perma.cc/4UA3-7DEG>].

119. See, e.g., Donald W. Light, *GAVI’s Advance Market Commitment*, 375 LANCET 638 (2010); Megan Scudellari, *Are Advance Market Commitments for Drugs a Real Advance?*, 17 NATURE MED. 139 (2011); *A Spoonful of Ingenuity*, THE ECONOMIST (Jan. 7, 2010), <http://www.economist.com/node/15213715> [<https://perma.cc/QJR2-A8A3>]; Naren Karunakaran, *The Dark Side of Giving: The Rise of Philanthro-Capitalism*, THE ECONOMIC TIMES (Mar. 25, 2011), <http://economictimes.indiatimes.com/news/company/corporate-trends/dark-side-of-giving-the-rise-of-philanthro-capitalism/articleshow/7783864.cms> [<https://perma.cc/C372-ZSLR>]; Donald W. Light, *Advanced Market Commitments: Current Realities and Alternate Approaches*, HEALTH ACTION INT’L (2009), <http://haieurope.org/wp-content/uploads/2010/12/27-Mar-2009-Report-AMC-Current-Realities-Alternate-Approaches.pdf> [<https://perma.cc/K4WH-2KE2>].

some proposed prize systems for drugs and national prescription-drug insurance programs,”<sup>120</sup> they have not undertaken in-depth treatments of the issue.<sup>121</sup> To date, there has been no broader theoretical treatment of this question, nor has insurance as a lever been contextualized within the existing universe of innovation incentives or applied to either of the cases focused on here. This Article begins to fill this gap by systematically examining the innovative potential of prescription drug insurance.

#### IV. PRESCRIPTION DRUG INSURANCE AS AN INNOVATION INCENTIVE

This Part will analyze the economic and institutional features of prescription drug insurance, considering the ways in which its features both resemble and differ from those of many traditional innovation policy levers. As typically practiced, prescription drug insurance strongly resembles a prize system that is layered on top of the existing patent and FDA regulatory systems. However, its institutional features may have several advantages over those of prize systems as they are commonly discussed in the literature. This Part then goes on to consider the ways in which prescription drug insurance may mitigate the innovation distortions described in Part II. Like prizes, it is naturally suited to compensate for market-related distortions. But it also has particular advantages when compared to prizes, and even more interestingly, it may well be more amenable to narrow tailoring to fill the duration- and scope-related innovation distortions than is either patent or FDA law.

##### *A. Understanding Prescription Drug Insurance*

Appreciating the potential for prescription drug insurance to serve as an innovation incentive requires understanding its ability to create, alter, or destroy markets for any given pharmaceutical product. Decisions made by insurers about which products to cover and at what

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120. Roin, *supra* note 74, at 1013; *see also* Arti K. Rai, *The Ends of Intellectual Property: Health as a Case Study*, 70 L. & CONTEMP. PROBS. 125, 128–29 (2007); William Fisher, *Intellectual Property and Innovation: Theoretical, Empirical, and Historical Perspectives*, BERKMAN KLEIN CENTER 12 (May 2001), <http://cyber.law.harvard.edu/people/tfisher/Innovation.pdf> [<https://perma.cc/9RUA-BAJA>].

121. Thus far, the most detailed analysis comes in Professor Kevin Outterson’s consideration of the ways in which insurance might be altered to promote incentives for both innovation and conservation in the case of antibiotics. Kevin Outterson, *The Legal Ecology of Resistance: The Role of Antibiotic Resistance in Pharmaceutical Innovation*, 31 CARDOZO L. REV. 613, 645–55 (2010).

rates are critical to ensuring that patients have the ability to obtain and pay for any particular drug. An insurer deciding to provide reimbursement for a class of drugs, after not doing so previously, would effectively create a market for such a class. An insurer making the opposite decision would strike a blow to innovation incentives, as manufacturers could no longer be certain that patients could afford their products. An insurer decreasing an existing reimbursement rate might dampen or even destroy innovation incentives, if the reimbursement rate dipped below typical production costs.

In this sense, prescription drug insurance may be broadly understood as a “pull” mechanism of the type articulated by economists in the global health literature.<sup>122</sup> It is a reward provided *ex post*, after the development of a successful technology. And although patients may be charged small amounts for any given prescription,<sup>123</sup> drugs are paid for in large part not by the users of the technology, but by a much broader segment of the population. Since the focus here is on public health insurance programs, this funding typically comes from the tax system. There are benefits to incentives with these features, but there are also drawbacks, about which more will be discussed in Section IV.B, *infra*.

Although all national insurance schemes involve these features of *ex post* rewards and taxpayer funding, other features of prescription drug insurance vary across different programs both between and within nations. Most notably, programs differ on the key questions that determine the size of any reimbursement award: whether they must cover any particular technology, and if so, how much they will pay for it. For some programs these questions are independent, but for others they are intertwined such that the government will only offer to cover a particular technology at a specified price or range of prices.

The answers to these questions (and thus the potential reward to be reaped) differ by insurance program and depend on how a particular system allocates the balance of power between the private sector and the government. Like most other consumer goods, the size of the

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122. See, e.g., Kremer, *supra* note 24, at 83.

123. This amount generally takes the form of a co-pay or co-insurance. These amounts are not formally connected to the marginal cost of producing a drug, and they vary widely by drug, insurance plan, and even by the value of other prescriptions a given patient is receiving. See, e.g., *Get Help with Prescription Costs*, NAT'L HEALTH SERV. (2015), <http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Prescriptioncosts.aspx> [<https://perma.cc/LVT3-8M93>] (imposing a flat fee of £8.20 for most prescriptions); Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 § 2713 (2010) (requiring private plans to cover certain preventive health services without cost-sharing); Theodore R. Marmor & Jacob S. Hacker, *Medicare Reform and Social Insurance: The Clashes of 2003 and Their Potential Fallout*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 475, 486 n.46 (2005) (describing Medicare Part D's infamous “doughnut hole”).

reward a pharmaceutical company receives will largely be determined by how its drug performs in the market, primarily measured in this case by the number of times it is prescribed and the price of each prescription.<sup>124</sup> Relatedly, the development of pharmaceuticals still relies on decentralized, private information about what kinds of inventions are likely to be most valuable to pursue. But unlike most consumer goods, the government plays a far larger regulatory role in the healthcare technology context. Particularly in the area of prescription drugs, there are two primary ways in which the government's involvement in constructing a health insurance system influences the size of the reward a company can expect to receive.

First, the government's construction of a public health insurance system generally expands the population with the ability to purchase a particular pharmaceutical.<sup>125</sup> Health insurance that covers a given prescription drug serves as a subsidy enabling consumers to purchase the drug beyond the population that would be able to afford it absent insurance coverage. The degree to which insurance expands the potential market depends on the nation enacting the scheme. Most Western nations have national health insurance schemes that provide care for the entire population, although they differ in their precise funding and coverage.<sup>126</sup> The United States, by contrast, provides publicly-funded care only to particular groups of people, with the elderly (through Medicare), the poor (through Medicaid), and veterans (through the

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124. Of course, prizes can be structured in this way. *See, e.g.*, FISHER, *supra* note 108; Shavell & Ypersele, *supra* note 104, at 540–41. However, insurance does incorporate more market elements in the valuation of the product.

125. In some ways, this aspect of public health insurance might be viewed as making the system more, not less, market-driven. Patents are more helpful as innovation levers where market signals are good proxies for the social value of an innovation. Providing subsidies to populations that are otherwise unable to pay for drugs better aligns market signals and social value in this way. On this view, the United States's system prior to the Affordable Care Act — in which middle- and upper-class populations possessed insurance through their employers, but the lowest-income populations were more typically uninsured — simply perpetuates the kinds of biases considered in Part II. Providing prescription drug coverage to those who could not otherwise afford it, like seniors under Medicare Part D or low-income Americans, should in theory begin to equalize the situation.

126. Most countries have adopted one of two different models. The United Kingdom is the paradigm example of the national health insurance or Beveridge model, in which a country financing its healthcare system through taxes provides services largely free at the point of sale to all citizens. Timothy Stoltzfus Jost, *Why Can't We Do What They Do? National Health Reform Abroad*, 32 J.L. MED. & ETHICS 433, 433–34 (2004). Germany is the paradigm example of the social insurance or Bismarck model, where citizens must obtain insurance, but they pay for it on the basis of their income, not their risk status. *Id.* Social insurance systems are not administered by the government, but the prices charged by the insurers and providers are tightly regulated. *Id.* Each of these systems has been adopted by a range of countries. Even Medicare Part A resembles Germany's model in many respects. *Id.* at 434. For a more detailed history of these two models, see Henry E. Sigerist, *From Bismarck to Beveridge: Developments and Trends in Social Security Legislation*, 20 J. PUB. HEALTH POL'Y 474 (1999).

Department of Veterans Affairs) being the most prominent examples.<sup>127</sup>

Second, public health insurance schemes typically place some type of limit on the price a company may charge for its prescription drugs.<sup>128</sup> The details of this scheme differ by jurisdiction. The United Kingdom's public insurance system is perhaps the most stark example. In much of the UK, the National Institute for Health and Care Excellence ("NICE") has the authority to determine which drugs will be covered by the National Health System ("NHS").<sup>129</sup> A key factor NICE considers in its analyses is cost-effectiveness — NICE generally will not recommend that the NHS cover a drug which costs more than £20,000 to £30,000 (approximately \$30,000 to \$45,000 USD) per QALY<sup>130</sup> gained,<sup>131</sup> placing a ceiling on the price a company can feasibly charge for its product if they want it to be available to the public.<sup>132</sup>

In contrast, commentators typically view the price-setting in the United States' public insurance systems as representing a vastly different allocation of power between the private sector and the government. The United States' primary public insurance plans — Medicare and Medicaid — lack the kinds of formal price controls enjoyed by

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127. Each of these groupings is slightly generalized. In addition to covering individuals over 65, Medicare covers the long-term disabled and those with end-stage renal disease. 42 U.S.C. § 1395c (2012). Even today, in many states Medicaid does not cover all poor individuals, only those that fall into specified groups, such as children and pregnant women. See *infra* Part V for a more detailed discussion of Medicaid eligibility. Finally, not all veterans receive VA coverage — most must first meet a minimum duty requirement. *Health Benefits: Veterans Eligibility*, U.S. DEP'T OF VETERANS AFFAIRS (Dec. 8, 2015), <http://www.va.gov/healthbenefits/apply/veterans.asp> [<https://perma.cc/PKG9-XTDE>].

