



School of Law
UNIVERSITY OF GEORGIA

Prepare.
Connect.
Lead.

Journal of Intellectual Property
Law

Volume 19 | Issue 2

Article 11

March 2012

The Health Impact Fund Proposal: Application in the United States' Era of Comparative Effectiveness

Katherine Jeanne Racz

Follow this and additional works at: <https://digitalcommons.law.uga.edu/jipl>



Part of the [Health Law and Policy Commons](#), and the [Intellectual Property Law Commons](#)

Recommended Citation

Katherine J. Racz, *The Health Impact Fund Proposal: Application in the United States' Era of Comparative Effectiveness*, 19 J. INTELL. PROP. L. 487 (2012).

Available at: <https://digitalcommons.law.uga.edu/jipl/vol19/iss2/11>

This Notes is brought to you for free and open access by Digital Commons @ University of Georgia School of Law. It has been accepted for inclusion in Journal of Intellectual Property Law by an authorized editor of Digital Commons @ University of Georgia School of Law. [Please share how you have benefited from this access](#) For more information, please contact tstriepe@uga.edu.

THE HEALTH IMPACT FUND PROPOSAL: APPLICATION IN THE UNITED STATES' ERA OF COMPARATIVE EFFECTIVENESS

*Katherine Jeanne Racz**

TABLE OF CONTENTS

I.	INTRODUCTION	488
II.	BACKGROUND.....	492
	A. THE CURRENT U.S. PATENT SYSTEM.....	492
	B. RECENT AND FORTHCOMING CHANGES: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT IN THE ERA OF COMPARATIVE EFFECTIVENESS.....	496
	1. <i>The Patient Protection and Affordable Care Act</i>	496
	2. <i>Where We Are Now: Scholarship's Perspective</i>	499
	C. THE HEALTH IMPACT FUND	501
	1. <i>HIF Summary</i>	501
	2. <i>Measuring Health Impact</i>	502
	3. <i>Funding</i>	504
	4. <i>Reimbursement</i>	504
	D. HEALTH CARE REFORM IN MASSACHUSETTS.....	505
III.	ANALYSIS.....	507
	A. A NEW ERA OF COMPARATIVE EFFECTIVENESS?.....	507
	B. APPLICATION OF THE HIF IN THE UNITED STATES.....	508
	C. OTHER NATIONAL OPTIONS?	512
	D. STATEWIDE IMPLEMENTATION OF THE HEALTH IMPACT FUND.....	513
IV.	CONCLUSION	514

* Katherine J. Racz, raised in Savannah, Georgia, attended the University of Georgia where she majored in International Affairs. As a student, Katherine conducted two research studies that explore health care systems, and interned in government offices where she helped to develop health care policy. Katherine entered the University of Georgia School of Law in the fall of 2010, and was later appointed to the Editorial Board of the *Journal of Intellectual Property Law*. She will serve as the *Journal's* Senior Notes Editor for the Academic Year 2012–2013 and is expected to graduate with a Juris Doctorate in 2013. Katherine hopes to use her law degree to advance public health.

I. INTRODUCTION

The United States' traditional patent system for pharmaceuticals, which currently affords pharmaceutical innovators protection of their intellectual property for several years, has been applauded for fostering innovation and incentivizing firms to develop new and beneficial drugs and therapies with the promise of market exclusivity to those firms for their patented drugs. Indeed, U.S. firms, which develop drugs in a largely unregulated market, have been at the forefront of developing cutting-edge therapies for the past several decades.¹

However, the U.S. patent system is not without deficiency; instead, the coveted exclusivity afforded to drug developers by patent protection often inadvertently creates socially undesirable incentives for those developers. These incentives, when pursued, contribute to the soaring costs of pharmaceuticals and ultimately contribute to the rising and unsustainable cost of public health care in the U.S.² Specifically, the patent system incentivizes pharmaceutical innovators to (1) create "me-too"³ drugs (which hardly differ from other firms' drugs that have already gained market approval and have proven to be lucrative) and (2) make incremental changes to their own drugs, which have patents that are nearing expiration, in order to prolong patent protection and thereby preserve market exclusivity. In pursuing these incentives, developing firms ultimately detract from the time and effort they would otherwise spend to develop genuinely innovative therapies in the interest of pursuing these socially suboptimal outcomes.

The socially suboptimal side effects of the patent system have contributed—and continue to contribute—to the rising and unsustainable costs of pharmaceuticals, which ultimately contribute to the rising and unsustainable costs of health care in the U.S. Few would dispute the need to address these rising costs, which continue to plague the United States' public health care system. According to the Centers for Medicare and Medicaid Services (CMS), overall U.S. health expenditure grew by 3.8% in 2009, totaling \$2.5 trillion for the year.⁴ This represents 17.9% of the nation's gross domestic product (GDP), and an average of over \$8,000 spent per person in 2009.⁵

¹ See *infra* notes 25–30 and accompanying text.

² See *infra* notes 27–33 and accompanying text.

³ AIDAN HOLLIS & THOMAS POGGE, INCENTIVES FOR GLOBAL HEALTH, THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL 4 (2008).

⁴ Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Nat'l Health Expenditure Data Sheet, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/tables.pdf>.

⁵ *Id.*

Further, spending on pharmaceuticals accounted for no small portion of total U.S. health care expenditure. In 2008, the U.S. spent \$234.1 billion on prescription drugs, more than double the total amount that the U.S. spent for prescription drugs in 1999.⁶ This total in pharmaceutical spending accounted for roughly 10% of total U.S. health care expenditures, which exceeded \$2.3 trillion in 2010.⁷

By 2010, the growth in U.S. spending on pharmaceuticals had slowed, but still grew by 2.3% from 2009 to total \$307.4 billion in “the world’s biggest market.”⁸ The stagnant U.S. economy, coupled with prohibitive unemployment, was likely the reason for a deceleration in pharmaceutical spending growth.⁹ A stagnant economy reinforces the fact that reduction in spending on pharmaceutical products—specifically through the exploration of options for reformation or supplementation of the traditional patent system—is just what the doctor ordered. A realization in savings on pharmaceutical expenditures could have major positive implications for the overall national budget.

The U.S. has recently taken steps to decrease spending on—and improve the effectiveness of—pharmaceuticals with the passage of the Patient Protection and Affordable Care Act of 2010 (PPACA).¹⁰ PPACA attempts to rein in costs—while maintaining or improving the quality—of pharmaceuticals with an increased focus on comparative effectiveness research (CER) for any given innovative pharmaceutical.¹¹

However, PPACA may not sufficiently address the problems that inhere in the patent system’s regulation of pharmaceuticals. Because part of the patent system’s inherent problem is that it offers little incentive to firms to develop a pharmaceutical that is effective as compared to others already on the market, a robust and radical remedy is required. PPACA, however, is neither robust nor radical: instead, it places critical limits upon the use of comparative effectiveness data (CER).¹² Most notably, PPACA prohibits the Centers for Medicare and

⁶ Qiuping Gu et al., Ctrs. for Disease Control & Prevention, *Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007–2008*, 42 NCHS DATA BRIEF 1 (2010), <http://www.cdc.gov/nchs/data/databriefs/db42.htm>.

⁷ Adara Beamesderfer & Usha Ranji, Kaiser Family Foundation, *U.S. Health Care Costs*, KAISEREDU.ORG, <http://www.kaiseredu.org/Issue-Modules/US-Health-Care-Costs/Background-Brief.aspx>.

⁸ Bill Berkrot, *U.S. Drug Spending Slows; Hits \$307 Billion in 2010: Report*, THOMSON REUTERS (Apr. 19, 2011, 1:33 PM), <http://www.reuters.com/article/2011/04/19/us-drug-spending-idUSTRE7314G920110419>.

⁹ *Id.*

¹⁰ See *infra* notes 56–73 and accompanying text.

¹¹ See *infra* notes 63–65 and accompanying text.

¹² See *infra* notes 89–91 and accompanying text.

Medicaid Services (CMS) from using CER as the sole basis for determining that CMS will not cover a particular drug for a Medicare enrollee.¹³ Sufficiently addressing the problems inherent in the U.S. patent regime, which are contributing to the costs and inefficiencies of the U.S. public health care system, may require the implementation of a more radical solution.

