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BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

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CONTENTS

Editor's Note
Seth Knocke

ARTICLES

Solidarity or Personal Responsibility? A Look at the Lessons Switzerland's Health Care System Can Teach the United States
Britany Fijolek ..……..….1

The High Cost of Health: The French System and What It Means for the U.S.
Mira Radadia.……..……...14

A Brief Summary of the Australian Universal Health Coverage System: Must Increased Access Equate to Decreased Quality and Efficiency?
Kelly Gallo ….……27

Chilean Health Reform and the AUGE Plan: Lessons for the United States in Implementing PPACA
Carrie Gilbert …...……...…….38

Cost Control: What the United States Can Learn from Japan's Fee Schedule
Timothy Black …..……52

Addressing the Unacceptable State of Health Care in the U.S.: Lessons to be Learned from Spain's Focus on Primary Care
Sean Walter..……..……...…….66

Health Information Technology and Primary Care: Health Care Lessons from Denmark
Alissa Bugh …….....……82

Advantages and Limitations of EHRs: A Global Perspective
Andrew Holmstrom …….……..……....93

Turkish Pharmaceuticals: An Industry In Transition
Keshia Carswell ……...…….……..……...……...…106

The National Essential Medicines List in China and What the United States Can Learn
Patrick Gleeson ……...…….…….……..117

Italy's Health Care System: Reducing Regional Disparities for At-Risk Populations
Alexandra Hall ……....126

Lessons from Canada's Equalization Regime: Examining America's Intergovernmental Efforts to Achieve Accessible Health Care Coverage Through Medicaid
Michaela Bantilan ……..…….……..…..139

Shortfalls of the Canada Health Act: Overstatements of Financial Benefits and Potential Pitfalls for the Critically Ill
Jeremy Ross …..…..……..152

The Future of Dementia Care: What the U.S. Can Learn From Norway
Chris McAdam ….……...…….……..…..163

Sex-Selective Abortion Law in China and Corresponding Conception in the United States
Tim Loveland ….……..…….……..…..173

Lessons From New Zealand: The "No-Fault" Alternative to Medical Malpractice
Jason Robin ...…..…….……..…..193

ANNALS OF HEALTH LAW

Advance Directive

Editor's Note

The *Annals of Health Law* is proud to present the Eighth Issue of our online counterpart, *Advance Directive.* Consistent with our goal of promoting student scholarship in the area of health law, this Issue features articles that explore various aspects of health systems around the world. Every country addresses health care differently, and our authors discuss what the United States can learn from international approaches.

The Issue begins with a look at two developed nations with universal health coverage: Switzerland and France. First, we examine how the Swiss successfully implemented an individual mandate and what lessons the U.S. can learn while implementing its own individual mandate set forth in the Patient Protection and Affordable Care Act. Second, our authors analyze the strengths and weaknesses of France's universal health care system, which is considered one of the best in the world.

The Issue then continues with an analysis of how Australia has maintained highly efficient and quality care under its universal health care system, and how the U.S. can emulate these methods to achieve quality care while increasing access. We then discuss how the U.S. can lower costs and improve quality of care for those with chronic conditions by taking lessons from Chile. Then, our authors examine the fee schedule used in Japan and argue that the adoption of a fee schedule in the U.S. could equalize care across populations while lowering costs.

Next, our authors explore the role of primary care in health systems. First, we examine Spain's extensive and strategic delivery of primary care; focusing on what lessons the U.S. can learn in reforming community health centers. Second, our authors analyze Denmark's emphasis on combining primary care with Health Information Technology and discuss how the U.S. Patient Centered Medical Home model may adopt similar practices. Third, we investigate the United Kingdom and Scandinavian countries to discuss the advantages and challenges of implementing Electronic Health Records in the U.S. and what is necessary for such systems to succeed.

The Issue transitions into discussing the transformation of Turkey's pharmaceutical industry through patent reform and regulation of clinical trial procedures. Then, our authors argue that using the Chinese essential medicine list as a template to reform the current system in the U.S. could help to contain rising costs and increase access to necessary medicine.

The Issue then delves into regional disparities in health care. We first examine the disparities in care caused by Italy's regionally divided system and whether the U.S. can equalize care across all areas. Our authors advocate for a state level National Solidarity Fund, similar to the one in Italy, to evenly distribute resources and equalize quality of care. Second, we examine the effectiveness of the U.S. Medicaid Federal Medical Assistance Percentage (FMAP) compared to Canada's equalization transfers based on a representative tax system (RTS). Our authors argue that remodeling the FMAP after the RTS system will equalize care and better allocate funds. Next, we address Canada's convoluted process of administrative claims for reimbursement and demonstrate that governments may be ill equipped to make coverage decisions.

The Issue then addresses how the U.S. can better serve specific populations of people. We investigate Norway's innovative Dementia Plan 2015 and speak to how the U.S. National Alzheimer's Project Act can embrace Norway's systemic changes to better care for the aging population. Our authors then provide a thorough analysis of China's regulation of sex-selective abortion; along with laws and regulations the U.S. has implemented to address this issue.

Lastly, the Issue provides an overview of the no-fault medical malpractice system employed in New Zealand and whether a similar system would work in the U.S. Our authors conclude that while possible, a no-fault system in the U.S. would present many challenges.

We would like to thank Gretchen Thomas, our *Advance Directive* Senior Editor, and Doriann Cain, our Technical Editor, for their invaluable contributions in launching this issue. We would specially like to thank our *Annals* Editor-in-Chief, Daniel Marino, for increasing access to *Advance Directive*. We are also grateful to our *Annals* Executive Board Members, Alexandria Ottens, Laura Ashpole, and April Schweitzer, for their editorial assistance. The *Annals* membership deserves particular recognition for writing timely, thoughtful articles and for editing

the work for their peers. Finally, we extend our warmest appreciation to the Beazley Institute for Health Law & Policy and our faculty advisors, Professor Lawrence Singer, Professor John Blum, and Megan Bess for their continued support, encouragement, and mentorship.

We hope you enjoy our Eighth Issue of *Advance Directive*.

Sincerely,

Seth D. Knocke
Advance Directive Editor
Annals of Health Law
Loyola University Chicago School of Law

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Solidarity or Personal Responsibility? A Look at the Lessons Switzerland's Health Care System Can Teach the United States

Britany Fijolek ∗

I. INTRODUCTION

In 1994, the year that President Bill Clinton's universal health care plan was "going down in flames", voters in Switzerland approved a national referendum guaranteeing health care for every Swiss citizen.[1] Almost two decades later, the Swiss health care system and its individual mandate, requiring every citizen to purchase health insurance directly from private insurers, emerged as a promising model for the United States during debates regarding reform.[2]

The Swiss model stood out as a viable option for the United States for a number of reasons.[3] Both countries are strong democracies with extremely competitive political parties.[4] Both have a rich and influential network of health insurance companies and hospitals.[5] Both hold capitalism in high

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1. T.R. REID, THE HEALING OF AMERICA: A GLOBAL QUEST FOR BETTER, CHEAPER, AND FAIRER HEALTH CARE 165 (2009).

2. *See* Press Release, Harvard Bus. Sch., Experts Debate Swiss Healthcare Model at Harvard Business School Forum (Mar. 8, 2010) (on file with author); *see also, e.g.*, Nelson D. Schwartz, *Swiss Health Care Thrives Without Public Opinion*, N.Y. TIMES, Oct. 1, 2009, at A1; Julie Rovner, *In Switzerland, A Health Care Model for America?*, NPR, July 31, 2008, at A1; Dall. Morning News, *Swiss Health-care System Might Serve as Model for U.S.*, PITTSBURGH TRIBUNE-REVIEW, Feb. 26, 2006, at A1.

3. T.R. REID, *supra* note 1, at 164.

4. *Id.*

5. *Id.*; *see also* Fazal Khan, *Towards Achieving Lasting Healthcare Reform: Rethinking the American Social Contract*, 19 ANNALS HEALTH L. (SPECIAL EDITION) 73, 75 (2010) (discussing political-structural explanations for the lack of universal health care in the U.S.).

esteem and are considered to be wealthy nations.[6] The most important similarity, however, is that, like the United States, Switzerland had a fragmented health care system marked by dependency on employers, large numbers of uninsured people, and high costs—that is, until Switzerland passed Loi Fédérale sur L'Assurance-Maladie[7] (LAMal) in 1994.[8]

With the recent passage of the Patient Protection and Affordable Care Act[9] (PPACA), the United States implemented many policies that the Swiss have had in effect for over ten years through LAMal.[10] The goal of this article is to describe some important aspects of the Swiss system since LAMal reforms took effect in 1996 and to explore the lessons that the United States can draw from the Swiss experience. In order to understand the Swiss experience, it is first important to understand the Swiss. Section II begins by discussing how the Swiss people and their values influenced the emergence of their current health care system. Section III will then discuss the similarities and differences between the Swiss system under LAMal and the proposed U.S. system under the PPACA. Finally, Section IV will discuss the lessons that the United States can learn from Switzerland's experience with mandated health care and other similar features.

II. THE SWISS PEOPLE AND THEIR SYSTEM OF HEALTH CARE

Switzerland is comprised of people from a variety of national and

6. T.R. REID, *supra* note 1, at 164.

7. *See generally* LOI FÉDÉRALE SUR L'ASSURANCE-MALADIE [LAMAL] [FEDERAL LAW ON HEALTH INSURANCE] Mar. 18, 1994, RS 832.10 (Switz.).