128. In theory, this is not an essential element of insurance schemes. Because health insurance may be understood as a two-part contract in which consumers pay a premium ex ante and a small co-pay ex post, it could be structured in such a way that consumers face lower prices but innovator drug companies continue to reap unconstrained profits. See, e.g., Darius N. Lakdawalla & Neeraj Sood, *Health Insurance as a Two-Part Pricing Contract*, (Nat'l Bureau of Econ. Research, Working Paper No. 12681, 2006).

129. *Can I Demand a Specific Treatment?*, NAT'L HEALTH SERV. (Oct. 6, 2015), <http://www.nhs.uk/chq/Pages/1317.aspx> [<https://perma.cc/A9DJ-9S2F>].

130. A QALY is calculated not only by considering the amount of time by which a given treatment will extend a patient's life, but also how healthy that person will be in that time. John Bronsteen et al., *Well-Being Analysis vs. Cost-Benefit Analysis*, 62 DUKE L.J. 1603, 1679–80 (2013). QALYs are particularly helpful in the area of cost-effectiveness, where the QALYs generated by two different interventions may be compared, but NICE has gone beyond this application by placing a dollar amount on each QALY.

131. Lesley Owen et al., *The Cost-Effectiveness of Public Health Interventions*, 34 J. PUB. HEALTH 37, 38 (2011). There is one exception to this. In response to public concerns that NICE has not recommended coverage of many expensive oncology medicines, the NHS has established a Cancer Drugs Fund to provide limited coverage for some of these therapies. See Darius N. Lakdawalla et al., *Careful Use of Science to Advance the Debate on the UK Cancer Drugs Fund*, 311 JAMA 25, 25 (2014).

132. Of course, it is likely that in practice this number functions as a floor as well.

other developed nations' healthcare systems.<sup>133</sup> Medicare and Medicaid cannot place price ceilings on drugs, nor can the federal government itself negotiate prices with drug manufacturers, leveraging its purchasing power to decrease costs below monopoly prices.<sup>134</sup> However, these programs are not powerless to limit drug prices. Medicare is primarily able to accomplish this through its use of privately administered Part D plans. Specifically, Medicare is not permitted to negotiate with drug companies — but the private prescription drug plans sold by the Centers for Medicare and Medicaid Services (“CMS”) are permitted to do so.<sup>135</sup> These contractors' bargaining power is likely less than that of purely private insurers, though, as there are background rules about the number and kinds of medications Part D plans must cover that limit their ability to threaten not to cover a treatment. Medicaid's price controls are more drastic, entitling state Medicaid programs to specified percentage discounts on the average manufacturer price of all pharmaceuticals.<sup>136</sup> State Medicaid programs are also empowered to negotiate further discounts.<sup>137</sup>

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133. The one notable exception is Oregon's experiment with cost-effectiveness control in 1989 and the early 1990s. *See generally* David C. Hadorn, *Setting Health Care Priorities in Oregon: Cost-Effectiveness Meets the Rule of Rescue*, 265 JAMA 2218 (1991); Caitlin J. Halligan, “Just What the Doctor Ordered”: *Oregon's Medicaid Rationing Process and Public Participation in Risk Regulation*, 83 GEO. L.J. 2697 (1995); Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015 (1997).

134. *See, e.g.*, DEP'T OF HEALTH AND HUMAN SERV. OFF. OF INSPECTOR GEN., OEI-03-10-00320, HIGHER REBATES FOR BRAND-NAME DRUGS RESULT IN LOWER COSTS FOR MEDICAID COMPARED TO MEDICARE PART D 3 (2011); Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832, w832 (2009).

135. *See* DEP'T OF HEALTH AND HUMAN SERV. OFF. OF INSPECTOR GEN., *supra* note 134, at 3; *see also* KAISER FAMILY FOUND., THE MEDICARE PART D PRESCRIPTION DRUG BENEFIT (2015), <http://files.kff.org/attachment/fact-sheet-the-medicare-part-d-prescription-drug-benefit> [https://perma.cc/7ATB-SN5H].

136. *See* text accompanying notes 210–15, *infra* for a more detailed explanation. Manufacturers set prices knowing that this rebate exists, but their ability to increase their prices to offset its existence is limited. Sovaldi, a drug capable of curing Hepatitis C, is now a cautionary tale. When Gilead priced Sovaldi at \$84,000 per course in the United States, the fact that Medicaid would pay far lower rates was absent from the intense media scrutiny. Gilead was excoriated by members of both Houses of Congress, who asked Gilead to justify publicly the price of Sovaldi. *See, e.g.*, *Wyden and Grassley Seek Details on Sovaldi Pricing*, S. COMM. ON FIN. (July 11, 2014), <http://www.finance.senate.gov/newsroom/chairman/release/?id=e1639d08-74d8-4f0a-88dc-532875ccc706> [https://perma.cc/9CFJ-7T75]; *see also* *Ranking Members Waxman and DeGette Call for Hearings on Medicare Part D Impact of High Costs of Sovaldi*, H. COMM. ON ENERGY & COM. (June 19, 2014), <https://degette.house.gov/media-center/press-releases/ranking-members-degette-and-waxman-call-for-hearings-on-medicare-part-d> [https://perma.cc/B5HU-VN6Y]. As described in Part V, *infra*, companies also face pressure from states if they set a price that is perceived to be too high.

137. *See* DEP'T OF HEALTH AND HUM. SERV. OFF. OF INSPECTOR GEN., *supra* note 134, at 6 n.26.

In many ways, this analysis aligns with scholars who have noted the close resemblance between prescription drug insurance and theorized prize systems.<sup>138</sup> Both award payouts *ex post*,<sup>139</sup> and just as prizes are funded by taxpayer subsidies,<sup>140</sup> the insurance market spreads the cost of any particular technology across a broader population of taxpayers.<sup>141</sup> Further, both prizes and insurance reserve a significant role for the government in setting the size of the award for any particular technology.<sup>142</sup>

In general, this is a favorable comparison. As a theoretical matter, a government-set prize system has the potential to avoid both the systemic underinvestment and deadweight loss problems that attend the patent system. In a classic prize system, an innovator who produces a desired invention is paid a government-set amount, and in exchange the innovator relinquishes their intellectual property rights,<sup>143</sup> allowing their invention to be produced at cost.<sup>144</sup> If the government has set the value of the prize appropriately — above that which the innovator could expect to recoup in the market — it can encourage inventors who would otherwise have been deterred by the systemic underinvestment problem to proceed with their work.<sup>145</sup> And since the invention could then be produced and sold at cost, rather than at the monopoly prices that lead to deadweight loss, in theory there should be no consumers who value the product at more than marginal cost but

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138. See, e.g., Roin, *supra* note 74.

139. Hemel & Ouellette, *supra* note 27, at 333.

140. *Id.* at 346; Shavell & Ypersele, *supra* note 104, at 544. This “who pays” question implicates serious moral and social debates. Questions about what we as a society owe our least well-off members, or about what we as citizens of the world owe the global poor, are not within the scope of this Article, and therefore I set aside these questions for now. For a discussion of these social and ethical issues, see generally William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581 (2006); Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 993–1006 (2012).

141. Hemel & Ouellette, *supra* note 27, at 346.

142. *Id.* at 327.

143. In reality, most prizes today do not require the winner to relinquish their intellectual property, although some may require that contestants negotiate a license with the prize offeror. Particularly in the context of many government-set prizes, the award amounts are typically small and the idea is to spur creativity and bestow public praise. See, e.g., Def. Advanced Research Projects Agency, *DARPA Forecasting Chikungunya Challenge*, INNOCENTIVE CHALLENGE (Aug. 15, 2014), <https://www.innocentive.com/ar/challenge/9933617> [<https://perma.cc/7PGL-CYTG>] (announcing a challenge with a top prize of \$150,000 for the development of a method to forecast the spread of Chikungunya virus, and noting that DARPA may negotiate a license for a solver’s intellectual property, if any exists).

144. See, e.g., Shavell & Ypersele, *supra* note 104, at 528–29.

145. Importantly, the innovator should not be permitted to recoup the full social value of the invention; there is an optimal returned fraction of total social value that maximizes overall social welfare. See, e.g., Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397, 439–42 (2009).

are unable to afford it.<sup>146</sup> The close resemblance between prescription drug insurance and traditional prize systems should cause us to be optimistic about its potential to address those innovation distortions.

Despite reasons to be optimistic, there are also problems with prize systems. A primary one is that a key phrase above — “if the government has set the value of the prize appropriately” — does the heavy lifting in creating the economic advantages of prizes. If the government’s information about the social value of the invention is inferior to the private sector’s information, it might under- or over-value the prize, with either case leading to inefficiencies.<sup>147</sup> There are, of course, other types of risks to be concerned about with prize systems, including credibility of awarding the prize,<sup>148</sup> mismanagement, or politicization.<sup>149</sup> Yet, putting those concerns aside for now, the patents-versus-prizes debate often comes down to the question of private versus public information and the identity of the actor setting the size of the reward.<sup>150</sup>

But insurance also differs in important ways from the standard conception of prize systems. First, although the economic literature views prizes as an alternative to the patent system, insurance instead functions as a supplement to the patent system. This matters for two primary reasons. First, insurance pays the supplier of a drug, regardless of whether that supplier is the initial innovator. Coupling insurance with the existing patent and FDA systems ensures that any innovation incentive implemented through insurance will go to the innovator, at least for some period of time. Second and more problematically, in theory the fact that patents are retained under an insurance system (as opposed to a true prize system) means that the dark side of patents — deadweight loss — will continue to operate to the detriment of consumers. Although in general this is the case, as I discuss in Part V, *infra*, this is not true in public health insurance, where consumer payments are highly regulated in a way that removes this concern.

A second key way in which insurance differs from a traditional prize fund is that insurance operates within a heavily regulated market, an additional variable which modulates its ability to affect innovation incentives. That is, in countries like the UK, where nearly the

146. In reality, of course, the problem of *ability* to pay becomes relevant.

147. HEMEL & OUELLETTE, *supra* note 27, at 327; *see also* Shavell & Ypersele, *supra* note 104, at 535.

148. *See* BURSTEIN, *supra* note 108, at 405–06, 413–14 (discussing the British Longitude Prize).

149. HEMEL & OUELLETTE, *supra* note 27, at 327.

150. Other innovation levers may also be characterized in terms of these factors, with tax credits relying primarily on private information, and government grants depending primarily on government information. *See, e.g., id.* at 333.



entire market is defined by reference to their national insurance structure, the incentive effect of altering reimbursement for any particular technology is likely to be greater than in the U.S., where our system is fragmented and defined by a number of separate insurance structures.