The Health Impact Fund (HIF) is a revolutionary solution that could considerably benefit American consumers by decreasing the price of pharmaceuticals and encouraging the development, production, and market entry of truly innovative drugs. The HIF is a proposal jointly crafted by Aidan Hollis and Thomas Pogge.¹⁴ The proposal—*The Health Impact Fund: Making New Medicines Accessible for All*—calls for an international organization that serves as an optional alternative to the traditional patent system for protecting individual drugs in which countries may participate.¹⁵ When applied in participating nations, the HIF could help to significantly reduce the price of the most effective and socially valuable pharmaceuticals to consumers.¹⁶ Under the HIF, instead of applying for a traditional patent for a newly developed drug, a pharmaceutical innovator could opt to register its drug with the HIF, and thereby receive the intellectual property protection and reimbursement that the HIF provides.¹⁷ Should the U.S. adopt the HIF proposal, U.S. pharmaceutical companies would have the option of registering their new pharmaceuticals with the HIF, forgoing the protection of the traditional U.S. patent system.¹⁸

However, the United States' adoption of the HIF proposal would create several complications. Apart from whether the U.S. would adopt the HIF proposal in the first place, the most important question upon adoption of the HIF would be whether Medicare—a federal program, as well as “the largest health maintenance organization in the Western world”¹⁹—would legally be able to reimburse the value of drugs registered with the HIF program to the drugs' innovators on behalf of Medicare enrollees. The HIF calls for the use of a quality-adjusted life years (QALY) measurement to determine a drug's value, and thus, to determine how much to reimburse the drug's developer for her intellectual property.²⁰ Although some scholars argue that the U.S. is entering a

¹³ See *infra* notes 89–91 and accompanying text.

¹⁴ HOLLIS & POGGE, *supra* note 3, at 83–89.

¹⁵ *Id.* at 1–2.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Bruce Patsner, *Marketing Approval Versus Cost of New Medical Technologies in the Era of Comparative Effectiveness: CMS, Not FDA, Will be the Primary Player*, 3 J. HEALTH & LIFE SCI. L. 38, 43 (2010).

²⁰ See HOLLIS & POGGE, *supra* note 3, at 9.

new era of comparative effectiveness—in which a drug’s efficacy, as compared to that of other, similar drugs, is more closely scrutinized²¹—there is little hope that the U.S. will embrace a comparative effectiveness evaluation system such as the QALY measurement. This is due to a deep-rooted social opposition to the use of standards, such as the QALY, which determine whether a drug will be made available to individual consumers. This reaction has been codified in the PPACA, which (as mentioned) restricts CMS’s use of comparative effectiveness data when making coverage decisions.²² This restriction could very well bar CMS from covering patients and reimbursing developers for drugs that have been registered with the HIF and are therefore evaluated under the QALY measurement of value.

As an alternative to adopting the HIF proposal nationwide, two possible applications of HIF are worth considering: (1) participation of individual U.S. states in the international HIF model, and (2) adoption of an intrastate version of the HIF model within individual U.S. states. Individual states have more freedom within the Medicaid program, which unlike Medicare, is not national but statewide, to implement novel systems of third party payment for pharmaceutical drugs. Further, because states are often required to meet certain national standards without financial help from the federal government (i.e., unfunded federal mandates), states may have a stronger incentive to rein in the costs of pharmaceuticals, as well as a persuasive argument for implementing dramatic changes and novel systems. Finally, the implementation of novel systems or radical changes within a single state—instead of nationwide—may meet with far less Congressional and popular resistance. Therefore, certain individual states may have a more realistic chance of achieving passage of legislation approving the HIF model than would the federal government.

This Note first explores the traditional patent system, focusing on some of its most critical failures. It then turns to recent efforts—both within Congress and other government administrations—to correct the problems perpetuated by the current patent system with the aim of improving the quality and decreasing the cost of pharmaceuticals. The Note then explores the HIF proposal, as well as an example of a U.S. state, Massachusetts, in which revolutionary health care reform has been implemented with mixed success.

This Note determines that the recent efforts to rein in costs and increase pharmaceutical effectiveness nationwide are steps in the right direction but are

²¹ See Richard S. Saver, *The New Era of Comparative Effectiveness: Will Public Health End Up Left Behind?*, 39 J.L. MED. & ETHICS 437, 437 (2011) (arguing that “[a]s a result of health care reform, medicine has entered a new era of comparative effectiveness”).

²² *Id.* at 439; see also *Patient Protection and Affordable Care Act*, Pub. L. No. 111-148, 124 Stat. 119 § 6301(a) (2010).

ultimately insufficient. It then determines that the HIF proposal, on the other hand, could provide radical change and considerable benefit to U.S. pharmaceutical consumers. However, the Note concludes that adoption of the HIF in the U.S.—at least, adoption without major caveats, the application of which may ultimately render the HIF ineffective—is unlikely, largely because of the adverse reaction the QALY measurement is likely to face among members of Congress and the public. It is more likely that certain individual states (such as those that are more politically liberal, like Massachusetts) may be able to implement a statewide version of the HIF.

II. BACKGROUND

A. THE CURRENT U.S. PATENT SYSTEM

The traditional pharmaceutical patent system is based upon the following premise: in order to incentivize the innovation of new pharmaceuticals, one must offer to a pharmaceutical company, which develops a new drug, a reward for its effort spent developing its intellectual property.²³ This reward has developed as patent protection: the exclusive right to advertise and sell a pharmaceutical, the product of one's intellect and effort, for a predetermined period of time.²⁴ This protection prevents competing firms from reproducing—and subsequently profiting from—a pharmaceutical company's intellectual property.²⁵

In many respects, the current U.S. system has been very successful: the incentive created by patent protection has indeed encouraged innovation.²⁶ This is evidenced by the past decade, in which the U.S. led the world in generating intellectual property that contributed to pharmaceutical innovations.²⁷ It has been noted that the U.S.'s *laissez faire* policy in regulating pharmaceutical prices “has caused the U.S. to be the world's primary profit center for new medical innovations.”²⁸ By contrast, the U.K.—in which the government exercises control over pharmaceutical costs—has inadvertently created “a gap between new medical innovations being offered and what the

²³ HOLLIS & POGGE, *supra* note 3, at 83–89.

²⁴ *Id.* at 83–84.

²⁵ *Id.*

²⁶ INNOVATION IN GLOBAL INDUSTRIES: U.S. FIRMS COMPETING IN A NEW WORLD, COLLECTED STUDIES, NATIONAL ACADEMIES PRESS 222 (J.T. Macher & D.C. Mowrey eds., 2008); *see also* HOLLIS & POGGE, *supra* note 3, at 84.

²⁷ Macher & Mowrey, *supra* note 26, at 222.

²⁸ Seth D. Knocke, *Incentivizing Innovation: Pharmaceutical Pricing in the United States and the United Kingdom*, 20 ANNALS HEALTH L. ADVANCE DIRECTIVE 177, 177 (2011).

government system will reimburse, leaving U.K. residents without the latest medical technology.”²⁹ This suggests that the U.K.’s restriction upon patients’ pharmaceutical consumption, which results from state-imposed limitations upon the reimbursement of pharmaceutical companies for their intellectual property, has stifled robust pharmaceutical innovation and consumption in the U.K.³⁰

Further, data suggests that the United States’ patent system, as part of the general public health care system, promotes overall health. For example, it provides widespread access to life-prolonging drugs: “the survival rate for prostate cancer is 92% in the U.S., compared with 57% in Britain. . . . [A]n American woman has a 97% chance of remaining alive for at least five years after a breast cancer diagnosis, while in Britain, only 78% survive that long.”³¹

However, the U.S. patent system is no panacea for public health care: although the U.S. has led the world in pharmaceutical innovation for the past several years, the U.S. also outstrips other nations in health care spending.³² In 2008, U.S. health care expenditure “was 16% of the gross domestic product” (GDP), whereas the U.K.’s total health expenditure accounted for only 8.7% of its GDP in 2008.³³ The difference in spending, however, did not positively correlate with life expectancy; the average life expectancies at birth for both males and females in the U.S. in 2010 were lower (75.78 and 80.81 years, respectively) when compared to the average life expectancies at birth for males and females in the U.K. (77.7 and 81.9 years, respectively).³⁴ By 2009, the U.S.’s health care expenditure had grown to 16.2% of its total GDP; only Malta spent a larger portion of its GDP (16.5%) on health care expenditures.³⁵

Pharmaceutical expenditure and benefit received in the U.S. closely mirror the U.S.’s overall health care expenditure: in 2003, the average U.S. consumer spent \$700 on pharmaceutical products, and spending is on the rise.³⁶ In 2008, national prescription drug expenditure increased by 5.3%, and was expected to

²⁹ *Id.*

³⁰ *Id.*

³¹ Rick Kahler, *Healthcare on the Critical List*, FINANCIAL PLANNING (Apr. 1, 2010), http://www.financial-planning.com/fp_issues/2010_4/healthcare-on-the-critical-list-2666256-1.html.