8. T.R. REID, *supra* note 1, at 164-79.

9. *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

10. Rachel Kreier & Peter Zweifel, *Health Insurance in Switzerland: A Closer Look at a System Often Offered as a Model for the United States*, 39 HOFSTRA L. REV. 89, 90 (2011).

cultural backgrounds.[11] Its eight million citizens are divided among twenty-six cantons, or states, and speak four official languages: German, French, Italian, and Romansch, a Latin derivative.[12] As a result, solidarity is a core value among Switzerland's diverse population.[13] For the Swiss, the word "solidarity" means community, equality, and that "despite our differences, we're all in this together."[14] Another meaning for "solidarity" in the Swiss context is an equal access to basic rights, and this includes access to health care.[15]

For most of the twentieth century, Swiss citizens received health coverage through their employers from nonprofit insurance companies.[16] By the 1980s, however, consolidation of the health insurance industry resulted in the replacement of nonprofit insurers with big profit-making businesses.[17] Consequently, health insurance costs escalated, leaving five percent of Swiss citizens without coverage by 1993.[18] For the Swiss, leaving five percent of the population uninsured violated their core value of solidarity, and in 1993, a special task force was established to examine this national problem.[19] LAMal was the result of this special task force.[20]

LAMal endeavored to bolster solidarity "between the healthy and the sick and the young and the old" by imposing the guaranteed issue and

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11. T.R. REID, *supra* note 1, at 176.
12. *Id.* at 175-76.
13. *Id.* at 176.
14. *Id.*
15. *Id.* at 177; *See also* Amanda Littell, *Can a Constitutional Right to Health Guarantee Universal Health Care Coverage or Improved Health Outcomes?: A Survey of Selected States*, 35 CONN. L. REV. 289, 306-307 (2002) (describing some cantons in Switzerland recognizing an unwritten constitutional right to subsistence, which includes essential medical care).
16. T.R. REID, *supra* note 1, at 177.
17. *Id.* at 177-78.
18. *Id.* at 178.
19. *Id.*
20. *Id.* at 179.

community rating requirements on insurers.[21] The "guaranteed issue" requirement means that insurers may not deny coverage on the basis of health status or risk.[22] The "community rating" requirement means that, subject to a few exceptions, each insurer must charge all people enrolled in a specific plan in a given canton the same premium, regardless of health status or risk.[23] Exceptions to the community rating requirement are afforded to individuals up to age eighteen and students up to age twenty-five, whose premiums are community-rated within those categories and are somewhat lower.[24] One more exception to the community rating requirement is for nonsmokers, who can receive premiums up to twenty percent lower than smokers.[25]

Another policy of LAMal, designed to bolster solidarity across income and class lines, is "individual premium reductions" for low-income citizens.[26] "Individual premium reductions" are subsidies administered by the cantons under federal guidelines.[27] The subsidies are intended to prevent any individual from having to pay more than eight to ten percent of their income on insurance.[28] As a rule, the maximum amount for the subsidy is based on each canton's average premium.[29] Therefore, if individuals receiving subsidies select especially expensive plans, they must pay the extra costs themselves.[30] As of 2009, approximately one-third of

21. Kreier & Zweifel, *supra* note 10, at 97.
22. *Id.* at 93.
23. *Id.*
24. Uwe E. Reinhardt, *The Swiss Health System: Regulated Competition Without Managed Care*, 292 JAMA 1227, 1228 (2004).
25. MICHAEL TANNER, CATO INST., THE GRASS IS NOT ALWAYS GREENER: A LOOK AT NATIONAL HEALTH CARE SYSTEMS AROUND THE WORLD 25-26 (2008).
26. *See* Kreier & Zweifel, *supra* note 10, at 97; *see also* TANNER, *supra* note 25, at 26.
27. Kreier & Zweifel, *supra* note 10, at 97 (explaining that roughly two-thirds of the subsidies are funded by the federal government, with the cantons funding the rest).
28. *See* Kreier & Zweifel, *supra* note 10, at 97; *see also* TANNER, *supra* note 25, at 26.
29. Kreier & Zweifel, *supra* note 10, at 97.
30. *Id.*

the Swiss population received some form of subsidy.[31]

The special task force that created LAMal anticipated that if every citizen was guaranteed coverage at a community-rated price, regardless of health status, then insurance pools would become flooded by sick, high-risk individuals driving premiums upward.[32] This would likely cause the healthy low-risk individuals to opt out of insurance.[33] Thus, the only way the community rating and guaranteed issue requirements work is if participation is mandated.[34] Under LAMal, this is exactly what the Swiss decided to do.[35]

LAMal requires all citizens to purchase Compulsory Basic Social Insurance (CBSI) from private insurers.[36] Insurers are prohibited from profiting on CBSI policies, although they may sell supplemental coverage for profit.[37] Likewise, employers may not offer CBSI coverage to their employees, but they may offer supplemental coverage.[38] The "basic" benefits included in CBSI policies are actually quite extensive.[39] Within their canton, they include "inpatient and outpatient care, care for the elderly and the physically and mentally handicapped, long-term nursing home care, diagnostic tests, prescription drugs, and even complementary and alternative therapies."[40] Supplemental coverage, on the other hand, entitles beneficiaries to services outside their canton, private rooms, doctor

31. TANNER, *supra* note 25, at 26-7.
32. *See* Paul J. Donahue, *Federalism and the Financing of Health Care in Canada and Switzerland: Lessons for Health Care Reform in the United States*, 21 B.C. INT'L & COMP. L. REV. 385, 424-25 (1998).
33. *Id.*
34. *Id.*
35. Kreier & Zweifel, *supra* note 10, at 92.
36. *Id.*
37. *Id.* at 94.
38. *Id.* at 92.
39. TANNER, *supra* note 25, at 25.
40. *Id.*

preferences in hospitals, and extra benefits like dental care.[41]

Without the ability to manage risks due to the guaranteed issue and community rating requirements, and because CBSI requires insurers to offer benefits packages that are nearly identical, insurers can only really compete on price points.[42] Insurers compete by offering plans with varying deductibles and copayments.[43] Generally, enrollees can opt for less expensive plans with higher deductibles or more expensive plans with lower deductibles.[44] However, LAMal sets some ground rules. The minimum annual deductible insurers may offer is approximately $400 and the maximum is $2,500.[45] For co-insurance, enrollees must pay ten percent of expenditures in excess of the deductible, not to exceed $700 per year.[46] Accordingly, the most cost-sharing an individual can incur is $3,200,[47] which is high by international standards.[48]

Under LAMal, prices for medical devices, pharmaceuticals, and providers are negotiated by associations of insurers and providers within each canton.[49] Private and public hospitals also must negotiate reimbursement prices in this way,[50] although public hospitals receive additional funding from cantonal governments.[51] All of these negotiated prices are subject to government regulation.[52] Through this negotiation and

41. ROBERT E. LEU ET AL., THE SWISS AND DUTCH HEALTH INSURANCE SYSTEMS: UNIVERSAL COVERAGE AND REGULATED COMPETITIVE INSURANCE MARKETS 2 (Commonwealth Fund, 2009).
42. TANNER, *supra* note 25, at 26.
43. *Id.*
44. *Id.*
45. Kreier & Zweifel, *supra* note 10, at 96 (exchange rates from 2010).
46. *Id.*
47. *Id.*
48. ROBERT E. LEU ET AL., *supra* note 41, at 2.
49. TANNER, *supra* note 25, at 27; *see also* Reinhardt, *supra* note 24, at 1229.
50. TANNER, *supra* note 25, at 27.
51. Kreier & Zweifel, *supra* note 10, at 98.
52. Reinhardt, *supra* note 24, at 1229.

regulation, the Swiss can ensure that differing perspectives are heard, but that ultimately, the decisions are made with solidarity in mind.

III. COMPARING THE SWISS SYSTEM TO THE U.S. SYSTEM

The PPACA, signed into law by President Obama on March 23, 2010, has many similarities with LAMal.[53] For instance, LAMal's compulsory basic social insurance[54] is similar to the PPACA's "minimum essential coverage" provision, mandating that U.S. citizens obtain health insurance that meets established standards.[55] LAMal's community rating and guaranteed issue requirements[56] are similar to the PPACA's provision prohibiting insurers from excluding individuals or discriminating against individuals due to preexisting conditions.[57] Additionally, both laws include public subsidies to make coverage more affordable for low-income individuals.[58] Both laws encourage competition between private insurers.[59] Due to their similar policies, LAMal and the PPACA are bound to have similar results within their respective countries. However, the Swiss experience with LAMal is also bound to have significant differences from the American experience with the PPACA in light of their various dissimilarities.

The first dissimilarity is that, unlike the PPACA, LAMal prohibits insurers from earning profits on most health insurance plans.[60] LAMal also

53. Kreier & Zweifel, *supra* note 10, at 90.
54. LAMal, Jan. 1, 2010, RS 832.0, art. 3, para. 1 (Switz); art. 25.
55. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§1501(a)(1), 5000A(a), 124 Stat. 119, 242, 244 (2010); §1302(a)-(b) (establishing the standards of the insurance).
56. LAMal. art. 13, para. 2(a).
57. Patient Protection and Affordable Care Act §2704(a).
58. Patient Protection and Affordable Care Act §1413; LAMal art. 66, paras. 1-2.
59. Patient Protection and Affordable Care Act §1311; LAMal art. 41, para. 1.
60. LAMal art. 43, paras. 4-5 (providing that insurance rates are based on a uniform tariff structure established by the Swiss federal government).

stipulates that prices for pharmaceuticals, medical devices, and the services of health care providers be negotiated and regulated.[61] Further, it makes cantonal governments primarily responsible for funding hospital care.[62] Another difference is that while almost a third of the health coverage in the United States is provided through government programs, such as Medicaid,[63] the Swiss system allows individuals of all income levels and ages to choose their health coverage from identical private insurance plans within their cantons.[64] Lastly, while LAMal expressly forbids employers from providing basic social health insurance as a benefit of employment,[65] the PPACA attempts to encourage employer-sponsored health insurance.[66] Despite all of these differences, the Swiss system through LAMal provides a number of lessons for the United States on what they can expect from the PPACA in the years to come.

IV. LESSONS THE U.S. CAN LEARN FROM THE SWISS SYSTEM

The Swiss are generally happy with their health care system,[67] where coverage is almost universal at 99.5% of the population.[68] Switzerland generally receives good scores on health status indicators and quality outcomes, particularly when compared to the United States.[69] Life

61. *Id.* para. 5; art. 44, para. 1.

62. *See Id.* art. 49, paras. 1-3.

63. CARMEN DENAVAS-WALT ET AL., U.S. CENSUS BUREAU, INCOME, POVERTY, AND HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2010, at 23 (2011).

64. LAMal art. 13, para. 2(a).

65. *Id.* art. 3 (making individuals and families responsible for their own CBSI insurance); art. 62, para. 2a (forbidding third parties from covering the differential premiums or out-of-pocket cost-sharing of individual's CBSI plans).

66. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 1421, 1511-1515, 124 Stat. 119, 237, 244, 252-58 (2010) (implementing employer incentives and penalties).