More fundamentally, though, insurance represents a series of policy choices. Even if consumers are willing to pay for cosmetic drugs, governments may choose to manipulate the insurance scheme to disfavor these (or other categories of) drugs. Prize theory, on the other hand, largely views prizes as avoiding these types of social choices.

As such, although prescription drug insurance broadly resembles prize systems, there are critical differences between them. But in many ways, prescription drug insurance can helpfully be analyzed as a quasi-prize system, in which the government doles out the reward based on the frequency of use of the drug.<sup>151</sup> Keeping these various dimensions of prescription drug insurance in mind, the remainder of this Part will consider whether prescription drug insurance has the potential to compensate for the innovation distortions identified in Part II.

*B. Using Prescription Drug Insurance to Remedy the Innovation Distortions in Patent Law*

Recall from Part II that patent law and FDA regulation introduce two different types of distortions into the innovation incentives they create: ones that are traceable to the doctrines of duration and scope at the heart of the two regimes, and ones that are traceable to the market-based nature of the regimes. This Section will primarily consider the ways in which prescription drug insurance, broadly conceived, may compensate for the market-based distortions in patent law in much the way that prizes can. It will then consider a more difficult case: whether prescription drug insurance can also be used to remedy the duration- and scope-shaped distortions. In doing so, it will explore the institutional competencies of insurance relative to those of prizes or the patent system.

Prescription drug insurance seems largely able to solve at least the deadweight loss concerns of the patent system, if not also the underinvestment concerns. The deadweight loss problem is simple to address. Although the government itself does not pay the marginal cost for any given therapy, consumers who would otherwise be priced

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151. Prize systems adopting this approach have been theorized in both the copyright and patent contexts, *see, e.g.*, FISHER, *supra* note 108; Shavell & Ypersele, *supra* note 104, at 540–42, and they are typically thought to be superior to unconditional prizes. *Id.* at 531.

out of the system receive subsidies that enable them to purchase the drugs they need.<sup>152</sup>

The underinvestment concern is more complicated, both in theory and practice. In theory, it is of course possible that a public insurance system could replicate this function of a prize system and construct a per-unit price that takes account of social benefits, which might not accrue to the individual. For instance, in a vaccination program, the government ought to take account of social benefits like herd immunity in setting its procurement price. Even in the context of traditional pharmaceuticals, the government might recognize that by providing certain prescription drugs now, it can save on other costs — including expensive healthcare interventions like surgery or extended hospitalization — and those forgone social costs could be incorporated into the social value of any given drug.<sup>153</sup> Cross-sectoral savings, such as long-term disability or welfare payments, might be achieved by appropriate use of preventive care services, and a government internalizing those costs might incorporate them in pricing a given pharmaceutical.

Yet in practice, national health insurance systems do not explicitly set prices by reference to social value. The closest case is NICE, which as noted above measures cost-effectiveness only by reference to the QALYs a drug can be expected to produce for any particular individual.<sup>154</sup> But most national health insurance schemes do not consider even these kinds of value questions. These systems are structured for the purpose of providing access to medicines, rather than providing incentives to pharmaceutical companies. As such, their primary concern seems to be obtaining the lowest possible price, rather than affirmatively trying to pay more for drugs with higher social value.<sup>155</sup>

That said, prescription drug insurance does have at least the potential to address the market-shaped innovation distortions in patent law. And importantly, it can be structured to avoid the problem of aggregating public and private information that lies at the heart of the patents-versus-prizes debate. Specifically, the government only needs

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152. Lakdawalla & Sood, *supra* note 128.

153. The United States government typically takes account of such benefits in promulgating regulations. *See, e.g.*, Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 18, 2011); FDA Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-01, 3972 (Jan. 24, 2006).

154. *See supra* text accompanying notes 129–32.

155. Even in such a case, in reality the amount a pharmaceutical company can expect to recoup under a national health insurance program may be higher than the amount it could expect to recoup in an unregulated market, providing a reward that is closer to a given invention's social value. The broad expansion of the population with the ability to obtain the drug may outweigh any decrease below the monopoly price the insurer can negotiate.

to be able to observe (1) the social value of a given pharmaceutical, and (2) the frequency of its use. If the social value of a pharmaceutical is measured in large part by its effectiveness and the overall healthcare burden it alleviates, the government is in a position to directly observe those facts by virtue of its dual roles as pharmaceutical regulator and health insurer. The government in its capacity as insurance company and reimbursement manager also has precise information about the frequency of use of any particular drug, especially in jurisdictions where the healthcare system has been almost completely nationalized, like the United Kingdom, rather than being administered largely by private contractors, like the United States. This allows the government to observe the frequency of use of the relevant product without relying on self-reported information from the drug maker.<sup>156</sup>

Prescription drug insurance's ability to address the duration- and scope-shaped innovation distortions, however, is less clear. In theory, neither the insurance system nor a prize system is naturally suited to do so. Nothing intrinsic to an insurance system requires nations to pay more for drugs that take longer to navigate the development process but are of equal social value to drugs that were approved more quickly. As such, the question is whether an insurance scheme can and should be designed to do this in a targeted fashion. We should rightfully be loath to create a blanket increase in the prices reimbursed by insurance programs, as much like in the patent context, the effect would be only to perpetuate existing biases in the system.

The real question, therefore, is whether prescription drug insurance schemes can be narrowly tailored to enable governments to provide a particular incentive for the development of drugs that are disadvantaged under the current patent and FDA regulatory systems. Part III rejected the idea of tailoring patent law and FDA regulation themselves, and suggested that tailoring those legal regimes would most likely be practically unworkable, subject to socially costly gamesmanship, or at best politically unwise. This Section seeks to embrace (cautiously, but optimistically) the potential to tailor prescription drug insurance in this way.

Specifically, several institutional and administrative features of national prescription drug insurance systems as they are typically constructed render them superior to patents for purposes of creating narrowly tailored incentives. Primarily, many scholars have pointed out the ways in which Congress lacks the ability and institutional capacity to tailor the patent system.<sup>157</sup> As Professors Dan Burk and Mark Lem-

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156. The United States has a mechanism to observe this information. See *infra* text accompanying notes 216–21 (explaining the Branded Prescription Drug Fee).

157. See, e.g., Stuart Minor Benjamin & Arti K. Rai, *Fixing Innovation Policy: A Structural Perspective*, 77 GEO. WASH. L. REV. 1, 40–46 (2008).

ley have recognized, Congress lacks the technological expertise to appreciate the concerns posed by different areas of technology, rendering suspect its ability to establish a reasoned time-to-market adjustment.<sup>158</sup> Further, the time gap between the passage of any statute and the accrual of its benefits may render the statute itself obsolete given the pace of technological progress, as occurred in the context of the Semiconductor Chip Protection Act.<sup>159</sup> Finally, most any statute is highly subject to rent-seeking behavior.<sup>160</sup> And since the U.S. Patent and Trademark Office (“USPTO”) lacks substantive rulemaking authority,<sup>161</sup> Congress cannot at present delegate these functions to an expert agency.<sup>162</sup>

These concerns are much smaller in the context of prescription drug insurance, where the relevant oversight body would likely be some combination of agencies that are already engaged in closely related activities. In the United States, the FDA and CMS are experts in the kinds of regulatory questions that would need to be addressed for an insurance scheme to be tailored based on value and quantity, as Part V, *infra*, discusses in greater detail. Further, external controls like those imposed by the Office of Information and Regulatory Affairs would constrain any attempts to game the rules.

There are a range of other, smaller benefits as well. One concern scholars have expressed with the idea of tailoring patent length or scope or with using a system of prizes to replace patents is the potential for such changes to violate the United States’ treaty obligations under the Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Agreement.<sup>163</sup> Because prescription drug insurance is layered on top of the patent system, it does not pose such concerns. Another often-expressed concern with the creation of a broad prize system is the need to develop new infrastructure to sustain it.<sup>164</sup> Since the government is already providing prescription drug insurance, start-up

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158. *Id.*

159. The Act established a set of rules specifically designed to protect semiconductors. Passed in 1984 after years of debate, the statute has almost never been used. Burk & Lemley, *supra* note 25, at 1636–37.

160. *Id.* at 1637.

161. Michael J. Burstein, *Rules for Patents*, 52 WM. & MARY L. REV. 1747, 1755 (2011); *see also* Ass’n for Molecular Pathology v. U.S. Pat. & Trademark Off., 653 F.3d 1329, 1380 (Fed. Cir. 2011) (Bryson, J., concurring in part and dissenting in part).

162. It is unlikely that Congress would give the USPTO substantive rulemaking authority only now, when it has declined to do so several times in recent years. *See, e.g.*, Letter from Gary Locke, Sec’y of Commerce, to Members of Senate Judiciary Committee (Oct. 5, 2009), [http://www.uspto.gov/sites/default/files/aia\\_implementation/locke-letter-oct-05-2009.pdf](http://www.uspto.gov/sites/default/files/aia_implementation/locke-letter-oct-05-2009.pdf) [<https://perma.cc/276W-4DD8>].

163. *See, e.g.*, DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT 97 (2009); Eisenberg, *supra* note 27.

164. Burstein & Murray, *supra* note 108, at 414.

costs here would be low, perhaps requiring only the creation of a subsidiary office within the Department of Health and Human Services (“HHS”), staffed from both the FDA and CMS.

There are, however, three practical concerns to address with the implementation of such a system: agency capture, credible commitment problems, and budgetary realities. First and perhaps most important are problems relating to agency capture. The fear is that the primary interest groups affected (largely pharmaceutical companies) would seek to influence the relevant public insurance agency to adopt a policy contrary to the broader public interest and provide special incentives to industry where they are not needed to induce drug development.<sup>165</sup> For example, a company may aim to secure special incentives for a class of diseases that does not require them or may fight for higher reimbursement rates than it would need to move forward with drug development.

Agency capture is of course a concern for any reward scheme that is run through administrative agencies, including the patent system.<sup>166</sup> But time and experience have demonstrated that different agencies have varying capacities for resilience in the face of interest group pressure. And although the FDA and CMS are not typically thought of as independent agencies in the sense in which that term is often used,<sup>167</sup> they have not been susceptible to capture in the way that other agencies, such as the Consumer Product Safety Commission (“CPSC”), have been.<sup>168</sup>

Specifically, the FDA and CMS have a long history of regulating a range of industries, including pharmaceutical companies that have had reason to lobby and attempt to influence the agencies. Professor Dan Carpenter’s canonical treatment of the FDA’s cultivation of its reputation observes that “FDA regulatory decisions have not, moreover, consistently favored the largest and most powerful firms in the industry, as capture theory predicts.”<sup>169</sup> Professor Barkow, seeking to identify additional institutional design features supporting agency independence, points to the technical expertise required of the FDA

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165. George J. Stigler, *The Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3, 3 (1971); Michael A. Livermore & Richard L. Revesz, *Regulatory Review, Capture, and Agency Inaction*, 101 GEO. L.J. 1337, 1343 (2013).