³² Leonard J. Nelson, *Rationing Health Care in Britain and the United States*, 7 J. HEALTH & BIOMEDICAL L. 175, 179 (2011).

³³ *Id.*

³⁴ *Id.*

³⁵ Central Intelligence Agency, *Country Comparison :: Health Expenditures*, THE WORD FACTBOOK, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2225rank.html>.

³⁶ Organisation for Economic Co-operation and Development, *Drug Spending in OECD Countries Up by Nearly a Third Since 1998, According to New OECD Data* (Aug. 6, 2005), http://www.oecd.org/document/25/0,2340,en_2649_201185_34967193_1_1_1_1,00.html.

grow another 5.2% in 2009 to \$246 billion.³⁷ Continued growth in spending is projected over the next several years.³⁸ Like its overall health care expenditure, the U.S.'s pharmaceutical spending habit does not positively correlate with a higher life expectancy. Although the U.S. spent more per person on pharmaceuticals in 2003 than any other OECD country spent,³⁹ the U.S. boasts an average life expectancy of 78.49 years, with forty-nine other countries (including the United Kingdom, ranked thirtieth) with higher life expectancies.⁴⁰

Certain inherent features of the patent system can help to explain the inefficiencies and high costs that currently plague the U.S. health care regime without bringing many correlative benefits.⁴¹ Under the traditional patent system, firms that develop new pharmaceuticals can only reap the benefits of the market exclusivity afforded to them by a patent if there is an efficient market for the patented drug that is willing and able to pay the price the monopoly-holding pharmaceutical company (largely alone) sets.⁴² Thus, under the auspices of the traditional patent system, the private for-profit pharmaceutical companies tend to focus on developing drugs that target the affluent, whom the companies reasonably anticipate will be willing participants in the market for the new drugs.⁴³ This tends to result in two phenomena: first, a pharmaceutical company that has already received patent protection for a drug will seek to extend the drug's patent protection by making "incremental changes" to the drug shortly before the patent expires.⁴⁴ Second, a private firm is incentivized to develop new drugs that are similar to those already available.⁴⁵ Similar to the incremental changes incentive, creating a drug that piggybacks off of another is less time-consuming, less research-intensive, and more cost-effective (as long as the new drug is sufficiently different from the first drug to warrant separate patent protection).⁴⁶ This phenomenon leaves the market saturated with "me-too" drugs that target the affluent, while conditions that are more common among those less wealthy go unaddressed.⁴⁷

³⁷ See CMS, *supra* note 4.

³⁸ *Id.*

³⁹ See OECD, *supra* note 36.

⁴⁰ Central Intelligence Agency, *Country Comparison: Life Expectancy at Birth*, THE WORLD FACTBOOK, <https://www.cia.gov/library/publications/the-world-factbook/rankorder/2102rank.html>.

⁴¹ See HOLLIS & POGGE, *supra* note 3, at 84–85.

⁴² *Id.* at 85–88.

⁴³ *Id.*

⁴⁴ *Id.* at 4.

⁴⁵ *Id.*

⁴⁶ *Id.* at 4–6.

⁴⁷ *Id.*

Pharmaceutical companies do not always intentionally price the less affluent out of the market.⁴⁸ In fact, the untargeted, would-be consumers represent an untapped market for pharmaceutical firms, and their non-participation represents market inefficiency.⁴⁹ Price discrimination—the practice of selling the same product at different prices based upon the different maximum prices varying consumers are willing and able to pay for a drug—is difficult to accomplish. As Hollis and Pogge explain, “[C]harging different prices in different countries can lead to parallel imports between countries—the importation of inexpensive drugs from poor countries into rich countries—which results in some loss to the patentee of sales at high prices in the richer countries.”⁵⁰ In addition to being priced out of the market for drugs that pharmaceutical companies do have an incentive to develop (i.e., those drugs that the affluent are willing and able to consume), the poor suffer an additional injustice under the traditional patent system: “diseases among the poor attract little or no pharmaceutical research.”⁵¹

Despite the U.S. system’s inefficiencies, it represents a type of rationing, which simply replaces another type (i.e., a state-regulated system).⁵² Allowing a governmental entity to determine the value of a medicine, and to base its decision of coverage upon that determination, causes the unavoidable death of at least some individuals who would otherwise have benefitted from the medicine.⁵³ The “rationing” of medication—determining which patients receive which medicines—occurs in public health care regimes as well as in the free market for pharmaceuticals: “[u]nder highly centralized national health care, the government inevitably makes cost-minded judgments about what types of care are “best” for society at large, and the standardized treatments it prescribes inevitably steal life-saving options from individual patients.’”⁵⁴ However, it is more palatable to the American consumer when that rationing occurs as a result of individuals’ market-based choices rather than at the institutional level.⁵⁵

⁴⁸ *Id.* at 84–85.

⁴⁹ *Id.*

⁵⁰ *Id.* at 85.

⁵¹ *Id.* at 1.

⁵² See Nelson, *supra* note 32, at 185–86 (arguing that rationing of health care occurs both in highly centralized health care regimes as well as in decentralized ones).

⁵³ *Id.* at 178.

⁵⁴ *Id.* (quoting Editorial, *Death Panels Revisited*, WALL ST. J. (Dec. 29, 2010), <http://online.wsj.com/article/SB10001424052748703960804576120103417920260.html>).

⁵⁵ *Id.* at 232.

B. RECENT AND FORTHCOMING CHANGES: THE PATIENT PROTECTION AND AFFORDABLE CARE ACT IN THE ERA OF COMPARATIVE EFFECTIVENESS

1. *The Patient Protection and Affordable Care Act.* On March 23, 2010, President Obama signed into law the Senate's "Patient Protection and Affordable Care Act" (PPACA).⁵⁶ The Act represents the fusion of "separate bills prepared by the Senate Finance and Health, Education, Labor, and Pensions Committee, supplemented by a nearly 400 page long manager's amendment adopted on the floor."⁵⁷ The manager's amendment, attached to the end of the Act as Title X, substantially alters or negates many of the provisions that appear in the preceding titles.⁵⁸ In addition to Title X, the Health Care and Education Reconciliation Act of 2010 further amends PPACA.⁵⁹ In order to demonstrate the relative impotency of PPACA (and to describe its helpful aspects), discussion of pertinent sections of the PPACA follows.

Section 300gg-17(a)(1) of the PPACA requires the Department of Health and Human Services (HHS) to "develop reporting requirements," to be utilized by group health plans and health insurance issuers, that "improve health outcomes" and "improve patient safety . . . through the appropriate use of best clinical practices, evidence based medicine, and health information technology . . ."⁶⁰ Subtitle G contains an "Access to Therapies Provision," which states that the "HHS shall not promulgate regulations that . . . interfere with provider/patient communications regarding the full range of treatment options, restrict the ability of health care providers to provide full disclosure of patients of information relevant to treatment disclosures, [or] violate informed consent or ethical principles. . ."⁶¹ PPACA further establishes a Center for Medicare and Medicaid Innovation—to operate as part of CMS—in which Congress vests "resources and flexibility to identify, develop, rapidly test and encourage widespread adoption of innovative care and payment models, laying the groundwork for a broader transformation of our healthcare system to one that delivers better health care at lower costs," according to the CMS mission statement.⁶²

⁵⁶ Timothy S. Jost, *Introduction to the Patient Protection and Affordable Care Act & the Health Care and Education Reconciliation Act of 2010*, 2010 EMERGING ISSUES 5106, § 1.01 (LexisNexis Grp. 2010); see also *Patient Protection and Affordable Care Act*, Pub. L. No. 111-148, 124 Stat. 119 § 6301(a) (2010).