67. TANNER, *supra* note 25, at 28; *see also* Schwartz, *supra* note 2, at A1.

68. TANNER, *supra* note 25, at 25.

69. *See, e.g.*, ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, OECD STATISTICS (last visited Feb. 22, 2012), stats.oecd.org/Index.aspx.

expectancy in Switzerland was the second highest in 2009, and four years longer than the life expectancy in the U.S.[70] Also, Switzerland's infant mortality rate in 2008 was 4 deaths per 1,000 live births, while America's was 6.5 deaths per 1,000 live births.[71]

Even though the Swiss system delivers a superior statistical performance relative to the U.S., it spends quite a bit less on health care.[72] In 2009, the Swiss per capita health care spending was $5,144, versus U.S. spending of $7,960.[73] Likewise, Switzerland devoted only 11.4% of its GDP to health care, while the U.S. spent 17.4%.[74]

Out-of-pocket spending, however, does not follow this same trend.[75] In 2005, the OECD reported that Switzerland and the United States had the two highest out-of-pocket spending per capita at $1,276 and $842, respectively.[76] However, despite such high out-of-pocket spending in Switzerland, medical bills do not pose as big of a problem for the Swiss as they do for Americans.[77] According to a joint study by Harvard Law School and Harvard Medical School, around 700,000 people in the United States go bankrupt annually due to medical bills.[78] In Switzerland, no one goes bankrupt due to medical bills.[79]

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70. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Health Status: Life Expectancy*, OECD STATISTICS (last visited Feb. 22, 2012), stats.oecd.org/Index.aspx.

71. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Health Status: Maternal and Infant Mortality*, OECD STATISTICS (last visited Feb. 22, 2012), stats.oecd.org/Index.aspx.

72. Reinhardt, *supra* note 24, at 1227-29.

73. ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, *Health Expenditure and Financing*, OECD STATISTICS (last visited Feb. 22, 2012), stats.oecd.org/Index.aspx.

74. *Id.*

75. Gerard F. Anderson & Bianca K. Frogner, *Health Spending in OECD Countries: Obtaining Value Per Dollar*, 27 HEALTH AFF. 1718, 1722 (2008).

76. *Id.*

77. T.R. REID, *supra* note 1, at 31.

78. *Id.* (citing David Himmelstein et al., *MarketWatch: Illness and Injury As Contributors to Bankruptcy*, Health Aff. Web Exclusive, February 2, 2005, W5-62).

79. *Id.*

Switzerland's ability to control costs may be attributed to citizen involvement in buying their own individual insurance.[80] By having to buy their own insurance, the Swiss citizens are more aware of the costs, and thus, they use health care services more conservatively, particularly when individuals choose plans with higher deductibles.[81] The transparency of the Swiss system provides a good lesson for the United States about encouraging consumers to make cost-versus-value decisions when purchasing health care.[82]

The transparency of the Swiss system, however, has become compromised over time.[83] The "basic" benefits included in CBSI policies have increased dramatically as health care providers and disease constituencies lobby for the inclusion of additional services or coverage.[84] By extending basic coverage, the Swiss may become insulated from the cost consequences of their health care decisions, thereby undermining the transparency of the system.[85] This trend in Switzerland serves as an excellent warning for the United States to keep the "minimum essential coverage" at a minimum.

Another important lesson for the United States is the need for some degree of personal responsibility. While the "community rating" and "guaranteed issue" requirements in Switzerland encourage solidarity, they discourage personal responsibility.[86] Peter Zweifel, a professor at the University of Zurich and a member of the Swiss Competitive Committee which oversees insurance regulation, argues that the Swiss system needs to

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80. Regina E. Herzlinger & Ramin Parsa-Parsi, *Consumer-Driven Health Care: Lessons From Switzerland*, 292 JAMA 1213, 1217 (2004).
81. *Id.*
82. *See* Tanner, *supra* note 25, at 29.
83. *Id.*
84. *Id.* at 28.
85. *Id.*
86. *Id.* at 29.

hold citizens accountable for their unhealthy lifestyle choices and the way to do that is by risk-rating.[87] As Zweifel says, "Let competition work its magic. Let those who are bad risks get the message that they need to become better risks. . ."[88] Without some degree of personal responsibility, Zweifel worries about the long-term success of the Swiss system.[89]

In the United States, the call for personal responsibility has been more prominent than the call for solidarity. In fact, a majority of Americans, when surveyed, say it is "fair" to ask people with unhealthy lifestyles to pay more for health insurance.[90] Even President Obama declared back in 2009 that "we've got to have the American people doing something about their own care."[91]

It is no wonder then that since the PPACA passed on March 23, 2010, it has been met with fierce opposition.[92] A recent poll by Washington Post-ABC News revealed that most Americans want the Supreme Court to invalidate either just the individual mandate requirement or the entire law altogether.[93] Unlike in Switzerland, where a mere five percent of the population being left without health insurance ignited the Swiss people to

87. *Id.*

88. *Id.*

89. *Id.*

90. Robert Steinbrook, *Imposing Personal Responsibility for Health*, 355 NEW ENG. J. MED. 753, 753 (2006).

91. Nancy Snyderman, *Obama on Health Care Policy: 'No Free Lunch'*, MSNBC.COM, (March 31, 2012, 3:11 p.m.) http://www.msnbc.msn.com/id/31929715/ns/health-health_care/t/obama-health-care-policy-no-free-lunch/.

92. *See generally* Pete Williams, *Individual Mandate Will Be in Supreme Court Spotlight*, NBC POLITICS (Mar. 23, 2012), http://nbcpolitics.msnbc.msn.com/_news/2012/03/23/10827006-individual-mandate-will-be-in-supreme-court-spotlight.

93. The poll revealed that forty-two percent of Americans want the Supreme Court to throw out the entire law; twenty-five percent want only the individual mandate to be thrown out; twenty-six percent want the entire law to be upheld; and seven percent had no opinion. *See* Scott Clement, *Toss Individual Health Insurance Mandate, Poll Says*, POST POLITICS (Mar. 19, 2012, 7:00 AM), http://www.washingtonpost.com/blogs/behind-the-numbers/post/toss-individual-health-insurance-mandate-poll-says/2012/03/18/gIQAaZtpLS_blog.html.

stand together behind a new health law,[94] the 16.3% of uninsured Americans has merely ignited disagreement.[95]

While the future of the U.S. health care system remains uncertain, Americans can and should look to other countries, like Switzerland, for lessons in sustainability. One such lesson is that a less fragmented society espousing solidarity can help create a less fragmented healthcare system and a happier nation.

V. CONCLUSION

The Swiss healthcare system under LAMal and the proposed U.S. healthcare system under the PPACA are quite similar. Both require every citizen to purchase health insurance. Additionally, both prohibit insurers from denying coverage or varying premiums due to heath status or risk. Although there are also a number of differences between the Swiss system and the proposed system in the U.S., the biggest difference is probably the motivation behind them. While the Swiss are motivated by a national desire for solidarity, Americans remain divided between the need for solidarity and the need for personal responsibility. That division has left the fate of the U.S. healthcare system up to the Supreme Court. If the Supreme Court decides to find the individual mandate unconstitutional, the rest of the proposed system may not be sustainable. However, if the Supreme Court decides to uphold the PPACA and its individual mandate, the Swiss system has ten-plus years of experience with LAMal that can provide valuable lessons for the United States.

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94. T.R. REID, *supra* note 1, at 178.

95. Les Christie, *Number of People Without Health Insurance Climbs*, CNNMONEY, (April 1, 2012, 3:30 p.m.), http://money.cnn.com/2011/09/13/news/economy/census_bureau_health_insurance/index.htm

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The High Cost of Health: The French System and What It Means for the U.S.

Mira Radadia *

I. INTRODUCTION

The French health care system has been heralded as the best in the word.[1] The entire population receives health care that is provided by both private entities and government.[2] The country has a low infant mortality rate while maintaining one of the highest birth rates in Europe.[3] The French are said to live longer and be healthier, but funding quality health care is expensive.[4] Globally, the health care program in France is one of the most expensive.[5] In 2007, the country experienced $9 billion in debt.[6] This forced President Nicolas Sarkozy to approve charging more for basic care.[7] With the first steps of implementing expanded health care in the U.S. already in place,[8] the U.S. health care system is facing untenable costs similar to those of France.[9] Providing quality medical care for the entire

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1. Joseph Shapiro, *Health Care Lessons from France*, NPR (July 11, 2008), http://www.npr.org/templates/story/story.php?storyId=92419273.

2. *Id.*

3. Joseph Shapiro, *France's Model Health Care for New Mothers*, NPR (July 10, 2008), http://www.npr.org/templates/story/story.php?storyId=92116914.

4. Shapiro, *supra* note 1.

5. *Id.*

6. *Id.*

7. *See id.* (reporting that the French President charged patients more for drugs and ambulance services).

8. *See The Affordable Care Act*, WHITEHOUSE.GOV, http://www.whitehouse.gov/healthreform/healthcare-overview#healthcare-menu (last visited Mar. 26, 2012) (explaining and listing the effects of the Affordable Care Act on health coverage for consumers).

9. Pierre Loiseau, *When the Clouds Hung Oppressively Low in the Heavens: Unhealthy Cost-Cutting in France and in the U.S.*, 70 LA. L. REV. 945, 947 (2010).

U.S. population will require more than a commitment to access; sustainable financial planning is imperative.[10]

This article begins by introducing the basic structure of the French health care system and deficiencies in access to care. Second, it will analyze the varying quality in medical care under the French system. Next, this article will detail the financial structure of the French model and discuss the rising costs of medical care. Finally, it will compare the financial weaknesses of the French system to the expected fiscal defects of the expanding U.S. health care system.

II. ACCESS TO HEALTH CARE

To begin, health care systems are unique to each nation's history and politics.[11] The French system can be traced back to the French Revolution, where the principle of solidarity was derived.[12] Solidarity means that all people have access to health care irrespective of their ability to pay.[13] It is the notion that universal access to health care is provided while maintaining substantially the same benefits for everyone.[14] Based on this principle, France committed to universal health care shortly after World War II, despite economic struggles.[15]

France's universal health care system is structured based on what is

10. *See* David Gauthier-Villars, *France Fights Universal Care's High Cost*, WALL ST. J., Aug. 7, 2009, http://online.wsj.com/article/SB124958049241511735.html (discussing the similar fiscal problems in the health care systems of France and the U.S.).

11. Timothy Stoltzfus Jost, *Global Health Care Financing Law: A Useful Concept?*, 96 GEO. L.J. 413, 416 (2008).

12. Vassilis Hatzopoulos, *Financing National Health Care in a Transnational Environment: The Impact of the European Community Internal Market*, 26 WIS. INT'L L.J. 761, 769 (2008).