166. See Melissa F. Wasserman, *The Changing Guard of Patent Law: Chevron Deference for the PTO*, 54 WM. & MARY L. REV. 1959, 2013–17 (2013).

167. Jacob E. Gersen, *Designing Agencies*, in RESEARCH HANDBOOK ON PUBLIC CHOICE AND PUBLIC LAW 333, 347 (Daniel A. Farber & Joseph O’Connell eds., 2010); see also Lisa Schultz Bressman & Robert B. Thompson, *The Future of Agency Independence*, 63 VAND. L. REV. 599, 610–11 (2010).

168. Rachel E. Barkow, *Insulating Agencies: Avoiding Capture Through Institutional Design*, 89 TEX. L. REV. 15, 71 (2010) (describing the CPSC as one of “the least politically independent . . . agencies in government”).

169. DANIEL CARPENTER, REPUTATION AND POWER 10 (2010).

Commissioner in agreeing that the FDA is comparatively more independent than other such agencies.<sup>170</sup> Indeed, the 2011 outrage from the regulatory community when HHS overruled an FDA decision regarding the morning-after pill on seemingly political grounds provides additional evidence regarding the strength of the FDA's independence.<sup>171</sup>

Although there has been less scholarly focus on CMS, scholars have not singled it out as an agency susceptible to capture. Further, the additional features Professor Barkow identifies would seem to affirmatively support CMS's independence, particularly in the Medicaid context, as its decisions are often constrained by its relationships with state governments.<sup>172</sup> This is of course not to say that the FDA and CMS could never be susceptible to interest group pressure.<sup>173</sup> But over time, the FDA and CMS have been comparatively resilient to interest group capture in a way that has not been true of other administrative agencies.

It is also critical to consider the alternative to running a non-patent reward system through FDA or CMS, which is not an ideal world even when involving model administrative agencies. Instead, it is a world in which either Congress directly offers a prize-like reward or in which a new agency is set up for that very purpose. Congress is likely more, not less, susceptible to capture than are the FDA and CMS. Further, as noted above and explored in more detail in Part V, *infra*, Congress is insufficiently expert in the types of information it would need to make the relevant decisions. And a new prize agency, of unknown provenance and with an undetermined internal culture, may similarly be more, not less, susceptible to capture. It is a strength, not a weakness, of regulating rewards through insurance that such a method locates decision-making authority within agencies that have a long history of dealing with pressures from precisely the same actors who would now have an additional, but not unfamiliar, reason to lobby the agencies.

A second concern is the problem of credible commitment that Professors Burstein and Murray have detailed in the context of prize systems.<sup>174</sup> The quintessential illustration of this problem is the 1714 prize of £20,000 offered by the British government for the development of a method that would reliably calculate longitude while at

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170. Barkow, *supra* note 168, at 47.

171. See Adrian Vermeule, *Conventions of Agency Independence*, 113 COLUM. L. REV. 1163, 1207–09 (2013).

172. Barkow, *supra* note 168, at 53–54.

173. See, e.g., Merrill Goozner, *Conflicts of Interest in the Drug Industry's Relationship with the Government*, 35 HOFSTRA L. REV. 737, 738–42 (2006).

174. See generally Burstein & Murray, *supra* note 108.

sea.<sup>175</sup> Despite John Harrison's development of an ingenious solution, the government refused to award the prize for many years, for a wide variety of reasons. Some were administrative pathologies involving conflicts of interest with other contestants. Others stemmed from the ambiguity of the statute.<sup>176</sup> Still others were scientific — Harrison had solved the problem using a method that others had not considered, calling its appropriateness into question.<sup>177</sup> Concerns about credibly committing to awarding a given prize while at the same time remaining open to unforeseen scientific advances remain today.

These concerns would surely need to be addressed in the alteration of any prescription drug insurance scheme with the intention to increase innovation incentives, and I will consider them in more detail *infra*.<sup>178</sup> For now, though, it is enough to say that patent law suffers from its own commitment problems. Once awarded, a patent remains vulnerable to challenge both administratively and through the court system.<sup>179</sup> Uncertainty in these areas is pervasive, and although policymakers must attempt to manage it, its presence is in no sense disqualifying. And although an FDA exclusivity period is much less vulnerable to challenge once it is awarded,<sup>180</sup> the improbability that any particular drug will survive the FDA review process make its award *ex ante* highly uncertain.

The third and final practical concern is budgetary. Patent rewards and FDA exclusivity periods are primarily administered “off-budget” in the sense that they generally “do not involve a direct expenditure of government funds.”<sup>181</sup> Providing longer or broader patent or FDA rights therefore provides a benefit to innovators without observably affecting the federal deficit.<sup>182</sup> Prizes more broadly and prescription drug insurance more specifically, by contrast, do require direct government expenditures,<sup>183</sup> and as such the political calculus of creating a prize system or expanding our governmental insurance schemes is

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175. *Id.* at 405.

176. *Id.* at 405–06.

177. Hemel & Ouellette, *supra* note 27, at 327 n.120.

178. *See infra* Section V.B.

179. Heled, *supra* note 27, at 431.

180. *Id.* at 432.

181. Robert P. Merges, *The Economic Impact of Intellectual Property Rights: An Overview and Guide*, 19 J. CULTURAL ECON. 103, 111 (1995). Of course, the government must operate the USPTO, but it is primarily funded by user fees. Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking?: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 69 (2013).

182. Merges, *supra* note 181, at 111.

183. Of course, some of these costs are already being borne, as we currently provide public health insurance to a large portion of the population. The change in expenditures might be relatively small.

typically more negative. Many legislators and interest groups will typically oppose an increase in direct spending of this type.

But these benefits of the patent system are illusory. First, although the costs may not be accounted for in the federal budget, the consumer ultimately pays higher prices for patented goods, creating a “shadow tax” in the system.<sup>184</sup> That is, although these higher prices “do[] not show up in annual appropriations or deficit calculations,” they are “ultimately borne by consumers (and thus by taxpayers).”<sup>185</sup> If the total cost to the taxpayer is equal under either system, the problem, then, is to make the total, systemic costs of each system apparent — and not simply the on-budget governmental expenditures.

Second, patent rewards and FDA exclusivity periods are not always off-budget in the prescription drug context, relative to the situation involving most other consumer goods. Because CMS itself purchases prescription drugs, if a longer patent or FDA exclusivity period resulted in higher costs for CMS, those costs could be considered by the Congressional Budget Office (“CBO”) in its analysis of any such extension. However, the fact that the CBO only considers costs incurred within five or ten years of the passage of any particular law<sup>186</sup> means that any additional costs would not appear in the CBO’s scoring of the relevant extension, as by definition an extension to patents or FDA exclusivity periods would take place years in the future. Here too, though, any innovation incentive implemented through a CMS insurance system would likely not take effect until years in the future, when the relevant drugs had been developed.

Third and finally, even if some drugs were reused for neglected purposes within a shorter time frame, the CBO does recognize that when reimbursements for particular health technologies rise, systemic costs may fall. Medicare again provides an illustrative example. When Medicare beneficiaries are asked to contribute more to the cost of their prescription drugs or physician visits, overall Medicare spending goes up, not down.<sup>187</sup> Patients respond to increased cost-sharing by reducing their consumption of both necessary and unnecessary care, leading to increased hospital utilization.<sup>188</sup> As a result, the CBO now takes overall Medicare spending into account when considering the

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184. Hemel & Ouellette, *supra* note 27, at 312.

185. *Id.*

186. CONGRESSIONAL BUDGET OFFICE, PRODUCTS: COST ESTIMATES (2015), <https://www.cbo.gov/about/products> [<https://perma.cc/UT53-WEAS>].

187. See, e.g., Amitabh Chandra, Jonathan Gruber, & Robin McKnight, *Patient Cost-Sharing and Hospitalization Offsets in the Elderly*, 100 AM. ECON. REV. 193 (2010).

188. *Id.* at 204–05. See generally JOSEPH P. NEWHOUSE, THE HEALTH INSURANCE STUDY — A SUMMARY (RAND Corporation, 1974), <http://www.rand.org/content/dam/rand/pubs/reports/2009/R965-1.pdf> [<https://perma.cc/Y98N-LS8N>].



implications of any individual policy proposal.<sup>189</sup> To the extent that implementing an innovation incentive through the insurance system would increase costs in one portion of the system, the CBO could capture decreases elsewhere.

This Part has remained largely theoretical, considering the general features of prescription drug insurance schemes and the potential, broadly conceived, of such insurance to compensate for the innovation distortions in patent law and FDA regulation. The next Part will provide a concrete example of how this might be accomplished.

## V. ANALYZING A REAL-WORLD CASE STUDY: MEDICAID

The previous Part examined the potential of prescription drug insurance to serve as an innovation incentive. This Part grounds that hypothetical treatment and explores in detail a sample of the potential modifications that might be made to a particular national insurance scheme — the United States' Medicaid system — to enable it to incentivize innovation more purposively. This Part will first provide a brief introduction to Medicaid, with special attention to the way in which Medicaid pays for prescription drugs. The principal features of Medicaid's payment scheme are logical when considered from an access perspective; they effectively make it easier for needy patients to afford existing treatments. However, many of Medicaid's most access-enhancing features may simultaneously decrease the incentives for pharmaceutical companies to invest in drugs that would primarily be prescribed for low-income populations. This Part will then consider a range of possible modifications to the way in which Medicaid pays for drugs in an effort to illustrate insurance's innovative potential.

### A. Medicaid's History and Mechanics

Medicare and Medicaid were enacted together as part of the Social Security Amendments of 1965.<sup>190</sup> But unlike Medicare, which is almost exclusively federally run and administered, Medicaid is a classic cooperative federalism program<sup>191</sup> jointly administered between

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189. CONG. BUDGET OFFICE, OFFSETTING EFFECTS OF PRESCRIPTION DRUG USE ON MEDICARE'S SPENDING FOR MEDICAL SERVICES 4–6 (2012).