⁵⁷ Jost, *supra* note 56.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ 42 U.S.C. § 300gg-17(a)(1)(A), (C) (2010).

⁶¹ Jost, *supra* note 56, § 1.36[3].

⁶² Center for Medicare and Medicaid Innovation, *Our Mission*, <http://innovations.cms.gov/abo>

Finally, Title VI of PPACA adds Part D—Comparative Clinical Effectiveness Research—to the Social Security Act (SSA).⁶³ According to the statute, the term “comparative clinical effectiveness research” is defined as “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).”⁶⁴ Subparagraph (B) states that

[t]he medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.⁶⁵

Part IV establishes the Patient-Centered Outcomes Research Institute to conduct and implement the patient-centered research described above to benefit patients.⁶⁶ Section 1320e(c) states that

[t]he purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B) [reproduced above].⁶⁷

ut-us/our-mission/index.html; *see also* 42 U.S.C. § 1315(a) (2010) (establishing the Center for Medicare and Medicaid Innovation).

⁶³ 42 U.S.C. § 1320e (2010); *see also* Jost, *supra* note 56, § 1.57 (summarizing the provisions of Part IV of the PPACA, which establishes the Patient-Centered Outcomes Research Institute).

⁶⁴ 42 U.S.C. § 1320e(a)(2)(A) (2010).

⁶⁵ *Id.* § 1320e(a)(2)(B).

⁶⁶ *Id.* § 1320e(c).

⁶⁷ *Id.*

The Research Institute's Board of Governors is to be comprised of (1) the Director of the Agency for Healthcare Research and Quality (AHRQ), (2) the National Institute of Health (NIH) Director, and (3) seventeen members to be appointed by the Comptroller General of the United States.⁶⁸ Those seventeen members shall include three patient and consumer representatives; seven physician and provider representatives; three representatives of private payers; three representatives of drug, device, and diagnostic manufacturers; one representative of quality improvement or health services researchers, and two representatives of the federal or state government.⁶⁹ Any board member of the Institute should resolve any conflict of interest, either real or apparent, as defined in § 1320e(a).⁷⁰ Finally, § 1320e-1 places limitations upon the use of the comparative clinical effectiveness research described in § 1320e.⁷¹

In an attempt to control runaway costs, PPACA establishes the New Independent Medicare Payment Advisory Board, which will “impose Medicare payment cuts if Medicare costs are otherwise not controlled.”⁷² The Board's authority “extend[s] beyond the Medicare program to allow it to make recommendations to the President and Congress (and, indirectly, to the states) as to measures that can be taken to slow the growth of non-federal expenditures.”⁷³

Title VI of PPACA “amends 42 U.S.C. 1395w-27 to . . . authorize intermediate sanctions where a Medicare Advantage plan . . . fails to comply with marketing restrictions, or employs or contracts with an individual who engages in marketing violations.”⁷⁴ Further, Title VI amends Title XI of the Social Security Act of 1965 (SSA) to add the Reporting of Information Relating to Drug Samples, which requires that manufacturers and distributors “submit to HHS . . . the identi[t]y and quantity of drug samples requested and distributed during the [preceding] year” on an annual basis.⁷⁵ Like the marketing restriction provision, the purpose of this provision seems to be to rein in costs through the control of—or at least monitoring of—the amount of pharmaceutical companies' advertising, be it directly to consumers or to prescribing physicians.

⁶⁸ *Id.* § 1320e(f).

⁶⁹ *Id.*; see also Jost, *supra* note 56, § 1.57[2] (identifying the criteria for the composition of the Board of Governors for the Patient-Centered Outcomes Research Institute).

⁷⁰ 42 U.S.C. § 1320e(h)(4) (2010); see also Jost, *supra* note 56, § 1.57[2].

⁷¹ 42 U.S.C. § 1320e-1 (2010).

⁷² Jost, *supra* note 56, § 1.39.

⁷³ *Id.*

⁷⁴ *Id.* § 1.45[2].

⁷⁵ *Id.* § 1.54[1].

Subtitle D delineates states' obligations under the PPACA.⁷⁶ Subtitle D requires each state to establish an American Health Benefit Exchange (exchange), as well as a Small Business Health Options exchange (SHOP) by January 1, 2014.⁷⁷ A state may apply for a federal grant to facilitate the state's establishment of an exchange; grants may be awarded until January 1, 2015, after which "exchanges must be self-sustaining through charging assessments or user fees to health insurers."⁷⁸ States may collaborate in order to create and offer regional exchanges, provided they obtain approval from HHS.⁷⁹ "Exchanges may contract with the state Medicaid agency or with 'eligible entities' that have relevant experience but are not health insurers to carry out certain exchange functions."⁸⁰

2. *Where We Are Now: Scholarship's Perspective.* Current scholarship offers mixed reports about the ability of the U.S.'s evolving health care regime, codified in PPACA's provisions, to exact the purposes for which it was enacted. "The PPACA represents perhaps the biggest change to Medicaid in the program's history."⁸¹ Part of the ongoing change evident in the PPACA legislation could be due to a greater emphasis on comparative effectiveness: that is, increased focus on (1) how a new therapy compares to other, existing therapies for a particular illness and (2) whether the new therapy produces benefits that outweigh its costs.⁸² On the other hand, perhaps the federal government should act as the regulator of pharmaceutical costs.⁸³

Emphasis upon comparative effectiveness was codified in the American Reinvestment and Recovery Act of 2009 (ARRA), which "included an appropriation of \$1.1 billion to fund CER allocated among the Department of Health and Human Services, the National Institutes of Health, and the Agency for Healthcare Research and Quality (AHRQ)."⁸⁴ The Act established the Federal Coordinating Council for Comparative Effectiveness Research to "coordinate CER efforts at the federal level."⁸⁵ Although the PPACA built

⁷⁶ *Id.* § 1.17.

⁷⁷ 42 U.S.C. § 18031 (2010); *see also* Jost, *supra* note 56, § 1.17[1], [2].

⁷⁸ Jost, *supra* note 56, § 1.17[1].

⁷⁹ 42 U.S.C. § 18031(f)(1) (2010).

⁸⁰ Jost, *supra* note 56, § 1.17[2].

⁸¹ *Id.* § 1.37.

⁸² Saver, *supra* note 21, at 445; *see also* Patsner, *supra* note 19, at 42 (arguing that CMS's rising prominence in the drug approval and marketing process will foster increased emphasis on comparative effectiveness).

⁸³ *See* Nelson, *supra* note 32, at 178 (quoting Editorial, *Death Panels Revisited*, WALL ST. J., Dec. 29, 2010).

⁸⁴ Saver, *supra* note 21, at 438.

⁸⁵ *Id.*

upon ARRA's efforts to fund CER, it also called for the replacement of the Federal Coordinating Council with an entity largely controlled by private interests, the Patient-Centered Outcomes Research Institute (PCOR Institute).⁸⁶ The establishment of a privately controlled institute represents a limitation on the federal government's power to wield comparative effectiveness information,⁸⁷ as will be explored in the Analysis section below. Further, as a result of Congressional debates prior to the passage of PPACA, which raised fears of rationing and death panels, the final version of PPACA significantly restricts the use of CER.⁸⁸ PPACA "prohibits the Medicare program from making coverage decisions 'solely on the basis' of CER."⁸⁹ When Medicare does consider CER as a factor affecting coverage, "Medicare cannot use the evidence to assert that some treatments are less effective because they primarily help patients with an allegedly lower quality of life."⁹⁰ Finally, Medicare "cannot use CER in a manner 'that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value' than the needs of other patients."⁹¹

Apart from public health care, PPACA does not directly regulate private health insurers' implementation of CER.⁹² However, that does not mean that private pharmaceutical firms will be unaffected by PPACA.⁹³ Since CMS is the single largest payer for pharmaceuticals in the world (CMS covers roughly 40% of all prescriptions in the U.S.),⁹⁴ it has significant bargaining power with pharmaceutical firms, which allows it to negotiate for competitive prices on pharmaceuticals.⁹⁵

The statutory shift toward funding and incentivizing CER has placed CMS in a position to reduce the costs and increase the effectiveness of the pharmaceuticals it covers.⁹⁶ CMS has traditionally been a mere financier of pharmaceutical products, while the Food and Drug Administration (FDA) has

⁸⁶ *Id.* at 438–39.