13. Timothy Stoltzfus Jost, Diane Dawson & Andre den Exter, *The Role of Competition in Health Care: A Western European Perspective*, 31 J. HEALTH POL. POL'Y & L. 687, 688 (2006).

14. *Id.*

15. *See* Arnold J. Rosoff, *Of Stars and Proper Alignment: Scanning the Heavens for the Future of Health Care Reform*, 159 U. PA. L. REV. 2083, 2089-90 (2011) (discussing France's push to implement universal health care as soon as possible after WWII).

known as the Bismarkian model.[16] Under this model, people receive insurance because they are employed or participate in a professional organization or similar group.[17] Complementary programs cover those people who do not fall within a sector-specific scheme.[18] This model results in many funds that are public or private, and each fund operates differently from another.[19] In addition, clinics, hospitals, and other facilities offering medical care are either public or private.[20] Because of the differing types of funds and the manner in which they operate, planning and coordinating health care under the Bismarkian design is complicated.[21] Nonetheless, the model allows France to provide medical insurance for 100% of the population.[22]

However, all members of the population do not have equal access to health care.[23] The country has faced difficulties in coordinating health care for the elderly,[24] and there are disparities in geographically distributing health care resources.[25] Most French find that the proximity of health care services is acceptable, but the number of hospitals and providers in rural areas is limited.[26] A recent survey revealed that roughly one-third of

16. Hatzopoulos, *supra* note 12, at 767. Chancellor Bismarck of Germany was the first to establish this model in the 1870s. *Id.*

17. *Id.*; *see* David Marrani, *Exclusion and Human Rights: The French Case*, 12 J.L. & SOC. CHALLENGES 38, 47 (2010) (criticizing the requirement to work to benefit under the health care system).

18. Hatzopoulos, *supra* note 12, at 767.

19. *Id.*

20. *Id.*

21. *Id.*

22. *See* Loiseau, *supra* note 9, at 946 (listing the different schemes under which the French population is insured).

23. *See infra* notes 24-31 and accompanying text (discussing the shortcomings in access to health care).

24. Chris Ham, *Victor G. Rodwin, Editor, Universal Health Insurance in France, How Sustainable?*, 33 J. HEALTH POL. POL'Y & L. 841, 842 (2008) (book review). In 2003, 15,000 elderly died because of a heat wave. Olivier Moréteau, *Policing the Compensation of Victims of Catastrophes: Combining Solidarity and Self-responsibility*, 54 LOY. L. REV. 65, 81-82 (2008). The deaths raised questions about care for the elderly in France. *Id.*

25. Ham, *supra* note 24, at 841-42.

26. *France*, KAISEREDU.ORG, http://www.kaiseredu.org/Issue-Modules/International-

respondents living in rural areas indicated that specialists were located too far away.[27] The country has also cut services.[28] For example, in June of 2009, France closed a hospital—including a maternity ward—in a southern village to reallocate resources.[29] As a result, expectant mothers must travel thirty miles to the nearest hospital.[30] In addition, when a flu and bronchitis epidemic spread in December of 2004, hospitals were not equipped with enough beds to treat the sick.[31] These complications illustrate the gap between France's universal coverage in theory and providing access in practice.

III. QUALITY OF CARE

The standard of care that physicians in France provide is ranked well internationally.[32] Patients may choose which doctors and hospitals they would like to provide their care.[33] Patients may also obtain elective surgery or see a specialist for treatment without the inconvenience of waiting lists.[34] The state even reimburses 100% of costs for patients with long-term illnesses such as cancer, diabetes, and mental afflictions.[35] The government also funds cancer patients' costs for expensive and experimental drugs.[36] In addition, costs for prenatal and postnatal care for mother and child are fully reimbursed, regardless of whether care is provided by hospitals or self-

Health-Systems/France.aspx (last visited Mar. 26, 2012).

27. SIMONE SANDIER, VALÉRIE PARIS & DOMINIQUE POLTON, EUR. OBSERVATORY ON HEALTH SYS. & POLICES, HEALTH CARE SYSTEMS IN TRANSITION, 63 (Sarah Thomson & Elias Mossialos, eds., 2004), *available at* http://www.euro.who.int/__data/assets/pdf_file/0009/80694/E83126.pdf.

28. Gauthier-Villars, *supra* note 10.

29. *Id.*

30. *Id.*

31. *French Healthcare Is 'Badly Run'*, BBCNEWS, (Jan. 23, 2004), http://news.bbc.co.uk/2/hi/europe/3423159.stm.

32. *Id.*

33. Jost, Dawson & Exter, *supra* note 13, at 694.

34. Shapiro, *supra* note 1.

35. *Id.*

36. *Id.*

employed physicians.[37] Furthermore, the insurance system covers required and recommended vaccination and alcohol and drug abuse prevention.[38] Generally, patient satisfaction is high and health outcomes are favorable according to international standards.[39]

Despite satisfaction with the overall care, the quality is uneven and results in disparities in health by social class.[40] The health care system lacks coordination and continuity of care, particularly where isolated professionals provide services.[41] To illustrate, a national study found that only forty percent of diabetes patients undergo an annual eye examination—as recommended by national guidelines—evidencing that physicians cannot monitor the entire process of their patients' care.[42] Because doctors can choose where they practice, the geographic concentration of physicians varies.[43] More physicians practice in Paris and southern France even though residents in northern areas are in poorer health.[44]

Furthermore, France's system has been criticized for shortcomings in continuing medical education[45] and monitoring medical practices.[46] Before the 1990s, only insurance fund medical advisers monitored abuses in practice.[47] The government then issued recommendations and guidelines for clinical practices including treatment, diagnosis and supervision.[48] Because of the guidelines, physicians significantly changed their

37. SANDIER, PARIS & POLTON, *supra* note 27, at 58.
38. *Id.* at 58-59.
39. Ham, *supra* note 24, at 841.
40. *Id.* at 842.
41. SANDIER, PARIS & POLTON, *supra* note 27, at 66.
42. *Id.*
43. *Id.*
44. *Id.*
45. Monika Steffen, *The French Health Care System: Liberal Universalism*, 35 J. HEALTH POL. POL'Y & L. 353, 382 (2010).
46. SANDIER, PARIS & POLTON, *supra* note 27, at 63.
47. *Id.*
48. *Id.*

prescribing behavior.[49] Ordinances in the 1990s also mandated continuing education and even established sanctions for failure to comply.[50] However, because implementing the system has been difficult, continuing education for doctors has seen no progress.[51]

IV. FINANCING

In addition, assuring high quality of care is increasingly difficult because of rising costs.[52] The means through which France finances its health care system is subject to criticism.[53] In France, the employed pay roughly twenty-one percent of their income to fund the national insurance, or public, program.[54] Employers also pay taxes to fund the program.[55] Semi-public insurance companies use these funds to negotiate with medical unions to determine physicians' fees.[56] The government then reimburses patients for roughly seventy percent of their costs.[57] Because the public system does not cover all medical costs,[58] individuals obtain private complementary or supplementary insurance to reimburse the remaining thirty percent,[59] and half the cost of the supplemental insurance for complementary coverage is funded by their employers.[60] More than ninety percent of the population obtains complementary insurance to fund services the public system does

49. *Id.* at 65.
50. *Id.*
51. *Id.*
52. J. Paul Singleton, *The Good, the Bad, and the Ugly: How the Due Process Clause May Limit Comprehensive Health Care Reform*, 77 TENN. L. REV. 413, 435-36 (2010).
53. *See* Gauthier-Villars, *supra* note 10 ("Since the 1970s, almost all successive French health ministers have tried to reduce expenses, but mostly managed to push through only minor cost cuts.").
54. Shapiro, *supra* note 1.
55. *Id.*
56. *Id.*
57. *Id.*; *see* Hatzopoulos, *supra* note 12, at 769 (noting that the government reimburses some medical costs).
58. Roger Feldman, *Quality of Care in Single-Payer and Multipayer Health Systems*, 34 J. HEALTH POL. POL'Y & L. 649, 660 (2009).
59. Shapiro, *supra* note 1.
60. *France*, *supra* note 26.

not cover.[61] The government also provides complementary insurance coverage for those who are not able to afford it[62] and regulates drug prices to keep them low.[63] With input from manufacturers, the government approves drug prices and reimburses the manufacturers.[64] This system renders France a country with one of the highest per capita government health expenditures in the world.[65]

Although the French model is more progressive in comparison to those of other countries,[66] long-term funding issues question its sustainability.[67] The country has faced significant debt for several decades.[68] The government has attempted to reduce the deficit through other taxes, but the deficit still remains.[69] In 1984 and 1989, the country placed budgetary responsibility on hospitals in hopes of ensuring "efficiency through accountability," rather than allowing the state to control.[70] The country also attempted to control the costs of ambulatory care by encouraging negotiations between government insurance providers and medical

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61. Jonathan P. Weiner, Joanna Case Famadas, Hugh R. Waters & Djordje Gikic, *Managed Care and Private Health Insurance in a Global Context*, 33 J. HEALTH POL. POL'Y & L. 1107, 1118 (2008).

62. *France*, *supra* note 26.

63. Davina Rosen, Comment, B*alancing Business & National Health: The Impact of Legislation on Pharmaceutical Drug Prices*, 26 TEMPLE J. SCI. TECH & ENVTL. L. 341, 352 (2007).

64. Todd A. Rosenfield, Comment, *The Counterfeit Drug Invasion: How Drug Reimportation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT'L ECON. L. 1047, 1053 (2004), *available at* http://www.law.upenn.edu/journals/jil/articles/volume25/issue3/Rosenfield25U.Pa.J.Int'lEcon.L.1047(2004).pdf.

65. *See* Eleanor D. Kinney & Brian Alexander Clark, *Provisions for Health and Health Care in the Constitutions of the Countries of the World*, 37 CORNELL INT'L L.J. 285, 295 (2004) (ranking France's per capita government expenditures for health care).

66. Jennifer Prah Ruger, *Health, Capability, and Justice: Toward a New Paradigm of Health Ethics, Policy and Law*, 15 CORNELL J.L. & PUB. POL'Y 403, 450 (2006).

67. Ham, *supra* note 24, at 842.

68. *France*, *supra* note 26.