190. *Key Milestones in Medicare and Medicaid History, Selected Years: 1965–2003*, HEALTH CARE FIN. REV., Winter 2005, 1 (2005), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/05-06Wingp1.pdf> [<https://perma.cc/C6QZ-9V98>].

191. Theodore W. Ruger, *Of Icebergs and Glaciers: The Submerged Constitution of American Healthcare*, 75 LAW & CONTEMP. PROBS. 215, 224 (2012).

the federal government and the states.<sup>192</sup> States are statutorily empowered to seek waivers to Medicaid's general framework, allowing them to experiment with new delivery systems or expand coverage to new populations.<sup>193</sup> As such, although the broad strokes of the program remain consistent throughout the country, every state's program differs in the details of its implementation. Each state even differs in the level of support it receives from the federal government — states receive federal matching payments that depend on both their own expenditures and state per capita income.<sup>194</sup>

When it was first enacted, Medicaid was largely conceived of as providing health insurance to the “deserving poor,”<sup>195</sup> including children, pregnant women, parents of minor children, and elderly<sup>196</sup> and disabled individuals.<sup>197</sup> Although the Affordable Care Act (“ACA”) attempted to impose a mandatory Medicaid expansion that would have covered everyone below 138% of the poverty line,<sup>198</sup> in *National Federation of Independent Business v. Sebelius*,<sup>199</sup> the Supreme Court effectively made the Medicaid expansion optional for states.<sup>200</sup> At

192. Abbe R. Gluck, *Intrastatutory Federalism and Statutory Interpretation: State Implementation of Federal Law in Health Reform and Beyond*, 121 *YALE L.J.* 534, 562, 577 (2011).

193. *Id.* at 563; see also Public Welfare Amendments of 1962, 42 U.S.C. § 1315 (1988) (providing for section 1115 waivers).

194. *Federal Medical Assistance Percentages or Federal Financial Participation in State Assistance Expenditures FMAP*, DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF THE ASSISTANT SECRETARY FOR PLANNING & EDUCATION (2015), <http://aspe.hhs.gov/health/fmap.cfm> [<https://perma.cc/8AUK-SG9F>]; see also KAISER FAMILY FOUND., MEDICAID FINANCING: AN OVERVIEW OF THE FEDERAL MEDICAID MATCHING RATE (FMAP) (2012). States with the lowest matching percentage, like Massachusetts, receive one dollar from the federal government for every dollar they spend. Mississippi, with the highest matching percentage, receives \$2.87 from the government for every dollar it spends. KAISER FAMILY FOUND., FEDERAL MEDICAL ASSISTANCE PERCENTAGE (FMAP) FOR MEDICAID AND MULTIPLIER, FY 2016 (Oct. 11, 2016), <http://kff.org/medicaid/state-indicator/federal-matching-rate-and-multiplier/> [<https://perma.cc/U9X4-FXMZ>].

195. See David Orentlicher, *Medicaid at 50: No Longer Limited to the “Deserving” Poor?*, 15 *YALE J. HEALTH POL'Y L. & ETHICS* 185, 185–86 (2015).

196. Seniors whose income and assets are sufficiently low qualify for both Medicare and Medicaid. There are currently nearly 10 million of these “dual eligibles.” KAISER FAMILY FOUND., MEDICAID'S ROLE FOR DUAL ELIGIBLE BENEFICIARIES (2013), <https://kaiserfamilyfoundation.files.wordpress.com/2013/08/7846-04-medicaids-role-for-dual-eligible-beneficiaries.pdf> [<https://perma.cc/G25C-83RT>].

197. Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 *YALE J. HEALTH POL'Y L. & ETHICS* 67, 70 (2015).

198. *Medicaid Expansion and What it Means for You*, HEALTHCARE.GOV (2015), <https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/> [<https://perma.cc/33WE-T67H>].

199. 132 S. Ct. 2566 (2012).

200. The Court held that although the Secretary of Health and Human Services could not constitutionally condition the grant of existing Medicaid funds on a state's failure to expand Medicaid, she could offer additional funds to states choosing to expand Medicaid. *Id.* at 2607.

present, thirty-one states have opted into the expansion,<sup>201</sup> meaning that in many states non-disabled childless adults still have little or no Medicaid coverage.<sup>202</sup>

The federal government does not require that state Medicaid programs cover outpatient prescription drugs, but all states have chosen to include such drugs in their coverage.<sup>203</sup> That choice comes with a set of responsibilities. States must cover all FDA-approved drugs, with a few classes of exceptions, such as drugs used for cosmetic purposes.<sup>204</sup> States are also limited in the amount of cost-sharing obligations they can impose on Medicaid beneficiaries, and for some populations (such as children and pregnant women under a certain percentage of the poverty line) they cannot impose cost-sharing obligations at all.<sup>205</sup>

But states are permitted to engage in utilization management strategies in an effort to control their prescription drug costs, although these strategies also have limits. States may subject drugs to prior authorization, in which case a patient's physician must justify why the drug is medically necessary.<sup>206</sup> Prior authorization is often coupled with step therapy, in which individuals are required to use older, cheaper therapies before gaining access to a newer drug, or in which individuals must meet some level of illness to qualify.<sup>207</sup> Medicaid may also use formularies to restrict access to some drugs, but only where substitutes exist.<sup>208</sup> A minority of states also impose limits

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201. KAISER FAMILY FOUND., CURRENT STATUS OF STATE MEDICAID EXPANSION DECISIONS (2016), <http://kff.org/health-reform/slide/current-status-of-the-medicaid-expansion-decision/> [<https://perma.cc/H7W6-NP2C>].

202. As with the original passage of the Medicaid statute, however, this process is likely to take some time. The last state to join Medicaid, Arizona, did so seventeen years after the law's passage. Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 484 n.69 (2011); see also KAISER FAMILY FOUND., MEDICAID TIMELINE (2015), <http://kff.org/medicaid/timeline/medicaid-timeline/> [<https://perma.cc/FPA5-P2BZ>].

203. Julia Paradise, *Medicaid Moving Forward*, KAISER FAMILY FOUND. (Mar. 9, 2015), <http://kff.org/health-reform/issue-brief/medicaid-moving-forward/> [<https://perma.cc/NGU7-ADJ3>].

204. Social Security Act § 1927, 42 U.S.C. § 1396r-8(d)(2)(C) (2006).

205. KAISER FAMILY FOUND., PREMIUMS AND COST-SHARING IN MEDICAID (2013), <https://kaiserfamilyfoundation.files.wordpress.com/2013/02/8416.pdf> [<https://perma.cc/6ET6-XED7>].

206. 42 U.S.C. § 1396r-8(d)(1)(A).

207. For example, the state of Illinois imposes 25 separate requirements before Sovaldi, mentioned in note 136, *supra*, can be prescribed. ILL. DEP'T OF HEALTHCARE AND FAMILY SERVS., INFORMATIONAL NOTICE RE: PRIOR AUTHORIZATION OF SOVALDI AND OTHER MEDICATIONS FOR THE TREATMENT OF CHRONIC HEPATITIS C (Aug. 8, 2014), <https://www.illinois.gov/hfs/MedicalProviders/notices/Pages/pm140808a.aspx> [<https://perma.cc/LL9W-TAM7>]; see also Joseph Walker, *Costly Vertex Drug Is Denied, and Patients Sue*, WALL ST. J. (July 16, 2014), <http://www.wsj.com/articles/costly-drug-vertex-is-denied-and-medicaid-patients-sue-1405564205> (last visited Dec. 15, 2016).

208. 42 U.S.C. § 1396r-8(d)(4)(C) (noting that drugs which have a "significant, clinically meaningful therapeutic advantage" over included drugs may not be excluded).

(which can be circumvented, but only with some inconvenience) on the number of prescriptions Medicaid recipients are permitted to fill.<sup>209</sup>

In addition to the obligations they impose on states and patients, Medicaid and closely related programs for the poor impose a series of financial obligations on pharmaceutical companies hoping to sell their products to Medicaid. This Section will briefly consider three such obligations here, each of which was either created or significantly expanded by the ACA.

First and most notably, Medicaid has long required pharmaceutical companies to remit a rebate to Medicaid for each unit of a drug they sell to the program. These rebates are graduated based on the entity and drug being sold: innovator drug companies must remit the larger of 23.1% of a drug's Average Manufacturer Price ("AMP")<sup>210</sup> and the difference between the AMP and the "best price" provided to another entity for the drug,<sup>211</sup> while non-innovator (or generic) drug companies must remit 13% of the AMP per unit.<sup>212</sup> These rebates are shared between the federal government and the states. Prior to the ACA, the rebate obligation was less onerous in two ways. First, the rebate percentages were smaller (15.1% and 11%, respectively).<sup>213</sup> Second, the rebate program did not apply to drugs purchased through most states' Medicaid managed care programs,<sup>214</sup> which typically enroll the majority of a state's Medicaid enrollees.<sup>215</sup>

For the first time, the ACA also introduced a Branded Prescription Drug Fee.<sup>216</sup> Essentially, the fee is levied on innovator companies for the privilege of selling products to government insurance programs, including not only Medicaid, but also Medicare, the VA, and a few other programs.<sup>217</sup> Companies whose sales to these programs ex-

209. Phil Galewitz, *States Cut Medicaid Drug Benefits To Save Money*, KAISER HEALTH NEWS (July 24, 2012), <http://khn.org/news/medicaid-cuts-sidebar/> [<https://perma.cc/5KLP-BQP3>].

210. 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI) (amended by Patient Protection and Affordable Care Act Pub. L. No. 111-148, § 9008(f)(2), 124 Stat.119) (2012); *see also* Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 9008(f)(2), 124 Stat.119 (to be codified as amended at 42 U.S.C. § 1396r-8(k)(1)(A)) (redefining AMP).

211. There are some small exceptions to this. *See infra* note 222.

212. 42 U.S.C. § 1396r-8(c)(3)(B)(iii) (amended by Patient Protection and Affordable Care Act Pub. L. No. 111-148, § 9008(f)(2), 124 Stat.119) (2012).

213. 42 U.S.C. § 1396r-8(c)(1)(B)(i)(V), (c)(3)(B)(ii) (2006).

214. Pub. L. No. 111-148, § 2501(c), 124 Stat.119 (to be codified as amended at 42 U.S.C. § 1396b(m)(2)(A)(xiii)).

215. *See* KAISER FAMILY FOUND., TOTAL MEDICAID MANAGED CARE ENROLLMENT (2014), <http://kff.org/medicaid/state-indicator/total-medicare-mc-enrollment/> [<https://perma.cc/FD3N-VZ3F>].

216. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 9008.