⁸⁷ *Id.*

⁸⁸ *Id.* at 439.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ Patsner, *supra* note 19, at 72.

⁹⁵ *Id.* at 72–73.

⁹⁶ *See id.* at 42 (arguing that CMS's decision on whether and how much it is willing to pay for a medical product or service is just as important, perhaps more important, than FDA's decision to allow the product or service on the market).

been the primary evaluator of new drugs.⁹⁷ As such, the FDA was concerned primarily with whether a new drug was safe for consumption, and rarely considered whether a drug was comparatively more effective than others already on the market.⁹⁸ CMS, on the other hand, has begun to take a more active role in the evaluation of new drugs with an eye toward their comparative effectiveness.⁹⁹ This, CMS hopes, will result in cost control, as it refuses to cover pharmaceuticals that are neither more effective nor cheaper than others already available.¹⁰⁰ Because CMS is the single largest consumer of pharmaceuticals in the U.S. market, it has significant bargaining power with the pharmaceutical industry. This will result in the development of drugs that are not only safe and effective, but that are also more effective or cheaper (or both) than their predecessors.¹⁰¹ However, CMS could be limited in the efficiency and cost-savings that it can achieve because of a deep-seated, cultural fear of the rationing of health services and medicines:

[E]fforts at cost control and payment based on purported comparative criteria have been criticized repeatedly when it appeared that patients were denied access to valuable, proven medical therapy that actually offered value for the money or a comparative advantage over existing therapy simply because private carriers did not want to pay for it.¹⁰²

Other scholars, cognizant of the same cultural fear of socialized medicine and rationing, are less optimistic that CMS will be able to achieve meaningful cost reform in pharmaceutical spending and efficiency.¹⁰³

C. THE HEALTH IMPACT FUND

1. *HIF Summary.* Proposed by Aidan Hollis and Thomas Pogge, *The Health Impact Fund: Making New Medicines Accessible for All* (HIF), seeks to remedy the market inefficiencies of the traditional patent system and decrease the cost of pharmaceuticals to all consumers.¹⁰⁴ The HIF is a “pay-for-performance

⁹⁷ *Id.* at 42–49.

⁹⁸ *Id.* at 45–49.

⁹⁹ *Id.* at 40–44.

¹⁰⁰ *Id.* at 56–59.

¹⁰¹ *Id.* at 42–45.

¹⁰² *Id.* at 64.

¹⁰³ See Nelson, *supra* note 32, at 223–24 (quoting Jacqueline Fox, *The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust*, 79 U. CIN. L. REV. 1, 5–6 (2010)).

¹⁰⁴ HOLLIS & POGGE, *supra* note 3, at 1–2.

scheme,” which would supplement, rather than replace, the patent system.¹⁰⁵ Under this scheme, a pharmaceutical company would have the option either to exercise its traditional intellectual property rights by seeking patent protection for a newly developed drug, or to register that drug with the HIF instead.¹⁰⁶ A firm’s decision to register one drug with the HIF would not affect its freedom to seek traditional patent protection for another drug later; a firm’s participation in the HIF system would be completely optional with each newly developed drug.¹⁰⁷ Registration of a drug with the HIF would require the firm to offer the drug to all consumers at a price “near the average cost of production and distribution.”¹⁰⁸ The firm would later receive proportional reimbursement from the HIF for its drug based upon how valuable the HIF determines the drug to be in comparison to all other registered drugs during a specific period of time.¹⁰⁹ This reimbursement would come from funds contributed to the HIF by “partner countries that agree to support [the HIF].”¹¹⁰

2. *Measuring Health Impact.* The HIF will determine the value of a particular drug by gathering data from the drug’s consumers.¹¹¹ This data will be used to calculate the number of quality-adjusted life years (QALYs) the drug has contributed to its consumers through its therapeutic effects.¹¹² The QALY measurement places a higher value on a year of perfect health than a year of imperfect health; therefore, in calculating a drug’s QALY rating, a year of perfect health would be ascribed a value of one, and a year of imperfect health would be ascribed a value between zero and one.¹¹³

Several nationalized health care regimes, including the U.K.’s National Institute for Health and Clinical Excellence (NICE), already use a cost-per-QALY-like formula when determining which therapies the state will cover for its participants.¹¹⁴ Essentially, the cost-per-QALY formula is a cost-benefit analysis. When making coverage decisions, NICE considers several factors when calculating the cost of a proposed therapy, including “all direct medical costs, cost of adverse side effects associated with treatment, savings due to prevention or alleviation of the disease in question, and future costs related to

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 1.

¹⁰⁸ *Id.*

¹⁰⁹ *Id.*

¹¹⁰ *Id.* at 4.

¹¹¹ *Id.* at 9.

¹¹² *Id.*

¹¹³ *Id.* at 28.

¹¹⁴ See Nelson, *supra* note 32, at 178 (describing NICE’s cost-effectiveness approach to making coverage decisions for patients in the U.K.).

the treatment of disease.”¹¹⁵ NICE then compares that cost to the therapy’s expected QALY.¹¹⁶ For example, a QALY calculation might look like this:

[C]onsider an individual . . . who will die unless she chooses either radiation or surgery. Radiation guarantees five additional years of life, with a quality adjustment of 0.8, and thus confers a QALY benefit of 4. Surgery is associated with a 20% risk of death; for those who do not die, however, it gives eight additional years of life in full health. Surgery thus confers a QALY benefit of 6.4 (an 80% chance of achieving an 8 QALY benefit).¹¹⁷

Similarly, this sort of cost-benefit analysis occurs in the U.S.’s private sector when insurance companies determine whether to cover a proposed therapy for a particular policyholder.¹¹⁸ The allocation of “scarce resources” within a particular society have been described as “tragic choices.”¹¹⁹ “[T]ragic choices’, i.e. rationing decisions through public and transparent processes that result in the suffering and death of specific persons, exacerbate social tensions. Thus, societies inevitably try to conceal the conflict in values to avoid the appearance of making a ‘tragic choice.’”¹²⁰ Americans generally accept the making of tragic choices, i.e., rationing, in the private sector, because its occurrence can be attributed to the forces of free market capitalism.¹²¹ Many Americans, however, find it particularly unpalatable when the Government engages in the same cost-benefit analysis; they find it to be a blatant, unwarranted allocation of resources.¹²²

Under the HIF, the more years of the highest possible level of health a drug contributes to a particular patient, the higher the drug’s QALY rating will be.¹²³ Further, the larger the pool of patients who benefit from a certain drug, the higher the QALY rating of the drug will be.¹²⁴ Theoretically, therefore, the HIF

¹¹⁵ Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015, 1049 (1997).

¹¹⁶ *Id.* at 1049–50.

¹¹⁷ *Id.* at 1050.

¹¹⁸ See Nelson, *supra* note 32, at 180 (recognizing that “some economists would define rationing to include allocation of health care services through both the market and political processes”).

¹¹⁹ *Id.* at 185 (citing GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* 31–50 (W.W. Norton & Co. 1978)).

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.* at 183–85.

¹²³ See HOLLIS & POGGE, *supra* note 3, at 28.

¹²⁴ *Id.*

scheme creates an incentive for firms to create drugs that provide the highest quality of life to the largest number of patients.¹²⁵ It is unclear whether the HIF would provide a different weighting to life years gained for patients of different ages.