69. Ham, *supra* note 24, at 842.

70. Patrick Hassenteufel, Marc Smyrl, William Genieys & Francisco Javier Moreno-Fuentes, *Programmatic Actors and the Transformation of European Health Care States*, 35 J. HEALTH POL. POL'Y & L. 517, 520 (2010).

professionals.[71] But by the mid-1990s it was clear that the negotiations and shift in budgetary responsibility were incapable of curbing the growing deficit.[72]

Although the French system appears inexpensive from the American perspective, it is costly compared to those of its European neighbors.[73] Part of the cause stems from the reluctance to encourage competition in the health care field because privatization, which could contain costs, is a strong departure from the fundamental philosophy of solidarity.[74] Even though France has a combination of private and public health care institutions, the government imposes a ceiling on profits that private facilities may generate.[75] Furthermore, employers question the financing system because they heavily fund the public insurance program through payroll taxes.[76] France's financial dilemma is also compounded by a growing demand for health care because the French are taking better care of themselves and they have access to new treatments.[77] France's budgetary crisis illustrates the difficulty in providing universal, quality medical care while controlling costs.

V. LESSONS FOR THE U.S.

France's health care system is considered to be more similar to the system in the U.S. than those of Germany, Britain, and Canada, yet France

71. *Id.*
72. *Id.* at 521.
73. Ham, *supra* note 24, at 842.
74. *France*, *supra* note 26; *see* Achim Schmid, Mirella Cacace, Ralf Götze & Heinz Rothgang, *Explaining Health Care System Change: Problem Pressure and the Emergence of "Hybrid" Health Care Systems*, 35 J. HEALTH POL. POL'Y & L. 455, 470 (2010) (privatizing health care is an efficient means of cost containment).
75. Hans Maarse, *The Privatization of Health Care in Europe: An Eight-Country Analysis*, 31 J. HEALTH POL. POL'Y & L. 981, 996 (2006).
76. Ham, *supra* note 24, at 843.
77. Gauthier-Villars, *supra* note 10.

spends less on health care than the U.S. while still performing efficiently.[78] Roughly 46.4 million people are completely uninsured in the U.S. and an additional number are underinsured,[79] while the entire population in France is covered.[80] France also has a healthier population than the U.S., even though its heath care expenditure was roughly half that of the U.S. per capita.[81] Despite their structural differences, both countries face growing unemployment, higher drug costs, and aging populations.[82] The U.S. is now presented with the problem of providing medical coverage for the entire population.[83] In doing so, the U.S. may gain valuable insight from France's health care coverage system.[84]

Although there is general agreement on the need for universal coverage in the U.S.,[85] achieving this goal will not be cheap.[86] In 2009, the U.S. spent $2.5 trillion in health care.[87] The U.S. is expected to consume roughly twenty percent of its GDP in health care by 2016,[88] and it is predicted to spend $4.5 trillion by 2019.[89] The eighty-two percent of nonelderly Americans who do have health insurance pay considerably more out-of-pocket than they have in past years.[90] Furthermore, many employers are eliminating health insurance benefits or passing on the cost to their

78. Ham, *supra* note 24, at 841.

79. Susan Adler Channick, *Will Americans Embrace Single-Payer Health Insurance: The Intractable Barriers of Inertia, Free Market, and Culture*, 28 L. & INEQ. 1, 1 (2010).

80. Gauthier-Villars, *supra* note 10.

81. Jeffrey W. Stempel, *Adam, Martin and John: Iconography, Infrastructure, and America's Pathological Inconsistency About Medical Insurance*, 14 CONN. INS. L.J. 229, 304 (2008).

82. Gauthier-Villars, *supra* note 10.

83. Loiseau, *supra* note 9, at 947.

84. Gauthier-Villars, *supra* note 10.

85. Channick, *supra* note 79, at 18.

86. *See* Meir Katz, *Towards a New Moral Paradigm in Health Care Delivery: Accounting for Individuals*, 36 AM. J.L. & MED. 78, 79 (2010) (noting that health care is costly).

87. *Id.*

88. Channick, *supra* note 79, at 2.

89. Katz, *supra* note 86, at 79.

90. Channick, *supra* note 79, at 1-2.

employees.[91] In addition, fewer and fewer Americans receive health insurance through their employers because the employee share of the costs renders the coverage unaffordable.[92]

To remedy the lack of insurance coverage for many Americans, more efficient financing can help ensure universal access.[93] Currently, the driving costs of health care are "overuse of hospital emergency departments, too much uncompensated care, unnecessary or non-efficacious treatments, continuous improvements in expensive technology, uncoordinated care, coverage and reimbursement of administrative costs, the heavy presence of the for-profit sector, grossly disproportionate compensation arrangements in both the for-profit and non-profit sectors, and insufficient preventive care."[94] These costs can be contained by providing universal care.[95] Because roughly eighty-five percent of Americans are already insured, finding an incentive to provide coverage for the remaining fifteen percent can be difficult.[96] But affordable access to care may encourage people to seek out preventative care, reducing unnecessary treatment costs in the future.[97] However, in taking steps to guarantee universal care, the U.S. must still consider the unique complications that such vast coverage generates.

President Barack Obama's Patient Protection and Affordable Care Act (PPACA) and related regulations promise to provide care for more Americans and cut costs.[98] For example, similar to France's reimbursement

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91. *Id.* at 2.
92. *Id.* at 19.
93. *See id.* ("As the cost of health care continues to outstrip the growth of the economy, thereby eroding the employer-based system, satisfying the insured population will become less important politically, and other models may become more attractive.").
94. *Id.* at 31-32.
95. *See id.* at 31 (arguing "that cost containment will not be achieved without universal access.").
96. *Id.* at 5.
97. *Id.* at 29.
98. Adam Marks, Comment, *Good Health and Low Costs: Why the PPACA's*

strategy that minimizes out-of-pocket costs, the PPACA prohibits cost-sharing for certain preventative services, eliminating deductibles and other expenses for patients with group and individual health insurance.[99] Covered preventative services include immunizations for children and screenings for cholesterol, diabetes, obesity and vitamin deficiencies during pregnancies.[100] Providing such preventative services can help contain diseases, improve health, and curb mortality rates.[101] Taking preventative measures can avert forty million cases of chronic illnesses by 2023.[102] This would reduce anticipated health care expenses by $1.1 trillion in that year.[103] However, availability of preventative services does not necessarily translate into effective care.[104] For example, many Americans are reluctant to seek preventative medical care; they currently use preventative services at only half the recommended rate.[105] Americans are more likely to seek care in response to a medical problem.[106] Therefore, participation in these services is not guaranteed.[107]

In addition, the PPACA heightens the tension between individualized physician-patient interaction and notions of solidarity.[108] Unlike France's commitment to solidarity, the U.S. has historically adopted individualism

Preventative Care Provision May Not Produce Expected Outcomes, 23 LOY. CONSUMER L. REV. 486, 486-87 (2011).

99. *Id.* at 488-89.

100. *Id.* at 490.

101. *Id.* at 492-93.

102. Channick, *supra* note 79, at 29.

103. *Id.*

104. *See* Marks, *supra* note 98, at 494 ("While one might expect a no-cost benefit to increase consumption, healthcare generally does not operate in the same manner as other consumer markets. Rather, there are other factors to consider that may impact the success of the PPACA's efforts in creating a healthier population.")

105. *Id.* at 494-95.

106. *Id.* at 495.

107. *Id.*

108. Theodore W. Ruger, *Can a Patient-Centered Ethos Be Other-Regarding? Ought It Be?*, 45 WAKE FOREST L. REV. 1513, 1513 (2010).

and capitalism as core values,[109] and the PPACA draws out the debate about whether the PPACA compels participation in social insurance "for the common good" or interferes with individual rights.[110] For example, the PPACA obligates almost all Americans to purchase insurance or pay a penalty,[111] and it is not surprising that citizens have lobbied for "health insurance freedom" in opposition to the requirement.[112] For many people, paying the penalty and buying insurance only when they need it will be cheaper than buying insurance immediately.[113] Although some Americans oppose the PPACA, the statute aims to protect the individual from serious financial risk by obligating him or her to buy insurance.[114] In effect, the PPACA promotes solidarity and collective responsibility as a means of cost containment.[115]

VI. CONCLUSION

Increasing accessibility, decreasing costs, and increasing consumer insulation from those costs are competing health care objectives.[116] Health care policy can only achieve two of these objectives at a time.[117] The French health care system illustrates this concept; it ranks well compared to other industrialized countries, but it faces rising health care costs.[118] Providing universal health care for the U.S. population may require taking a

109. *See* Nan D. Hunter, *Health Insurance Reform and Intimations of Citizenship*, 159 U. PA. L. REV. 1955, 1967-68 (2011) (noting the political need to preserve capitalism and individualism in the New Deal era).

110. *Id.* at 1980-81.

111. *Id.* at 1959.

112. *Id.* at 1981.

113. J. Paul Singleton, *Can You Really Have Too Much of a Good Thing?: How Benevolent Tax Policies Have Attributed to the Explosion of Health Care Costs and How New Policies Threaten To Do More of the Same*, 8 DEPAUL BUS. & COM. L.J. 305, 325-26 (2010).

114. Hunter, *supra* note 109, at 1996.

115. *Id.* at 1995-96.

116. Singleton, *supra* note 113, at 324-25.

117. *Id.* at 325.

118. Gauthier-Villars, *supra* note 10.

few lessons from France.[119] Though the PPACA is taking steps towards reducing health care expenses, sustainable financial planning is imperative.

119. *Id.*

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A Brief Summary of the Australian Universal Health Coverage System: Must Increased Access Equate to Decreased Quality and Efficiency?

*Kelly Gallo**

I. INTRODUCTION

A common misperception and argument against universal health coverage is that countries that adhere to this system are forced to trade efficiency and freedom of care for overall access to care.[1] However, a 2010 study performed by the Commonwealth Fund compared the health care systems of seven nations - Australia, Canada, Germany, the Netherlands, New Zealand, the United Kingdom, and the United States.[2] The United States' health care system, which does not provide universal health coverage, consistently ranks last or next-to-last in the five determinative measures in the assessment of a well performing health care system.[3] Those areas include quality, access, efficiency, equity, and a healthy life.[4] In contrast, the study referred to the performance of countries like Australia and the U.K., both of which have incorporated universal coverage, as demonstrating "superior performance" overall.[5]

The World Health Organization (WHO) is a strong proponent of

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1. Susan Taylor Martin, *Myths, truths of Canada's Universal Coverage*, SEATTLE TIMES, July 21, 2009, *available at* http://seattletimes.nwsource.com/html/health/2009506926_canahealth21.html.