217. *See, e.g.*, Dep't of the Treasury Branded Prescription Drug Fee, 26 C.F.R. 43,631, 43,632 (2014).

ceed \$5 million in any given year are collectively responsible for paying the fee, which is apportioned proportionally to the companies' sales to the government. All told, the fee — between \$2.5 and \$4.1 billion a year, depending on the year<sup>218</sup> — is not particularly large relative to the overall United States prescription drug market,<sup>219</sup> but it is fairly large relative to Medicaid's overall prescription drug expenditures, which in 2013 ran to nearly \$22 billion.<sup>220</sup> Once collected, the fee is used to subsidize Part B coverage for Medicare beneficiaries.<sup>221</sup>

Finally, the 340B Program allows certain health care organizations to purchase drugs for their patients at significant discounts. Unlike Medicare or Medicaid, the 340B Program sets an explicit price ceiling: companies must sell their drugs to covered entities at prices at or below the rates available to Medicaid.<sup>222</sup> Prior to the ACA, the set of organizations entitled to purchase drugs through the 340B Program was fairly limited, notably including federally qualified health centers, AIDS drug purchasing assistance programs, black lung clinics, and disproportionate share hospitals.<sup>223</sup> The ACA expanded the range of covered entities, adding children's hospitals, free-standing cancer hospitals, critical access hospitals,<sup>224</sup> and rural referral centers to this list.<sup>225</sup>

Medicaid has always been intended to provide access to health care for those who would otherwise be unable to afford it. Yet at the same time, both the federal and state governments have long attempted to minimize the amount they spend on Medicaid enrollees. States' extensive use of utilization management techniques, as explained above, is one example. More broadly, state efforts to cut covered services, reimbursement rates, or both have resulted in several lawsuits

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218. INTERNAL REVENUE SERV., ANNUAL FEE ON BRANDED PRESCRIPTION DRUG MANUFACTURERS AND IMPORTERS (2015), <http://www.irs.gov/Businesses/Corporations/Annual-Fee-on-Branded-Prescription-Drug-Manufacturers-and-Importers> [https://perma.cc/RB2F-TCD9] (setting forth the fee schedule).

219. The United States market is roughly \$270 billion annually. See CTRS. FOR MEDICARE & MEDICAID SERVS., NAT'L HEALTH EXPENDITURE DATA (2014), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> [https://perma.cc/C63N-X3DF].

220. *Id.*

221. INTERNAL REVENUE SERV., *supra* note 218.

222. Public Health Service Act, 42 U.S.C. § 256b(a)(1) (2012). Importantly, the price at which companies sell to 340B organizations is not included in the "best price" analysis for Medicaid.

223. 42 U.S.C. § 256b(a)(4) (2012).

224. See Social Security Act § 1820(c)(2)(B)(i), 42 U.S.C. § 1395i-4(c)(2)(B)(i) (defining a critical access hospital as one that is located more than thirty-five miles from another hospital or is so designated by the State).

225. See Patient Protection and Affordable Care Act, 42 U.S.C. § 256b(a)(4)(M)-(O).

in recent years,<sup>226</sup> in which Medicaid beneficiaries or providers argue that a given state has neglected its statutory obligation to ensure that “payments . . . are sufficient to enlist enough providers so that care and services are available under the plan.”<sup>227</sup>

Each of these three examples is best understood in the context of these competing considerations. For instance, although the ACA significantly expanded the population of Medicaid enrollees, providing companies with a broader consumer base, the corresponding increase in the amount and reach of prescription drug rebates can be viewed as an effort to counterbalance the increased spending that would ordinarily be thought to attend the expanded population. From an access perspective, these rebate percentages make sense. Innovator drugs are typically more expensive than generic drugs, and Medicaid would logically prefer to recoup greater rebates on those medicines.

However, although Medicaid may function to provide access to existing therapies, it comparatively penalizes innovation into therapies for diseases primarily affecting poor Americans. We have essentially created a tiered pricing system within the United States, where the private market pays more for treatments than does Medicare, and Medicare pays more than does Medicaid. Sometimes these disparities can be quite extreme. A recent study by the HHS Office of Inspector General comparing rebates obtained by Medicare Part D and Medicaid found that Medicaid’s net unit costs were less than half of Medicare’s for a majority of the drugs under study.<sup>228</sup>

In the presence of a paying private market, tiered pricing is a “win-win” strategy for producers seeking profits and low-income consumers seeking access.<sup>229</sup> However, where the primary market is the low-income market, the promise of tiered pricing is typically insufficient to incentivize the development of a drug in the first instance. Here, the investment calculation looks comparatively dim where the primary market for a drug is among low-income Americans. And it is precisely drugs for conditions primarily affecting low-income populations (including mental health conditions and the Neglected Tropical Diseases) that are underproduced within the current patent and FDA

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226. See, e.g., *Armstrong v. Exceptional Child Ctr.*, 135 S. Ct. 1378 (2015); *Douglas v. Indep. Living Ctr.*, 132 S. Ct. 1204 (2012).

227. 42 U.S.C. § 1396a(a)(30)(A).

228. DEP’T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 7 (2015).

229. See PRASHANT YADAV, DIFFERENTIAL PRICING FOR PHARMACEUTICALS 8 (2010), <http://www.dfid.gov.uk/Documents/publications1/prd/diff-pricing-pharma.pdf> [<https://perma.cc/BK4M-FMPT>]; Jens Plahte, *Tiered Pricing of Vaccines: A Win-Win Situation, Not a Subsidy*, 5 LANCET INFECTIOUS DISEASE 58 (2005).

exclusivity system, due to the market-based distortion discussed in Part II.

In some ways, the idea that the very same drugs will be reimbursed at higher rates when sold to those with employer-based health insurance or to the elderly than when they are sold to the poor is, among Western nations, uniquely American. This fact is enabled by the extreme fragmentation of our healthcare system<sup>230</sup> and by the largely independent way in which private insurance, Medicare, and Medicaid operate, which permits disparate reimbursement rates. As such, we might expect the bias against low-income populations to be more extreme in the United States than in England, for instance, where the National Health Service covers everyone and reimburses not based on the income of the patient, but on the effectiveness of the treatment.<sup>231</sup>

But in other ways, this problem is of global concern. The United States is the world's largest pharmaceutical market by a significant margin.<sup>232</sup> More than a third of all pharmaceutical sales globally are made in the United States.<sup>233</sup> Japan, in second place, spends less than a third of this, and the five largest European markets *combined* (Germany, France, Italy, the UK, and Spain, in that order) still spend less than half of what we spend.<sup>234</sup> The way consumers pay for drugs in the United States has a direct effect not only on what drugs are available to patients in the United States, but also to patients globally.

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230. Einer Elhauge, *Why We Should Care About Healthcare Fragmentation and How to Fix It*, in *THE FRAGMENTATION OF U.S. HEALTH CARE* 1, 3–6 (Einer Elhauge ed., 2010). Nearly 60% of Americans receive insurance through their employers, 22% through Medicaid, 16% through Medicare (although there is overlap in these last two groups), and others through the individual insurance market, other government programs, or not at all. See KAISER FAMILY FOUND., *TOTAL MONTHLY MEDICAID AND CHIP ENROLLMENT* (2015), <http://kff.org/health-reform/state-indicator/total-monthly-medicare-and-chip-enrollment/> [<https://perma.cc/Y39C-ZHW8>]; KAISER FAMILY FOUND., *MEDICARE BENEFICIARIES AS A PERCENT OF TOTAL POPULATION* (2012), <http://kff.org/medicare/state-indicator/medicare-beneficiaries-as-of-total-pop/> [<https://perma.cc/SKJ8-BUCE>]; ROBERT WOOD JOHNSON FOUND., *STATE-LEVEL TRENDS IN EMPLOYER SPONSORED INSURANCE: A STATE-BY-STATE ANALYSIS 3* (2013), [<https://perma.cc/3NVX-6USM>].

231. See *supra* text accompanying notes 129–32.

232. ASS'N OF THE BRITISH PHARM. INDUS., *GLOBAL PHARMACEUTICAL INDUSTRY AND MARKET* (2014), <http://www.abpi.org.uk/industry-info/knowledge-hub/global-industry/Pages/industry-market.aspx> [<https://perma.cc/27SN-8ATP>]; *Annual Report 2011*, CANADA PATENTED MEDICINE PRICES REVIEW BOARD (2012), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=895> [<https://perma.cc/XMT8-AXYV>].

233. See ASS'N OF THE BRITISH PHARM. INDUS., *supra* note 232. The U.S. makes up an even larger share (49%) of the global biologics market. IMS HEALTH, *SEARCHING FOR TERRA FIRMA IN THE BIOSIMILARS AND NON-ORIGINAL BIOLOGICS MARKET 2* (2013).

234. As such, these figures cannot be explained through simple demographics — those five countries combined have roughly the same population size as the United States. See ASS'N OF THE BRITISH PHARM. INDUS., *supra* note 232.

Consider Chagas Disease, briefly discussed earlier in this Article. Chagas affects roughly 8 million people worldwide,<sup>235</sup> 300,000 of whom reside in the United States.<sup>236</sup> Under normal circumstances, a market of 300,000 Americans ought to be sufficient to encourage the development of treatments for a given condition. The Orphan Drug Act itself is suggestive of this fact — the Act provides special incentives for conditions affecting 200,000 or fewer Americans, implicitly suggesting that diseases affecting a greater number do not require particular supplemental incentives.<sup>237</sup> Chagas primarily afflicts poor Americans, and because most of its sufferers live in southern states, only some of which have chosen to expand Medicaid, many remain uninsured. Developing an effective drug or vaccine for Chagas Disease would redound not only to the benefit of Americans and our health care system, but also to much of Latin America, where Chagas has long been endemic.

Essentially, although the way in which Medicaid pays for drugs is salutary from an access perspective, it is problematic from an innovation perspective. Medicaid likely has the unintended effect of decreasing the incentives for pharmaceutical companies to invest in drugs that would be prescribed primarily for low-income Americans, relative to a system in which drugs are reimbursed not based on the identity of the recipient but on the quality of the drug.<sup>238</sup>

This result is not inevitable. Our various systems of prescription drug insurance might be altered to mitigate or eliminate this concern.

Several scholars and policymakers have proposed alterations in the spirit of “equalizing down,” in various ways, the rates that private insurers and Medicare pay for drugs to more closely approximate the rates paid by Medicaid.<sup>239</sup> The effect would be to mitigate the innovation distortion in favor of diseases of affluence, while at the same time spending less than we currently do on prescription drugs.