Critics of the QALY measurement “argue that the quality of life cannot be determined on the basis of mathematical terms”¹²⁶ Further, critics contend that a decisionmaker’s process of determining whether to make a therapy available based upon a cost-per-QALY cost-benefit analysis “creates obstacles for patients who are willing to receive the drug, especially those who can afford the cost of the treatment.”¹²⁷

3. *Funding.* Hollis and Pogge suggest two types of funding for the HIF: (1) a state can opt to become a member of the HIF by committing to make pre-structured payments, or (2) states and non-state actors alike can make “unstructured payments into the HIF at any time.”¹²⁸ States that commit to membership in the HIF would be responsible for contributing a predetermined percentage of its gross national income (GNI), calculated annually, to the HIF for a predetermined incentive period.¹²⁹ The authors suggest that this period should be roughly twelve years.¹³⁰ A period of this length would reassure the pharmaceutical industry that reward incentive funds would be available during the most expensive stage of research and development for a drug, namely the clinical trials during the few years prior to market clearance.¹³¹

4. *Reimbursement.* Reimbursement from the HIF to a firm will depend on (1) the QALY rating of the drug compared to other HIF-registered drugs for a particular year and (2) the amount of money that member countries have invested in the HIF for that particular year.¹³² The use of QALY measurement for determining a drug’s value—and therefore, a firm’s proportion of reimbursement—gives firms an incentive to ensure that patients use their pharmaceuticals properly, so that those patients can receive the highest therapeutic effect possible. This will also increase the QALY rating of the firm’s drug.¹³³

¹²⁵ *Id.*

¹²⁶ See Sonsy Pulikotil Rajan, *Comparative Effectiveness Research in the United States*, 10 J. INT’L BUS. & L. 431, 437 (2011).

¹²⁷ *Id.* at 437–38.

¹²⁸ See HOLLIS & POGGE, *supra* note 3, at 43.

¹²⁹ *Id.* at 43–44.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.* at 13–14.

¹³³ *Id.* at 6.

D. HEALTH CARE REFORM IN MASSACHUSETTS

In 2006, the Massachusetts legislature succeeded in passing substantial reform to its public health care regime.¹³⁴ These reform measures include a mandate that all Massachusetts residents carry insurance coverage, as well as government subsidies for health insurance, which seek to ensure the affordability of the obligatory insurance.¹³⁵ Employers with eleven or more employees are required to provide health insurance, or otherwise to pay a “Fair Share” contribution which may not exceed \$295 annually per employee.¹³⁶ The legislation also creates a Commonwealth Health Insurance Connector through which individuals and small businesses can purchase health insurance.¹³⁷ Further, the legislation establishes the Commonwealth Care Health Insurance Program, which offers sliding-scale subsidies for health care insurance to residents who earn up to 300% of (or three times) the federal poverty level, and provides fully-subsidized health care for those earning up to 150% of the poverty level.¹³⁸ The expansion of MassHealth extends Medicaid coverage to children whose guardians earn up to 300% of the federal poverty level, and enrollment caps on existing Medicaid programs for adults have also been elevated.¹³⁹ Further, Massachusetts’ health care plan calls for a merger between individual and small-group insurance markets, after a legislation-mandated study projected that such a merger would raise the cost of premiums for small employers by about 1.5%, but would also lower the average cost of premiums to individuals by 15%.¹⁴⁰ The legislation further replaces the “Uncompensated Care Pool” with the “Health Safety Net Trust Fund.”¹⁴¹ Money from this fund is to be utilized—along with Medicaid Disproportionate Share Hospital Funds—to reimburse hospitals for emergency services rendered to uninsured patients.¹⁴²

Funding for the Massachusetts health care reform program comes from existing sources—the federal Medicaid program, as well as a “redistribution of existing funding”—and additional contributions from employers and “General

¹³⁴ Kaiser Comm’n on Medicaid & the Uninsured, Henry J. Kaiser Family Found., *Massachusetts Health Care Reform Plan – An Update*, 1 (June 6, 2007), <http://www.kff.org/uninsured/upload/7494-02.pdf>.

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

Fund revenues.”¹⁴³ The Massachusetts legislature determined that “minimum creditable coverage” includes “preventive and primary care, emergency services, hospitalization benefits, ambulatory patient services, mental health services,” and significantly, “prescription drug coverage.”¹⁴⁴

Massachusetts’ health care reform initiative has met with mixed success.¹⁴⁵ On one hand, almost all of Massachusetts’ residents now carry health insurance: “[m]ore than 98[%] of Massachusetts’ residents now have insurance, including 99.8[%] of all children, making Massachusetts’ rate of uninsured the lowest in the United States.”¹⁴⁶ Further, “[a]bout 77[%] of private companies are providing health insurance to their employees, compared to 70[%] before the law was passed”¹⁴⁷ However, while the law has increased the number of insured, as well as the number eligible for government subsidies, the law has not succeeded in reducing costs to insurance policy holders.¹⁴⁸ “Private spending per member grew by 15.5[%] on average between 2006 and 2008. Meanwhile, average premiums for full insurance increased 12.2[%] from 2006 to 2008, according to the Massachusetts Division of Health Care Finance and Policy.”¹⁴⁹ However, support for the legislation remains vigorous: “[t]wo out of three adults in the state support the law, while 88[%] of doctors say it improved, or did not affect, the quality of care, per the BCBS survey.”¹⁵⁰

Those opposing the Massachusetts reform measures indicate that individual policy holders have largely carried the financial burden of the law’s enactment: “[t]he median health insurance premium for a policy holder in Massachusetts was \$442 in 2009, a 21[%] jump from 2005. Meanwhile, employers’ share of premiums fell in the same time period.”¹⁵¹ Additionally, the number of Massachusetts residents who filed for bankruptcy due to medical expenses increased by more than 33% between 2007 and 2009.¹⁵²

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Huma Khan, *Has Mitt Romney’s Massachusetts Health Care Law Worked?* ABC NEWS BLOGS (May 12, 2011), <http://abcnews.go.com/blogs/politics/2011/05/has-mitt-romneys-massachusetts-health-care-law-worked/>.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* (citing David U. Himmelstein, Deborah Thorne & Steffie Woolhandler, *Medical Bankruptcy in Massachusetts: Has Health Reform Made a Difference?*, 124 AM. J. MED. 224, 224–28 (2011)).

III. ANALYSIS

A. A NEW ERA OF COMPARATIVE EFFECTIVENESS?

While current scholarship offers mixed reviews about whether the United States has truly moved into an era of comparative effectiveness,¹⁵³ directives have been codified in the PPACA order to ensure higher-quality health results,¹⁵⁴ which should have positive implications for the cost and quality of pharmaceuticals. Section 300gg-17(a)(1) of the PPACA is exemplary: although this section does not directly affect the patenting of pharmaceuticals that are approved by the FDA, the section does directly affect a payer's or insurer's decision of whether to cover a particular drug.¹⁵⁵ Because the section calls for the HHS to develop reporting requirements that provide payers and insurers with improved information regarding how "clinical practices" compare with one another, these payers will theoretically be better positioned to offer to their insured only the most effective and least expensive treatments. Cheaper and more effective treatments might in turn incentivize pharmaceutical companies to develop and produce drugs that are truly innovative (rather than "me-too" drugs), or to offer drugs similar to those already available at a lower price.

At first blush, the Access to Therapies provision may seem to cut against the goals of comparative effectiveness: it appears to allow patients to choose treatment options other than the most cost-effective, continuing to foster doctor-patient "communications regarding the full range of treatment options."¹⁵⁶ However, patients are likely to make the most cost-effective decisions for themselves based on the resources available to them and how much value they place on the health benefits associated with each proffered therapeutic option. Therefore, the more information that is available to each patient, the more likely he will be to make a rational cost-benefit analysis, leading to a collective trend of increased use of the most cost-effective treatment. This sharply contrasts with the traditional FDA regime, under which comparative effectiveness data is largely unavailable.¹⁵⁷

Title VI of PPACA's amendment to 42 U.S.C. 1395w-27 suggests that one of PPACA's tools for cutting costs is restricting faulty information from

¹⁵³ See Saver, *supra* note 21, at 437–38 (addressing the optimism and the concern surrounding comparative effectiveness research).

¹⁵⁴ See Jost, *supra* note 56, § 1.04[9] (listing the different reporting requirements established in the PPACA).

¹⁵⁵ 42 U.S.C. § 300gg-17(a)(1) (2010).

¹⁵⁶ Jost, *supra* note 56, § 1.36[3].

¹⁵⁷ Patsner, *supra* note 19, at 41–42.

reaching consumers.¹⁵⁸ In other words, marketing restrictions were put in place to keep consumers from making treatment decisions based on skewed or biased advertising, which may lead to less effective treatment decisions than might otherwise be made, while lining the pockets of the drug manufacturer.¹⁵⁹ If the enforcement of marketing restrictions is a goal of the PPACA, then it is a goal harmonious with the HIF proposal: a pharmaceutical company that registers a drug with the HIF may have a decreased incentive to advertise its product to consumers since the profit that the company realizes comes not from sales, but from the health impact of the drug, as measured by the HIF.¹⁶⁰ However, a pharmaceutical company's incentive to advertise would not be reduced to zero under the HIF. Since the company's reimbursement will depend in part upon how many consumers of the drug realize a health benefit,¹⁶¹ the company will necessarily want as many consumers as possible to purchase and use the drug.