2. KAREN DAVIS ET AL., THE COMMONWEALTH FUND, MIRROR, MIRROR ON THE WALL: HOW THE PERFORMANCE OF THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY v (2010).

3. *Id.*

4. *Id.*

5. *Id.* at v, vii.

universal health coverage.[6] Its 2010 Health System Financing Report emphasized the importance of promotion and protection of health as a staple for human welfare and social development.[7] It further declared that all people should have access to health care without risking their own financial ruin in the process.[8] But access is not the only important factor of universal health coverage.[9] To be effective, access must be timely and equitable; and health services must be properly promoted with a balanced focus on rehabilitation and prevention.[10] The system must also have a successful means for monitoring and evaluating its own effectiveness.[11]

This paper will offer a brief introduction to the structure and financing of Australia's health care system. The paper will then address the misperception that access and quality must be inversely related through an evaluation and comparison of the results of the Commonwealth study as it relates to the United States and Australia. Lastly, this paper will evaluate the current state of the United States health care system and offer some reconciliation to the apparent discrepancy between perception and the reality and offer some recommendations for change in the United States.

II. AUSTRALIA HEALTH CARE

Regardless of age or economic status, the Australian national public health care system provides universal health coverage for all of its citizens, permanent residents, and to visitors from countries with whom Australia has signed a reciprocal health care agreement.[12] Formulated in 1984,[13] this

6. WORLD HEALTH ORG., HEALTH SYSTEMS FINANCING: THE PATH TO UNIVERSAL COVERAGE 5 (2010) [hereinafter WORLD HEALTH REPORT], *available at* http://www.who.int/whr/2010/whr10_en.pdf.
7. *Id.* at 7.
8. *Id.* at 8.
9. *Id.* at 7.
10. *Id.*
11. *Id.*
12. THE COMMONWEALTH FUND, THE AUSTRALIAN HEALTH CARE SYSTEM 8 (Jane Hall

comprehensive health care system, Medicare, offers free or subsidized medical care, some optometry services, and a laundry list of prescription drugs to all individuals.[14]

There are three main branches of the Medicare system.[15] First, the Australian Health Care Agreements (AHCAs) is the system through which federal money is disbursed amongst the states and territories to the various public hospitals.[16] The second branch is the Pharmaceutical Benefits Scheme (PBS), which subsidizes the cost of prescription drugs.[17] The last branch, the Medicare Benefits Scheme (MBS), covers seventy-five percent of the scheduled fee for care by general practitioners and specialists within the public hospitals, along with 100% of the scheduled fee of care outside of the hospital.[18] Care outside of hospitals can be covered completely when the practitioner agrees to accept the government scheduled fee and in effect leave nothing for the patient to pay.[19]

This national, local, state, and territory governments jointly fund the public health care system.[20] Medicare is funded primarily by general goods and services tax and also by a tax levy on personal income of most taxpayers.[21] The levy, which is generally at 1.5%, can be reduced for individuals making less than a certain threshold level, or waived for the very poor.[22] Australians whose income is higher than a certain threshold

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& David Squires eds., 2009) [hereinafter SYSTEM].

13. AUSTRALIAN GOV'T DEP'T OF FOREIGN AFFAIRS & TRADE, ABOUT AUSTRALIA: HEALTH CARE IN AUSTRALIA 1 (2008) [hereinafter ABOUT AUSTRALIA].

14. SYSTEM, *supra* note 12.

15. JOAN STIEBER, AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING, PREVENTATIVE HEALTH CARE IN AUSTRALIA: THE SHAPE OF THE ELEPHANT, RELIANCE ON EVIDENCE, AND THE COMPARISONS TO U.S. MEDICARE 4 (2005).

16. *Id.*

17. *Id.*

18. *Id.*

19. *Id.*

20. ABOUT AUSTRALIA, *supra* note 13.

21. SYSTEM, *supra* note 12, at 9.

22. AUSTRALIAN GOV'T AUSTRALIAN TAXATION OFFICE, GUIDE TO MEDICARE LEVY

who do not obtain private health insurance for themselves or their dependants are subject to the additional Medicare Surcharge Levy which equals one percent of the sum of taxable income, reportable fringe benefits, and any amount on which family trust distribution has been paid.[23]

The Australian government covers approximately two-thirds of total health expenditures -forty-three percent of which comes from the Australian government and twenty-six percent from the local state and territory governments.[24] The Government is responsible primarily for universal medical services, the funding of public hospitals, pharmaceuticals, health research, and training of health professionals.[25] Patients on Medicare are treated for free at public hospitals where they are appointed a doctor or specialist for each episode of care.[26]

Administration of the health care system takes place on the state and territory level and provides more specific care with the provision of a number of other direct health related services, such as the acute and psychiatric hospitals and community and public health services.[27] The local government also works to shape the culture by providing school health, dental care, maternal and child health services, occupational health, and disease control services.[28] In addition, they also provide home care, preventative care, and immunization coverage.[29] Outside of prevention and health maintenance measures, patients in need of a higher level of care in a given year are eligible to obtain safety net coverage, which aids in the

(JULY 19, 2011), *available at h*ttp://www.ato.gov.au/individuals/content.aspx?doc=/content/00250854.htm. In 2010-11, the levy was reduced for individuals with a taxable income of $22,163 or less, and waived for individuals with a taxable income of $18,839 or less. *Id.*

23. *Id.*
24. SYSTEM, *supra* note 12, at 9.
25. ABOUT AUSTRALIA, *supra* note 13.
26. *Id.*
27. *Id.*
28. *Id.*
29. *Id.*

payment of out of pocket fees not covered by Medicare; or if that is insufficient, the Extended Medicare Safety Net, which subsidizes eighty percent of non-hospital out-of-pocket costs once the annual limit is reached.[30]

Approximately half of all Australians have private health insurance, which the government incentivizes with a thirty percent rebate on the cost of the premium.[31] And one-third of the hospital beds in Australia are held in private hospitals.[32] In addition to access to private hospitals, private health insurance also covers enhanced "private patient" care in public hospitals, which provides patients with improved treatment such as shortened waiting times, the ability to choose one's own physician, increased access to private hospitals for elective and other ancillary medical services such as dental, eye care and chiropractic treatment.[33]

Australia is a successful example of a universal coverage system, especially in light of The Commonwealth Fund's findings of its "superior performance" and highest rankings with regard to long, healthy, and productive lives.[34]

III. A COMPARISON OF THE UNITED STATES HEALTH CARE SYSTEM TO THE AUSTRALIAN HEALTH CARE SYSTEM

The overall ranking report by The Commonwealth Fund demonstrates that there does not need to be a tradeoff between quality and efficiency in the conversion to universal health coverage, as many countries have successfully implemented this type of system without compromising those

30. SYSTEM, *supra* note 12.
31. ABOUT AUSTRALIA, *supra* note 13, at 2.
32. *Id.*
33. STIEBER, *supra* note 15, at 5.
34. DAVIS ET AL., *supra* note 2, at vii.

measures.[35] The Commonwealth Report dispels this frequent misperception through examples in the Netherlands and Germany - both universal health coverage countries - that have timely access to specialists with little cost to the individual.[36] Overall, Australia scored higher with regard to affordability and access, while the United States had shorter waiting times for elective surgery.[37] An objective, statistical analysis of cost and coverage metrics is more indicative as to the general value and merit of each of the systems.

In 2009, Australia spent 8.7% of its gross domestic product (GDP) on its universal health coverage system, equating to approximately $3,357 (USD) per capita.[38] The United States spent nearly double that, sixteen percent of its GDP on health care, equating to $7,290 (USD) per capita.[39] While Australia provides universal health coverage, the United States spends more than twice per capita than Australia and still manages to leave over forty-seven million people without health insurance.[40] Even more alarming, in spite of the money spent and people overlooked, the United States still ranked last overall in measures of access, patient safety, coordination of care, efficiency, and equity; whereas Australia trailed closely behind first-place Netherlands.[41]

From an accessibility perspective, the report demonstrates that many Americans with legitimate health problems are forced to forego needed care because of the cost.[42] Interestingly, while there are longer waiting times for

35. *Id.* at v.
36. *Id.* at vi.
37. Alan Mascarenhas, What the US can learn from Aussie health care, GLOBALPOST (Aug. 20, 2009), http://www.globalpost.com/dispatch/asia/090819/what-can-americans-learn-aussie-health-care.
38. *Id.*; DAVIS ET AL., *supra* note 2.
39. Mascarenhas, *supra* note 37; DAVIS ET AL., *supra* note 2.
40. Mascarenhas, *supra* note 37.
41. DAVIS ET AL., *supra* note 2.
42. *Id.* at vi.

elective procedures, Australia ranked second for overall efficiency.[43] The United States ranked last for efficiency partly because of its health expenditures, administrative costs, low performing information technology systems, hospital readmission rates, and performance of unnecessary medical procedures.[44] The United States and Australia were also on opposing sides of the spectrum with regard to "long, healthy and productive lives," with the United States ranking last overall and Australia ranking first.[45]

IV. REEVALUATION OF HEALTH CARE IN THE UNITED STATES

The astounding disparities found between the United States and the other industrial nations by The Commonwealth Fund point to a profound need for expanded coverage and increased quality and efficiency in the United States.[46] It also demonstrates that increased spending does not necessarily lead to better access or outcomes for a nation's people, as the United States stands out among other nations as unable to provide value in return for the health care dollars spent, and its overall quality and efficiency stands strides behind other industrial nations.[47]

Recent health care legislation in the United States attempts to address some of these concerns.[48] For increased efficiency and quality, President Barack Obama signed the American Recovery and Reinvestment Act (ARRA) in 2009, which allocated $19 billion for expanded use of information technology.[49] The Patient Protection and Affordable Care Act of 2010 (PPACA) will help extend public government health care coverage

43. Mascarenhas, *supra* note 37; DAVIS ET AL., *supra* note 2 at vi.
44. *Id.*
45. *Id.* at vii.
46. *Id.* at v.
47. *Id.*
48. *Id.* at vi.
49. *Id.*

to thirty-two million people by 2014.[50] This extension will contribute to the overall stability of the health care system in the United States, while at the same time promote enhanced quality and efficiency throughout the country by realigning provider incentives, encouraging efficient care, and promoting prevention and overall health throughout the community.[51]