Some of these proposals are fairly dramatic, while others are more narrow. President Obama’s fiscal year 2016 proposed budget would have allowed HHS to negotiate Medicare drug prices directly with manufacturers, which would broadly affect the entire Medicare

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235. *Chagas Disease*, WORLD HEALTH ORG. (2015), <http://www.who.int/chagas/en/> [<https://perma.cc/V3K5-JNJJ>].

236. CTRS. FOR DISEASE CONTROL, *supra* note 12.

237. 21 U.S.C.A. § 360bb(a)(2) (2006).

238. Of course, I acknowledge that this is the only baseline from which to assess this claim about Medicaid’s effect on innovation incentives. Relative to a world without Medicaid, the creation of Medicaid *increases* incentives for the development of drugs that treat conditions common among low-income Americans.

239. *See, e.g.*, Kevin Outterson & Aaron S. Kesselheim, *How Medicare Could Get Better Prices on Prescription Drugs*, 28 HEALTH AFF. w832 (2009).



population.<sup>240</sup> More narrowly, his budget would have allowed Medicare Part D to pay Medicaid prices for only the dual eligible population.<sup>241</sup> An even more limited proposal comes from a recent Office of Inspector General report, which suggests that Part D adopt a provision in the Medicaid statute insulating the program when drug prices increase faster than inflation.<sup>242</sup>

Rather than exploring these proposals, the rest of this Part will focus on an alteration to Medicaid itself, “equalizing up” its rates to provide a bonus to innovators who bring drugs for conditions primarily affecting low-income populations to market. This choice to equalize payments up or down depends on a range of considerations, including empirical debates among economists about whether incentives for innovation in the presence of both patents and insurance are excessive, such that we could equalize down without diverting socially valuable innovation, or whether incentives are still insufficient, given the existence of significant unmet health needs.<sup>243</sup> Yet this debate is often conducted in the abstract. Where the existing patent and insurance systems have failed to produce socially valuable treatments for particular conditions like those examined here, additional incentives are worth considering.

### *B. Altering Medicaid Reimbursement to Bolster Incentives to Innovate*

Within Medicaid, several policy levers might be pulled to recalibrate incentives for innovation into particular diseases. An examination of Medicaid’s rebate provisions illustrates not only the diversity of potential approaches but also the complexity of the considerations involved. Recall that in the year prior to the ACA’s enactment, pharmaceutical companies were required to remit as rebates 15.1% of the AMP for innovator drugs and 11% for generic drugs.<sup>244</sup> These rebates

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240. David Morgan, *Obama Administration Seeks to Negotiate Medicare Drug Prices*, REUTERS (Feb. 2, 2015), <http://www.reuters.com/article/us-usa-budget-medicare-idUSKBN0L61OW20150202> [<https://perma.cc/4WDZ-XXGK>].

241. Gretchen Jacobson et al., *Summary of Medicare Provisions in the President’s Budget for Fiscal Year 2016*, KAISER FAMILY FOUNDATION (Feb. 3, 2015), <http://kff.org/medicare/issue-brief/summary-of-medicare-provisions-in-the-presidents-budget-for-fiscal-year-2016/> [<https://perma.cc/46JX-XKA3>].

242. See DEP’T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., *supra* note 228, at 9.

243. Compare Alan M. Garber et al., *Insurance and Incentives for Medical Innovation* (Nat’l Bureau of Econ. Research, Working Paper No. 12080, 2006) (arguing that pharmaceutical companies possess excessive incentives for innovation), with Darius Lakdawalla & Neeraj Sood, *Insurance and Innovation in Health Care Markets* (Nat’l Bureau of Econ. Research, Working Paper No. 11602, 2005) (arguing that incentives for innovation are insufficient). The increasing role played by venture capital firms in funding drug development may alter this calculus as well.

244. 42 U.S.C. § 1396r-8(c)(1)(B)(i)(V), (c)(3)(B)(ii) (2006).

were shared between the states and the federal government according to the relative funding contributions made by each entity. But when the ACA increased the amount pharmaceutical companies must remit as rebates to 23.1% for innovator drugs and 13% for generic drugs, it clarified that the amounts “attributable” to the percentage increase all belong to the federal government.<sup>245</sup>

The rest of this Part focuses on potential alterations to the rebate system that would maximize the prize-like aspect of prescription drug insurance by providing additional carrots to companies who bring neglected products to market. In particular, policymakers might address the market-based distortion in patent law by directly financially rewarding companies who focus on diseases that are more prevalent among low-income populations, such as mental health conditions or Neglected Tropical Diseases.

This reward could be administered in at least two primary ways. Administratively, the simplest solution would be to subject relevant drugs to the pre-ACA rebate levels, or even to no rebate at all. Alternatively, or even in addition, some portion of the collected rebate total could be apportioned each year to companies providing innovative drugs that meet the relevant criteria. In either case, these reward levels might be calibrated to the degree of effectiveness or availability of a given treatment. For instance, a drug that cures or prevents an underserved condition might not be required to remit any rebate, while a drug that simply treats the condition might remit a reduced rebate.

In light of prior pharmaceutical company attempts to game other reward systems, any such system would need to be sufficiently specified as to avoid particular types of gaming.<sup>246</sup> One key strategy would be to tie the provision of the reduced rebate level to adequate access to the drug in question. Under this strategy, an option is to tie the rebate reduction or payout to ensuring that a particular percentage of a drug’s prescriptions occurred through Medicaid.<sup>247</sup> A more nuanced method might compare prescription rates across populations. If a given drug is not made available to the Medicaid population at rates that approximate its particular disease’s prevalence among that population, but that drug is made more widely available to Medicare beneficiaries or those enrolled in private plans, the company providing the drug would forfeit the benefit.

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245. Affordable Care Act, Pub. L. No. 111-148, § 2501(a)(2)(C)(i)(II), 124 Stat. 119, 307 (2010).

246. See *supra* text accompanying notes 89–93 (discussing the FDA’s Priority Review Voucher).

247. Although this would not be an ideal solution for all unmet health needs, where a majority of the possible market for a medication is Medicaid-eligible, this system might be simplest to administer.

Altering Medicaid on a national scale in this way would require congressional action, as the current rebate system is largely mandated by statute. As previously discussed in the context of the patent system, involving Congress creates opportunities for rent-seeking behavior by the regulated industry, on top of concerns that Congress lacks the needed expertise to implement such a detailed system. But unlike in the patent context, within Medicaid Congress has the option to create only the outlines of the program by statute and then empower agencies to make rules implementing the program and to adjudicate applications to consider particular drugs under the program. Housing these responsibilities within an agency could not only mitigate opportunities for direct rent-seeking but also permit the agency to respond more nimbly to changing technological conditions.

Importantly, CMS and FDA already have experience performing each of these tasks. CMS's experience comes through its implementation of the new technology add-on payment ("NTAP") system in Medicare. In response to policymakers' concerns that Medicare's system of paying for inpatient hospital services did not sufficiently reward the development of new technologies and their incorporation into medical practice, Congress in 2000 added a provision to the Medicare statute directing CMS to create a procedure for identifying new medical technologies and providing additional payments for their use.<sup>248</sup>

Although the NTAP statute is highly general, CMS has created finely specified procedures to implement the program. By regulation, CMS has established criteria for determining which medical technologies are eligible for the add-on payments, created an annual application system for interested developers, and developed a formula for calculating the size of the payments.<sup>249</sup> Although many of these regulations would need to be reframed to fit the needs of the Medicaid program, the expertise CMS has developed in the past decade of implementing the NTAP program could certainly be brought to bear on this related area.

The FDA's experience overseeing the Priority Review Voucher program, discussed above,<sup>250</sup> is similarly relevant. When first established, the list of conditions meriting a voucher overlapped incompletely with the WHO's list of Neglected Tropical Diseases. The FDA's list did not include conditions like Chagas disease and cysticercosis, which are on the WHO list. But Congress foresaw the possi-

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248. 18 U.S.C. § 1886(d)(5)(K) (2000); *see also* Alexandra T. Clyde et al., *Experience With Medicare's New Technology Add-On Payment Program*, 27 HEALTH AFF. 1632, 1632–33 (2008).

249. 42 C.F.R. § 412.87; 42 C.F.R. § 412.88.

250. *See supra* text accompanying notes 89–93.

bility that the FDA might wish to add diseases to the PRV list, and it authorized the FDA to “designate[] by regulation . . . [a]ny other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations” as deserving of a voucher.<sup>251</sup>

The FDA has since exercised this authority, recently issuing a final order adding Chagas and neurocysticercosis to the list of designated tropical diseases such that manufacturers of drugs approved for these conditions may be awarded a voucher.<sup>252</sup> In its order, the FDA both specified the factors it intends to consider in interpreting the terms of the statute and applied those factors to the two diseases at issue.<sup>253</sup> The FDA’s experience fielding applications to add diseases to the PRV list and giving reasons in its adjudication thereof would be useful in the Medicaid context.

The total amount of funds that a program along these lines could make available to companies is significant. The simplest program, involving only the federal rebates due to the ACA’s percentage increase, would come to nearly \$2.5 billion each year.<sup>254</sup> That amount might be deployed more productively through a true prize fund apportioned only to companies meeting the qualifying criteria, rather than through simply eliminating rebates for relevant companies — an 8% increase in reimbursement might not achieve the desired effect.

A program that also involved the statutory rebates made to state governments would be able to marshal far more resources, likely to be between \$5 and \$10 billion annually. In 2012, Medicaid spent \$35.5 billion on pharmaceuticals before rebates were factored in. Of that total, 76% or about \$27 billion came from branded drugs, with the remaining \$8.5 billion coming from generic drugs.<sup>255</sup> As a result, the federally mandated rebates should have netted the government \$7.34 billion in 2012 alone, with 85% of that amount coming from branded drugs.<sup>256</sup> An annual rebate fund of nearly \$7.5 billion, or a 23% in-

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251. 21 U.S.C. § 360n(a)(3)(S) (2012).

252. *Designating Additions to the Current List of Tropical Diseases in the Federal Food, Drug, and Cosmetic Act*, 80 Fed. Reg. 50,559 (Aug. 20, 2015), <https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-20554.pdf> [<https://perma.cc/YC5K-7TB3>] (codified at 21 C.F.R. § 317).

253. *Id.*

254. Brian Bruen & Katherine Young, *What Drives Spending and Utilization on Medicaid Drug Benefits in States?*, KAISER FAMILY FOUNDATION (Dec. 14, 2014), <http://kff.org/report-section/what-drives-spending-and-utilization-on-medicare-drug-benefits-in-states-issue-brief/> [<https://perma.cc/KC3A-QNV9>].