Despite PPACA's advancements—and despite CMS's ability to bargain for higher quality and lower costs for the pharmaceuticals it chooses to cover¹⁶²—there is significant evidence that the U.S. has a collective resistance to the idea of institutions such as CMS basing its decision to cover a particular drug upon its own judgment that the drug's benefits outweigh its costs.¹⁶³

B. APPLICATION OF THE HIF IN THE UNITED STATES

The HIF proposal has several positive implications for the developing world, but those implications will remain largely unaddressed in this Note. Arguably, the developing world stands to gain the most from the correction of the patent system's deficiencies discussed above (namely, the pricing-out of the poor for existing drugs and the lack of incentives for pharmaceutical companies to develop drugs to address conditions that largely affect the poor).¹⁶⁴ The benefits that U.S. consumers stand to gain may be less evident. In light of the

¹⁵⁸ 42 U.S.C. § 1395w-116(f)(2) (2010) (amended by Patient Protection and Affordable Care Act, tit. VI, Pub. L. No. 111-148, 124 Stat. 119 (2010)).

¹⁵⁹ *Id.*

¹⁶⁰ See HOLLIS & POGGE, *supra* note 3, at 13 (noting that “[t]he essence of the HIF mechanism is that innovators are rewarded in proportion to the measurable net health impact of their innovations”).

¹⁶¹ *Id.* at 29.

¹⁶² See Patsner, *supra* note 19, at 43.

¹⁶³ See Nelson, *supra* note 32, at 185; see also *supra* notes 120–22 and accompanying text. The resistance has also been codified in PPACA. Patient Protection and Affordable Care Act, tit. VI, § 6301(c), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified at 42 U.S.C. § 1320e); see also Saver, *supra* note 21, at 439.

¹⁶⁴ HOLLIS & POGGE, *supra* note 3, at 18.

ever-growing cost of health care in the U.S., the HIF offers an alternative to the patent system and may allow pharmaceutical companies to offer their drugs at lower prices while still realizing economic gain for their intellectual property.¹⁶⁵

A major complication that the HIF proposal does not address is the incorporation of third party payers for prescription drugs. There are a variety of ways in which consumers worldwide—whether aided by their government or not—finance the pharmaceuticals they consume. In many developing countries, consumers pay a substantial amount of the full price out-of-pocket for pharmaceuticals they consume.¹⁶⁶ In these countries, there is no public safety net in place for those who cannot afford essential medicines, and access to medicine is, therefore, very limited.¹⁶⁷

However, most countries in the developed world implement very different systems for financing patients' pharmaceuticals, which involve a third party payer.¹⁶⁸ This third party payer can range from a number of entities: a private insurer, the national government, or a combination of the two.¹⁶⁹ The HIF proposal fails to address the way in which third party payers will fit into its scheme; it appears, however, that application of the HIF would be more complicated when utilized alongside a third party payment system than when utilized alongside a direct payment system. For example, in a direct payment system, the state presumably would pay into the HIF, and then participating firms would offer their pharmaceutical innovations to that state's citizens at the cost of production of the drug.¹⁷⁰ Perhaps then, the at-cost payments that the consumers make for their prescriptions would be made to the pharmacy, which would keep a portion to cover its costs and then pass along the rest of that payment to the drug's developing firm.

However, under the U.S. third party payment system, the HIF process would work slightly differently. Currently in the U.S., most prescription drug users do not pay out-of-pocket for the prescriptions they have filled, but

¹⁶⁵ *Id.* at 84–85, 91–92.

¹⁶⁶ RAMESH GOVINDARAJ, MICHAEL R. REICH & JILLIAN C. COHEN, WORLD BANK HUMAN DEVELOPMENT NETWORK, WORLD BANK PHARMACEUTICALS 8–9 (2000), <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1095698140167/Govindaraj-WBPharmaceutical-whole.pdf>.

¹⁶⁷ *Id.* at 9–11 (discussing inadequate government regulatory capacity and inadequate access to essential drugs as two of the most important issues regarding developing countries' struggle to achieve pharmaceutical industry stability).

¹⁶⁸ See MILTON SILVERMAN ET AL., BAD MEDICINE: THE PRESCRIPTION DRUG INDUSTRY IN THE THIRD WORLD 229 (1992) (discussing the inadequacies of existing safety nets in third world nations).

¹⁶⁹ *Id.*

¹⁷⁰ HOLLIS & POGGE, *supra* note 3, at 9.

employ a third party, such as a private insurer or a governmental program (such as Medicare or Medicaid), to reimburse the provider of the drug on the patient's behalf.¹⁷¹ Of course, third party coverage is rarely unlimited; patients may face coverage limits or they may be required to contribute a co-payment.¹⁷² Presumably, upon opting into the HIF, the U.S. would make an initial payment to the HIF as a contribution to the HIF's future pay-for-performance reimbursements to pharmaceutical firms.¹⁷³ The U.S. would also act as a third party payer to the pharmacy from which a patient received his medicines, a portion of which would subsequently go to the drug's manufacturer. Thus, the federal government would effectively pay twice for the same treatment: once as an up-front payment into a fund held in escrow, which would later be divvied up by the HIF based on the effectiveness of each treatment, and then again as an at-cost payment directly to the pharmaceutical company that produced the drug. Because the federal government would effectively be making two payments, the HIF may not result in cost savings in the U.S. market.

Aside from administrative complications, uncertainties about the perceived value of the HIF proposal remain. More specifically, the contentions raised by measuring one's quality of life in mathematical terms might be more pronounced in the U.S., where citizens tend to value individual liberties over social equality. However, if the HIF is applied in the U.S., the fact that a particular drug's cost-per-QALY ratio is not high enough to warrant sufficient reimbursement from the HIF would not bar the drug's innovator from exercising his patent rights and offering the drug for sale on the open market.¹⁷⁴ Therefore, patients who are willing and able to pay for a drug with a QALY rating too low to be covered under and reimbursed by the HIF would still be able to purchase the drug if it was offered for sale on the open market.

Even if the average number of additional years that a therapy provides could be determined with some certainty, the quality of those additional years is highly subjective. Further, it is likely that, if the HIF were in fact implemented in the U.S., there would be significant reaction against its QALY measurement method for determining a drug's value and reimbursing pharmaceutical companies for their intellectual property registered with the HIF. This is because the QALY measurement is much like the CER standard, which has

¹⁷¹ THE HEALTH STRATEGIES CONSULTANCY, LLC, FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 14 (2005), available at <http://www.kff.org/rx/drugs/upload/Follow-The-Pill-Understanding-the-U-S-Commercial-Pharmaceutical-Supply-Chain-Report.pdf>.

¹⁷² *Id.*

¹⁷³ See HOLLIS & POGGE, *supra* note 3, at 43–44.

¹⁷⁴ See *supra* notes 106–08 and accompanying text.

been incorporated into the PPACA with strict limitations upon its scope of implementation.

Because the HIF would significantly reduce inter-firm competition, pharmaceutical companies could benefit from decreased spending on advertising its products and pursuing litigation against other firms.¹⁷⁵ This might increase the appeal of the HIF to the pharmaceutical industry, making it more feasible in the U.S. market.

Because the HIF calls for generous investment in gathering data about registered drugs, implementation of the HIF in the U.S. could help to solve the problem of the lack of information, which must be resolved in order to identify and deploy the most effective treatments.¹⁷⁶ In order for prescribers to prescribe—and payers to cover—the most cost-effective pharmaceuticals, they must have access to information comparing pharmaceuticals to one another. The traditional patent system does not foster access to this information; instead, manufacturers conduct clinical trials for their own products, which often proffer outcomes that do not reflect the drug's effectiveness for the general population.¹⁷⁷ The HIF's proposed globally comprehensive database could foster more centralized, more inclusive, and less biased information about a drug's value based upon prescriber and patient feedback. Further, this information would reflect the effect of a particular drug upon a broad range of real-world patients.