Both forms of legislation take proactive strides toward better access and quality of care, but these are only the first steps toward universal health coverage and the nation must be vigilant supporters and monitors in order for it to be successful.[52]

The need for vigilant supporters may present a challenge, however, as Republicans are unanimous in their opposition to the health care reform legislation.[53] In fear of socialized medicine, and even totalitarianism, Republicans have vowed to repeal this legislation once they regain power in the White House.[54] The country remains sharply divided in its opinion of the merits of the legislation, and many fear the burden that increased regulation and taxes will have on small businesses nationwide.[55] Others fear that the imposition of universal health coverage will delay care for weeks, months, and in some cases, years.[56] Others fear a lack of resources, availability of elective procedures, and hospital beds.[57] While it is true that access to healthcare for the insured may be faster, this is not the case for those who have lost their jobs or other for others who cannot afford to

50. *Id.* at 17.
51. *Id.* at vi.
52. *Id.* at 18.
53. Alan Greenblatt, *House Passes Historic Health Care Bill* NPR (March 21, 2010), http://www.npr.org/templates/story/story.php?storyId=124997304.
54. *Id.*
55. *Obama Seeks to Reassure Small Business on Health Care,* CNN (April 1, 2010), [hereinafter *Reassure*] http://articles.cnn.com/2010-04-01/politics/obama.health.care_1_health-care-small-businesses-small-business-owners?_s=PM:POLITICS.
56. Martin, *supra* note 1.
57. *See Id.*

purchase their own insurance.[58] What society needs to come to terms with is the apparent discrepancy between these limited situations and the reality of the finding of The Commonwealth Fund wherein the United States underperforms various countries who have implemented universal health coverage in the areas of access, patient safety, coordination, efficiency, and equity.[59]

The WHO provides three steps in the path to universal coverage.[60] First, countries must raise sufficient funds.[61] Some suggestions for raising sufficient funds are through the taxation of various financial transactions to include a "sin tax" and other excise taxes such as upon airline tickets.[62]

Second, countries must reduce reliance on direct payments to finance services.[63] The overreliance on payment for care is a barrier to universal health coverage because it forces those without adequate financial backing to forgo care or risk severe financial hardship.[64] The requirement for upfront payment, co-payments, co-insurance, and deductibles needs to be subsidized or eliminated for universal health coverage to succeed.[65]

An inefficient and inequitable health care system is the third major barrier to universal health coverage.[66] Approximately $1.2 to $2.2 trillion is being attributed to waste in the United States and account for more than half of all health care spending.[67] Waste can be decreased through the practice of defensive medicine, more efficient claims processing, and

58. *Id.*
59. DAVIS ET AL., *supra* note 2.
60. WORLD HEALTH REPORT, *supra* note 6, at 9.
61. *Id.*
62. Council on Foreign Relations, Universal Health Coverage: How Do We Get There? (Transcript) (July 9, 2012), http://www.cfr.org/global-health/universal-health-coverage-do-we-get-there-transcript/p27092.
63. WORLD HEALTH REPORT, *supra* note 6, at 9.
64. *Id.*
65. *Id.*
66. *Id.*
67. PRICEWATERHOUSECOOPERS' HEALTH RESEARCH INSTITUTE, THE PRICE OF EXCESS: IDENTIFYING WASTE IN HEALTHCARE SPENDING 1 (2010).

focused care on preventative conditions such as obesity.[68]

The key to eliminate waste and inefficiency in the United States is a widespread culture shift.[69] Then, once the culture shift takes place, politics, money, and system-wide incentives will shift toward collaboration in order to solve these issues and work toward this shared value.[70]

V. CONCLUSION

The findings of the Commonwealth Report demonstrate that the incorporation of universal health coverage will not inevitably lead to a tradeoff of access for quality and efficiency.[71] The Australian national public health care system, Medicare, offers universal coverage.[72] Despite spending less than half per capita as the United States,[73] Australia still outperforms them in the categories of quality care, access, efficiency, equity, and long, healthy, productive lives.[74] The ongoing implementation of the PPACA and other forms of health reform legislation in the United States aims to improve performance in each of those areas.[75] Yet the nation still remains deeply divided on the topic,[76] and many want to avoid the issues of government run systems, such as delays in care and shortages of doctors.[77] The Commonwealth Fund Report concludes its report with the suggestion that "when a country fails to meet the needs of the most vulnerable, it also fails to meet the needs of the average citizen."[78] The citizens of the United States must realize the immense importance of equity

68. *Id.*
69. *See Id.*
70. *Id.*
71. DAVIS ET AL., *supra* note 2.
72. SYSTEM *supra* note 12.
73. DAVIS ET AL., *supra* note 2.
74. *Id.*
75. *Id.* at vi.
76. *Reassure*, *supra* note 55.
77. Martin, *supra* note 1.
78. DAVIS ET AL., *supra* note 2, at 18.

and support the implementation of a system that works for everyone.[79] The first steps have been taken in that direction, the nation now needs to stand united as vigilant supporters and monitors in order for universal health coverage to emerge and succeed in this country.[80]

79. *Id.*
80. *See id.*

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Chilean Health Reform and the AUGE Plan: Lessons for the United States in Implementing PPACA

Carrie Gilbert ∗

I. INTRODUCTION

Healthcare spending in the United States continues to grow at an unsustainable rate.[1] Today, one-fifth of the national gross domestic product is spent on healthcare.[2] The Patient Protection and Affordable Care Act (PPACA) aimed to create a more efficient and less expensive healthcare system.[3] Unfortunately, unless the manner in which Americans pay for healthcare undergoes fundamental change, the noble intentions of the PPACA's coverage expansions will ultimately prove wasteful.[4]

One of the keys to achieving true cost savings is altering the way in which chronic conditions are prevented and treated.[5] Some estimates indicate that as much as seventy to eighty percent of all healthcare expenditures are devoted to treating patients with chronic conditions.[6] Studies have shown the potential to improve the quality of care of chronic

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1. *Bending the Healthcare Cost Curve with Accountable, Patient-Centered, Coordinated Care*, W.P. CAREY SCHOOL OF BUSINESS ARIZONA STATE UNIVERSITY (Dec. 21, 2009), http://knowledge.wpcarey.asu.edu/pdf.cfm?aid=171 [hereinafter *Bending the Healthcare Cost Curve*].

2. *Id.*

3. David Cutler, *Analysis & Commentary: How Health Reform Must Bend the Cost Curve*, 29 HEALTH AFF. 1131, 1131 (2010).

4. Jane Sarasohn-Kahn, *It's Time for a Chronic Healthcare Bailout*, KAISER HEALTH NEWS (Sept. 24, 2009), http://www.kaiserhealthnews.org/Columns/2009/September/092409SarasohnKahn.aspx.

5. *Id.*

6. *Bending the Healthcare Cost Curve*, *supra* note 1.

illness, while realizing $800 billion in annual savings.[7]

The United States is not the only country struggling to reduce the amount of resources it wastes through inefficient management of chronic conditions.[8] In fact, the cost of treating chronic disease is a worldwide problem.[9] The South American country of Chile recognized the need to address chronic disease in the early 2000s.[10] Chilean leaders implemented vast health reform, including an extensive plan for guaranteeing care for individuals with certain chronic conditions.[11] Chile called its plan Explicit Guarantees and Universal Access (AUGE),[12] and since AUGE went into place in 2005,[13] Chile has learned a number of valuable lessons that can prove instructive as lawmakers consider ways to improve the delivery of care to patients with chronic conditions in the United States.

II. CHILE'S HEALTH SYSTEM: BACKGROUND

Chile is one of the most economically stable Latin American countries,[14] and achieves health outcomes comparable to those of highly industrialized nations.[15] The success of Chile's health outcomes means that the country faces problems similar to those of highly industrialized nations, including a significant burden of caring for chronic illness.[16]

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7. Sarasohn-Kahn, *supra* note 4.

8. Ricardo Bitran, Lilian Escobar & Patricia Gassibe, *After Chile's Health Reform: Increase in Coverage and Access, Decline in Hospitalization and Death Rates*, 29 HEALTH AFF. 2161, 2161 (2010).

9. *Id.*

10. *Id.*

11. Veronica Vargas & Sergio Poblete, *Health Prioritization: The Case of Chile*, 27 HEALTH AFF. 782, 783 (2008).

12. *Id.*

13. Bitran, Escobar & Gassibe, *supra* note8, at 2161.

14. *Id.* at 2162. In 2006, 13.7% of the Chilean population was considered poor. This is much lower than the Latin American, which is 40%.

15. *Id.*; *see* Vargas & Poblete, *supra* note 1111, at 782. Life expectancy of for women is 80, and 73 for men. Infant mortality rate is 8.6 per 1,000 live births.

16. Bitran, Escobar & Gassibe, *supra* note 8, at 2162.

Chile's health insurance system is a joint public and private system.[17] FONASA, the public insurer, covers sixty-nine percent of the Chilean population.[18] The ISAPRE plans, or the private plans, cover about seventeen percent of the population.[19] Both plans are financed through a seven percent tax on the salaries of Chile's employed.[20] FONASA copayments are relatively small and correspond to an individual's income.[21] Alternatively, individuals who choose an ISAPRE plan pay additional premiums for better coverage.[22] While the theory behind the joint system is that citizens can freely choose public or private coverage, in reality an individual's income ultimately determines which plan he chooses.[23] An individual's gender influences which plan an individual chooses as well. ISAPREs require high premiums from women of childbearing age, rendering ISAPREs unaffordable for many Chilean women who traditionally earn substantially less than their male counterparts.[24] Therefore, traditionally, the ISAPREs are overwhelmingly populated by men.[25] Additionally, ISAPREs use risk selection to reduce costs, which results in the sicker and riskier populations obtaining FONASA insurance.[26] This in turn means that a greater number of individuals with chronic conditions are on the FONASA plans. Ultimately, the dual-system creates