255. *Id.*

256. In reality, though, the government did not spend even close to \$28 billion on drugs through Medicaid in 2012. The states are empowered to negotiate supplemental rebates, and as a result drug spending totaled only \$19.6 billion in 2012. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., NAT’L HEALTH EXPENDITURE DATA FOR 2012 (2013),

crease in reimbursement for any particular drug, is more likely to make a difference for many companies, given empirical estimates suggesting that prizes in the \$3.5 billion range would be sufficient to incentivize the production of new drugs.<sup>257</sup>

But any strategy that implicated the rebates accruing to the states would likely run into difficulty.<sup>258</sup> As discussed above, states have concocted intricate utilization management schemes in an effort to minimize the amount they spend on expensive innovator drugs through Medicaid. Any move to decrease, let alone eliminate, their rebates even for a small subset of these drugs would be vigorously opposed on a combination of economic and political grounds.

Economically, states might be concerned that a reimbursement intervention like the one proposed here will increase their Medicaid costs. Importantly, this is not obviously true. The prospect of achieving cost savings elsewhere in the Medicaid program through such reimbursement interventions, such as in long-term care costs, is real. Yet since few health care interventions are truly *cost-saving* to the health sector, even if they are *cost-effective*,<sup>259</sup> it is certainly possible that state Medicaid costs may increase somewhat.

More fruitfully, states may also achieve cost savings external to the Medicaid program but still internal to the state. Some savings might come through the tax system.<sup>260</sup> Other savings might come through the criminal justice system, particularly if individuals with severe mental illness can be treated in the community.<sup>261</sup> Still other

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<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html> [https://perma.cc/C63N-X3DF]. I have not proposed here to affect the states' ability to collect supplemental rebates, but a proposal which did so would make available closer to \$20 billion annually for innovation purposes.

257. See, e.g., Kate Kelland, *Review Suggests \$3.5 Billion Prizes for Antibiotic Drug-makers*, REUTERS (May 13, 2015), <http://www.reuters.com/article/2015/05/13/health-antibiotics-idUSL5N0Y446920150513> [https://perma.cc/2JTW-JVNS].

258. In actuality, these concerns might also apply to a program that only involved the federal rebates from the ACA. Because this program would ideally function not only to encourage innovation but also to increase access, states might continue to fight a program designed to increase the amount of volume they purchase, even if not the unit price. These concerns might be smaller in that context, however.

259. Ron Z. Goetzel, *Do Prevention Or Treatment Services Save Money? The Wrong Debate*, 28 HEALTH AFF. 37 (2009).

260. David W. Brown et al., *Medicaid as an Investment in Children: What is the Long-Term Impact on Tax Receipts?* 22 (Nat'l Bureau of Econ. Research, Working Paper No. 20835, 2015).

261. See, e.g., *Kasich Says Obamacare Empties Prisons — In a Good Way*, TIME (Aug. 7, 2015), <http://time.com/money/3988642/kasich-defends-medicaid-expansion/> [https://perma.cc/2NTX-LL83].

savings might come from decreases in disability expenditures.<sup>262</sup> Yet whether or not the creation of the rebate fund would save the states money overall, there will surely be additional opposition to it on political grounds, as we have seen in the Medicaid expansion context.<sup>263</sup>

This is essentially the credible commitment problem raised by Burstein & Murray in the prize context.<sup>264</sup> Even if the federal government could increase reimbursement rates for a given pharmaceutical, a company could not be assured that the states would not attempt to block it from claiming the reward. As such, the enabling statute might attempt to constrain the ability of the states to behave opportunistically. These constraints might take the form of carrots or sticks.

For instance, just as the federal government assumed 100% of the initial cost of insuring the newly eligible Medicaid populations under the ACA,<sup>265</sup> the federal government might increase the Federal Medical Assistance Percentages (“FMAPs”) attributable to prescription drugs to cover 100% of the cost of any drug subject to the decreased rebate.<sup>266</sup> More pessimistically, if states attempt to impose particularly extreme utilization review requirements on drugs subject to the increased payments, non-discriminatory treatment could be legislated, or even achieved through the court system.<sup>267</sup>

Perhaps more interestingly, enterprising states may seek to impose this system only within their own borders. States might seek to eliminate the statutorily required rebates for particular drugs or to create a scaled-down prize fund with the rebates through the use of section 1115 waivers, discussed above.<sup>268</sup> The adoption of such a waiver in just a few states with large Medicaid programs, such as California,<sup>269</sup> could prove influential. California has previously demonstrated

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262. See, e.g., Paul Demko, *Arkansas Disability Claims Fall 19% After Medicaid Expansion*, MODERN HEALTHCARE (Aug. 26, 2014), <http://www.modernhealthcare.com/article/20140826/NEWS/308269939> [<https://perma.cc/WJF9-EV99>].

263. See, e.g., Mark A. Hall, *States’ Decisions Not to Expand Medicaid*, 92 N.C. L. REV. 1459 (2014).

264. Burstein & Murray, *supra* note 108, at 413–14.

265. *HHS Finalizes Rule Guaranteeing 100 Percent Funding for New Medicaid Beneficiaries*, DEP’T OF HEALTH & HUMAN SERVS. (Mar. 29, 2013), <http://www.hhs.gov/news/press/2013pres/03/20130329a.html> [<https://perma.cc/ZE93-6Z64>].

266. This would be administratively very simple. CMS breaks down its FMAP contributions by service area and could easily alter the FMAP for a single category without affecting the rest of the state’s overall matching rate.

267. Cf. Michelle Andrews, *Some Plans Skew Drug Benefits To Drive Away Patients, Advocates Warn*, KAISER HEALTH NEWS (July 8, 2014), <http://khn.org/news/some-plans-skew-drug-benefits-to-drive-away-patients-advocates-warn/> [<https://perma.cc/UA5S-MCML>].

268. See Public Welfare Amendments of 1962, 42 U.S.C. § 1315 (1988).

269. TOTAL MONTHLY MEDICAID AND CHIP ENROLLMENT (2015), *supra* note 230.

a willingness to support innovative activity on a sub-national level,<sup>270</sup> and it might display a similar willingness in this case.

Importantly, though, any such waiver must be “budget neutral” to the federal government.<sup>271</sup> Under section 1115 a state could not deprive the federal government of its portion of the rebate without achieving savings elsewhere. But these savings do not have to be contemporaneous, and interested states might adopt an argument employed in the context of other waivers: that increased expenditures now will decrease expenditures in the near future. States have used this theory to justify waivers that expand HIV care or family planning care, concluding that these services will pay for themselves.<sup>272</sup> In this case, states might argue that providing increased care now for those with certain communicable diseases or mental health conditions might decrease costs later.

For many of the infectious diseases affecting low-income populations in the United States and elsewhere, where the primary innovation distortion is market-based, providing increased reimbursements is likely to make a meaningful difference in innovation incentives. But in reality the most efficacious solution will require a menu of complementary approaches. In a situation like the one facing mental health conditions, where the science is too underdeveloped to permit researchers to proceed in drug development with significant confidence, increasing funding for basic research is likely to be needed as well.

The rebate similarly may be altered in service of this goal. The federal government might divert unclaimed money from a rebate fund on an annual basis to relevant National Institutes of Health (“NIH”) Institutes or Centers. Although the NIH’s total budget comes to about \$30 billion, the budgets of three institutes that address unmet health needs to a high degree (the National Institute of Allergy and Infectious Diseases, the National Institute of Mental Health, and the National Institute of Neurological Disorders and Stroke) totaled just \$7.39 billion in 2014.<sup>273</sup> A program diverting unclaimed rebate money to the NIH could significantly increase their budgets. Alternatively,

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270. See, e.g., Joel W. Adelson & Joanna K. Weinberg, *The California Stem Cell Initiative: Persuasion, Politics, and Public Science*, 100 AM. J. PUB. HEALTH 446 (2010) (describing California’s efforts to encourage stem cell research on the state level).

271. Public Welfare Amendments of 1962, 42 U.S.C. § 1315 (1988).

272. CHARLES MILLIGAN, STATE COVERAGE INITIATIVES, SECTION 1115 WAIVERS AND BUDGET NEUTRALITY: USING MEDICAID FUNDS TO EXPAND COVERAGE 2 (2001), <http://www.statecoverage.org/files/Section%201115%20Waivers%20and%20Budget%20Neutrality%20-%20Using%20Medicaid%20Funds.pdf> [https://perma.cc/98BY-7TQN].

273. *History of Congressional Appropriations, 2000–2014*, NAT’L INSTS. OF HEALTH 1 (2014), <http://officeofbudget.od.nih.gov/pdfs/FY16/Approp%20%20History%20by%20IC%20through%20FY%202014.pdf> [https://perma.cc/C3MC-VWQM].

these funds might be used to bolster the government's ability to conduct studies into producing new information about existing drugs or other nonexcludable technologies like those identified by Professors Kapczynski and Syed.<sup>274</sup>

This Part has endeavored to demonstrate the potential of one single national insurance scheme — the United States' Medicaid system — to affect innovation more globally. More precisely, it has largely demonstrated this potential by focusing on the alterations that might be made to a single provision of the Medicaid reimbursement system — the structure of its statutorily mandated rebates. The solutions proposed here will not be sufficient to solve every innovation problem on their own, and as such they must be used in combination with the familiar innovation mechanisms discussed elsewhere in this Article, including grants, tax credits, prizes, and FDA exclusivity periods. But in light of their potential to fill many of the innovation distortions in our current regulatory system, the current state of affairs in which we ignore their existence almost entirely is surely a mistake.

## VI. CONCLUSION

This Article has endeavored to demonstrate that prescription drug insurance can operate much like a prize in promoting incentives to innovate in many of the lacunae left behind by the structure of our existing patent law and FDA exclusivity systems. Exploring both the theoretical and practical aspects of prescription drug insurance not only establishes its theoretical feasibility for this purpose, but also reveals the nearly limitless ways in which insurance may be altered on a micro level. The ultimate point of this Article, though, is broader. It aims to find a point of commonality between two formerly disparate areas of law — patent law and health law — and consider the ways in which they might work together, rather than in opposition, going forward. As such, this Article both introduces real-world possibilities for specific interventions into prescription drug insurance schemes and opens new avenues of scholarship, seeking to explore additional — and perhaps unexpected — ways in which patent law and health law may cohere.

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274. Kapczynski & Syed, *supra* note 27.