For the HIF to be an effective solution to the lack-of-information issue, several different pharmaceuticals that target the same illness would need to be registered. If one of these proved to be a significantly more effective treatment for most or all patients than any other treatments, then that drug's manufacturer would receive a significantly greater portion of reimbursement funds from the HIF. This may prompt the manufacturer's unsuccessful competitors to withdraw their similar products from the program and perhaps attempt to exercise their traditional patent protection rights on the free market. This use of the HIF, theoretically, could result in more comparative data being made available to consumers about several pharmaceutical treatment options

¹⁷⁵ See HOLLIS & POGGE, *supra* note 3, at 6–7.

¹⁷⁶ See Rajan, *supra* note 126, at 436 (stating that “CER in the US must first involve consolidation of all studies, clinical trials, post market surveillance and the like carried out in a therapy area for a specific disease condition. Second, it must apply the result of the studies to determine the value afforded by various treatment options available in the market. Third, it must weed out treatment options that are not beneficial to the patient population as a whole.”); see also Saver, *supra* note 21, at 442–43 (discussing the need for randomized, controlled trial (RCT) data to “reflect real world circumstances”).

¹⁷⁷ See HOLLIS & POGGE, *supra* note 3, at 29–30.

for a particular illness. Alternatively, it could result in the most universally effective drug being made available to consumers through the HIF—again, assuming sufficient participation of pharmaceutical companies in the first place.

Competing and comparable drug therapies that treat the same illness should not be confused with the “me-too” drugs that plague the patent system, which the HIF seeks to disincentivize. Standards would be set in place within the HIF system, which would bar firms from registering drugs with the HIF that are too similar to drugs already registered.¹⁷⁸ This is likely to raise two issues: (1) windfall profits for a firm that develops a wildly successful therapy and enjoys market exclusivity for the therapy under the HIF, and (2) disagreement—and possibly litigation—between the HIF and private firms over what constitutes a sufficiently dissimilar pharmaceutical therapy. Although adoption of the HIF in the U.S. could bring about cost savings and beneficial innovation in the pharmaceutical market, the HIF’s implementation raises complex legal and logistical issues.

C. OTHER NATIONAL OPTIONS?

Because the QALY measurement for a drug’s value is likely to be controversial if the HIF is applied in the U.S., it may be prudent to consider other alternatives that address the patent system’s deficiencies yet are unlikely to face similar resistance in the U.S. market. CMS’s role in the approval process of new pharmaceuticals—and the growing significance of its decision to cover the cost of those pharmaceuticals for its patients—may be the preferred tool for bringing down the cost of pharmaceuticals, as well as for ensuring the efficacy of newly developed drugs.¹⁷⁹ This solution is unlikely to face much opposition in the United States. The CMS has been an established and accepted part of the American regime for decades, whereas the HIF, in contrast, is a revolutionary, yet-to-be implemented proposal.

Alternatively, significant cost-savings on healthcare spending may be realized by converting Medicare from a service benefit program to a voucher program.¹⁸⁰ However, even this change would require the general public’s recognition of the need for “fundamental reform” of the Medicare program, as well as significant bipartisan cooperation to pass reform legislation.¹⁸¹

¹⁷⁸ See *id.* at 14.

¹⁷⁹ See Patsner, *supra* note 19, at 41–43 (discussing the shift in power in the relationship between the FDA and CMS).

¹⁸⁰ Nelson, *supra* note 32, at 231–32.

¹⁸¹ *Id.*

D. STATEWIDE IMPLEMENTATION OF THE HEALTH IMPACT FUND

Although it is unlikely that the U.S. will adopt the Health Impact Fund nationwide, it is more likely that individual states could successfully participate in the worldwide HIF, or alternatively, could adopt a statewide HIF model within their own borders. Because the HIF model is likely to be highly controversial on a nationwide scale, individual states—some of whose constituents are more politically liberal—have a better chance of passing controversial legislation statewide instead of vying for similar measures nationwide. This phenomenon may help to explain the passage of Massachusetts' contentious health care reform in 2006.

If individual states were to subscribe to the worldwide HIF, they would have to devise a way to pay into the fund before their citizens begin receiving the benefit of at-cost prices for pharmaceutical products. This may be accomplished with or without federal funding. Without federal funding, the burden to raise the revenue required for participation within the HIF would fall largely upon the taxpayers within the particular state. Otherwise, the federal government may grant funds for a specific state to participate, in which case the tax-paying burden would be more evenly spread throughout the whole U.S. (although the whole U.S. would not receive the benefits of the state's participation in the HIF). The federal government could make grants to a participating state contingent upon the program's success and might demand repayment if the program realized extensive cost savings.

However, the alternative implementation of the HIF within individual states would not be without its own complications. If a state experiences success under the HIF program—that is to say, if it realizes cost-reduction of pharmaceuticals for its consumers—out-of-state patients may be tempted to fill their prescriptions within the HIF-participant state's borders. This closely mirrors the complications of price discrimination among disparate countries, which occurs when residents of Country *A* travel to neighboring Country *B* to purchase pharmaceuticals that are sold at a lower price in Country *B* than Country *A*.¹⁸² This parallel importation problem could also apply between different interstate transactions (i.e., between various U.S. states) as easily as it applies between countries, such as Mexico, the U.S., and Canada.¹⁸³

¹⁸² See HOLLIS & POGGE, *supra* note 3, at 85.

¹⁸³ *Id.*

IV. CONCLUSION

The United States has experienced much success in implementing its national patent protection system for pharmaceuticals. The U.S. has been the worldwide leader in pharmaceutical innovation for the past several years, and there is evidence that the patent system has fostered—and continues to foster—the type of beneficial innovation that it seeks to promote.¹⁸⁴

However, the patent system does not foster pharmaceutical innovation very efficiently.¹⁸⁵ Instead, the patent system has contributed to the high cost of pharmaceuticals and often incentivizes the developers of pharmaceuticals to pursue goals that are socially suboptimal.¹⁸⁶ As health care costs generally—and pharmaceutical costs specifically—continue to rise, it is essential to explore options for reforming or supplementing the traditional patent system for the protection of pharmaceuticals. These options could help to bring down costs while maintaining or improving the quality of pharmaceuticals.

Although it neither alters the structure of the patent system nor supplements it with another system of intellectual property protection, the Patient Protection and Affordable Care Act does remedy some of the problems that inhere in the patent system to a certain extent.¹⁸⁷ The Act calls for increased research into a therapy's comparative clinical effectiveness with the goal of reining in costs of health care interventions while preserving or increasing the quality of those interventions.¹⁸⁸ However, a national sentiment which strongly opposes a centralized, single-payer health care system—much like the ones found in Western European countries—has been largely responsible for the installation of tight restrictions on CMS's use of comparative effectiveness research.¹⁸⁹ Given these restrictions and the sentiments they reflect, it is highly unlikely that the U.S. would opt to participate in a global implementation of the Health Impact Fund, although participation could help decrease the financial burden upon the U.S. that global disease poses, as well as poverty and disease of the U.S.'s own impoverished populations.

Although the U.S. is not likely to implement the HIF system in the foreseeable future—largely because of popular resistance—individual states could experience success either by (1) participating in the global HIF program should it come to fruition, or (2) creating their own intrastate HIF models to be

¹⁸⁴ See Macher & Mowrey, *supra* note 26.

¹⁸⁵ See HOLLIS & POGGE, *supra* note 3, at 85–88.

¹⁸⁶ *Id.*

¹⁸⁷ See Saver, *supra* note 21, at 437.

¹⁸⁸ *Id.*

¹⁸⁹ *Id.* at 439.

used within and among other states, perhaps even in conjunction with other countries, such as Canada and Mexico. As the Massachusetts health care reform indicates, this sort of radical change is more likely to occur in a statewide health care regime rather than at the national level because it is easier for a state to act collectively to implement radical legislation than it is for the entire U.S. Further, the statewide Medicaid programs, which serve a poorer population that is more likely than the general population to benefit from HIF-registered drugs, may have greater incentives than does the general U.S. to implement a HIF model. Although the HIF would be difficult to implement nationwide, the proposal could prove instrumental in bringing the U.S. (or its individual states) closer to an ideal pharmaceutical market as the country continues to struggle with making health care effective, affordable, and accessible to all.