17. Vargas & Poblete, *supra* note 11, at 782.
18. *Id*.
19. *Id*.
20. Walker Elliot Rowe, *Is Chilean Health Insurance Better Than That of The USA?*, THE SANTIAGO TIMES (July 2, 2011, 2:12pm), http://www.santiagotimes.cl/blogs/146-walker-elliot-rowe/21835-is-chilean-health-insurance-better-than-that-of-the-usa.
21. Ricardo Bitran & Liliana Escobar, *The Politics of the AUGE Health Reform in Chile: A Case Study Prepared for the Results Development Institute*, BITRAN Y ASOCIADOS 9 (May 2008) , *available at* http://www.resultsfordevelopment.org/publications/politics-auge-health-reform-chile-case-study [hereinafter *The Politics of AUGE*].
22. Bitran, Escobar & Gassibe, *supra* note 8, at 2162.
23. *The Politics of the AUGE*, *supra* note 21, at 9.
24. *Id.* at 853-4.
25. Charles Dannreuther & Jasmine Gideon, *Entitled to Health? Social Protection in Chile's Plan AUGE*, 39 DEVELOPMENT AND CHANGE 845, 853 (2008).
26. Bitran, Escobar & Gassibe, *supra* note 8, at 2162.

an inequitable approach in which the wealthiest Chileans receive better care and the poorer Chileans are guaranteed healthcare, but of a lower quality.[27]

III. THE AUGE PLAN

Given the inequity in the healthcare system and the growing cost of treating chronic disease, the Chilean government began to focus its attention on controlling certain conditions.[28] A 2003 health survey conducted by the Chilean government revealed a high prevalence of chronic disease, and further concluded that very few of these patients were effectively managing their diseases.[29] To address these concerns, the government developed AUGE. With AUGE, the Chilean government aimed to create a more equitable system, which guaranteed certain services to all users regardless of insurance plan or socioeconomic status.[30] Additionally, the government sought to create a system which emphasized prevention, early examination of symptoms, and primary care.[31] The legislation establishing AUGE states that the plan guarantees enrollees four things: 1.) access; 2.) quality; 3.) opportunity; and 4.) financial protection.[32]

Guaranteed access ensures enrollees will receive identified curative services for certain prioritized diseases.[33] In an effort to guarantee quality, the law mandates that the services must be provided by certified providers in accordance with established guidelines.[34] The law also limits the waiting

27. Dannreuther & Gideon, *supra* note 25, at 852.
28. Bitran, Escobar & Gassibe, *supra* note 8, at 2163.
29. *Id.*
30. The World Bank Group, Social Development Dep't, *Realizing Rights Through Social Guarantees: An Analysis of New Approaches to Social Policy in Latin America and South America*, REPORT NO. 40047- GLB (2008), *summarized in Chile: Regime Explicit Health Guarantees (Plan AUGE)* §12, http://siteresources.worldbank.org/EXTSOCIALDEV/Resources/3177394-1168615404141/3328201-1192042053459/Chile.pdf?resourceurlname=Chile.pdf [hereinafter *Plan AUGE*].
31. *Id*.
32. Bitran, Escobar & Gassibe, *supra* note 8, at 2163.
33. *Id.*
34. *Id.*

periods that enrollees experience when trying to access care.[35] Moreover, AUGE is uniform for all beneficiaries regardless of whether their healthcare is paid for through FONASA or ISAPREs.[36] FONASA and ISAPREs have to reimburse at a guaranteed level for the mandated services so that the out-of-pocket costs to enrollees do not exceed a predefined share of household income.[37]

The Chilean government organized what is likely the most thorough prioritization-analysis ever undertaken to determine for which conditions and diseases it should guarantee access.[38] An intricate algorithm was devised for determining which conditions to include.[39] Those diseases with the highest rates of mortality and disability received priority.[40] Then, the government determined which of the conditions it could effectively treat for all individuals regardless of socioeconomic status.[41] Essentially, the prioritization was based on the danger of a disease and the ability to cure or control the disease. Despite the extensive review, some criticized the prioritization. For example, a report by the Fourth Women's Parliament was critical of the final prioritization for its failure to account for gender

35. *Id.*

36. Mari Edlin, *Chile's Healthcare Offers Public and Private Plans*, MANAGED HEALTHCARE EXECUTIVE (Dec. 1, 2009), http://managedhealthcareexecutive.modernmedicine.com/mhe/Managed+Care+Outlook/Chiles-healthcare-offers-public-and-private-plans/ArticleStandard/Article/detail/647865.

37. Britan, Escobar & Gassibe, *supra* note 8, at 2163.

38. Vargas & Poblete, *supra* note 11, at 790.

39. *Id.* at 783. The algorithm is as follows: "1) indicators measuring the burden of disease of different conditions: incidence, prevalence, and mortality rate; 2) inequity measured by gaps in mortality across socioeconomic groups; 3) effectiveness of different treatments – health conditions were stratified into high, medium, and low treatment effectiveness, and those conditions with high or medium treatment effectiveness were preselected; 4) evaluation of the capacity of public and private systems to deliver the services – the group of conditions for which there were enough available resources was preselected; 5) estimation of cost per case and total cost per condition based on treatment protocols suggested by experts and national scientific associations; 6) high-cost conditions – identified as those with annual treatment costs greater than or equal to annual minimum wage; and 7) people's preferences were elicited such that reformers could use the information and prevent special-interest groups from defining the health plan."

40. *Plan AUGE*, *supra* note 30, at §13.

41. *Id.* at §14.

differences which contribute to health, ignoring many of the diseases with the highest rates of female morbidity.[42] After much debate and analysis, fifty-six chronic conditions were chosen.[43] The list was later expanded, in 2010, to sixty-six conditions.[44] In addition to the list conditions, the government also defined curative services that were mandated to treat beneficiaries of AUGE.[45] Further, the government mandated coverage for early detection and intervention for hypertension, type 1 and type 2 diabetes, HIV/AIDS, cervical cancer, and other chronic diseases.[46]

Beneficiaries in AUGE can opt for care by a "closed" mode or a "free-choice" mode.[47] Individuals who choose closed mode receive care for little to no copayment.[48] Free choice mode requires a higher copayment, but usually offers faster, better quality care.[49] Moreover, given that the costs of many of the mandated services in AUGE are expensive, the copayments are devised to ensure that providers are compensated at a level that ensures they continue to treat patients in the program.[50]

Before AUGE could be implemented, it had to be funded. The debate around funding AUGE explored various funding sources.[51] AUGE is ultimately funded from four sources: 1.) a four year increase in consumer tax; 2.) a tobacco tax; 3.) customs revenues; and 4.) sale of the state's shares in public health enterprises.[52] In preparation of implementation of AUGE, the government established a new entity to supervise public and private

42. Dannreuther & Gideon, *supra* note 25, at 856.
43. Bitran, Escobar & Gassibe, *supra* note 8, at 2163; *The Politics of AUGE*, *supra* note 30, at 11.
44. Bitran, Escobar & Gassibe, *supra* note 8, at 2169.
45. *Id.* at 2163.
46. *Id.*
47. *Id.* at 2164.
48. *Id.*
49. *Id.*
50. Dannreuther & Gideon, *supra* note 25, at 857.
51. *Plan AUGE*, *supra* note 30, at §15.
52. *Id.*

health plans together to ensure that the program was executed effectively.[53] The new entity was the first of its kind in the country.[54] The success of AUGE also required and interdisciplinary network of providers, as well as involvement from the external community and corporate contributions.[55] Care for the prioritized conditions is provided in a team-based setting through a network of Non-Governmental Organizations (NGOs).[56] Due to the need for contribution and buy-in from various stakeholders, development of AUGE brought together trade unionists, academics, physicians and other service providers, the private health insurance companies, the ISAPREs, and NGOs including grassroots women's groups and neighborhood associations.[57]

AUGE faced opposition from various stakeholders as well.[58] The Chilean Medical Association opposed reform, fearing AUGE would restrict the physician-community's freedom to make decisions for patients.[59] ISAPREs feared that, because both they and FONASA had to pay into a compensatory fund based on clients' actuarial risk, they would end up paying more than FONASA and would essentially subsidize FONASA.[60] Following the extensive work that went into devising AUGE and reconciling the opposition, AUGE went into effect in 2005.

IV. THE RESULTS OF AUGE

Since its inception, 3.2 million Chileans have used AUGE.[61] Between

53. *Id.* at §16.
54. *Id.*
55. Geoffrey Meads et al., *The Management of New Primary Care Organizations: An International Perspective*, 19 HEALTH SERVICES MANAGEMENT RESEARCH 166, 170 (2006).
56. *Id.*
57. Dannreuther & Gideon, *supra* note 25, at 855.
58. *The Politics of AUGE*, *supra* note 21, at 4.
59. *Id.*
60. *Id.*
61. *Plan AUGE*, *supra* note 30, at §19.

2006 and 2009, alone, AUGE grew to over two million cases per year.[62] The country has seen a rapid and significant increase in access to care for the mandated services.[63] Notably, Chile has experienced improved health outcomes since the beginning of AUGE. Mortality rates for several types of cancer on the prioritization list have declined.[64] Studies have also found that AUGE participants have benefited from earlier detection and more timely treatment.[65] Moreover, case-fatality rates for hypertension, type 1 and type 2 diabetes, HIV/AIDS, epilepsy, and depression have all dropped since AUGE's inception.[66] Surveys of public perception also indicate that AUGE is working and that Chileans like it.[67] In fact, sixty-nine percent of individuals surveyed reported that Chilean healthcare has improved.[68]

Evidence suggests that more public health insurance beneficiaries are utilizing AUGE than private beneficiaries.[69] In fact, in AUGE, FONASA beneficiaries outnumber ISAPRE beneficiaries by four to one.[70] Additionally, FONASA beneficiaries outnumber ISAPRE beneficiaries in services performed by twenty to one.[71] Evidence has also shown that "[t]he higher the perceived economic benefit of an AUGE service, the higher [the] propensity to demand care under AUGE."[72] This likely means that the sicker the individual is, the more likely he or she is to choose to use AUGE. When ISAPREs customers have used AUGE, it has been primarily for high-cost treatments.[73] Ultimately, those individuals most in need of

62. Bitran, Escobar & Gassibe, *supra* note 8, at 2163.
63. *Id.* at 2168.
64. *Id.* at 2163.
65. *Id.* at 2168.
66. *Id.*
67. *Plan AUGE*, *supra* note 30, at §21.
68. *Id*.
69. Bitran, Escobar & Gassibe, *supra* note 8, at 2163.
70. *Id*. at 2164.
71. *Id*.
72. *Id*.
73. *Plan AUGE*, *supra* note 30, at §19.

controlling chronic illness are receiving the care they need; however, consistent use across all income levels is the surest way to bend the cost curve.

Despite the evidence that AUGE is making strides in improving the health of Chilean citizens, no major healthcare overhaul is without problems after implementation. AUGE has improved access to care; however, problems with waiting lists for care and inequitable access to services persist.[74] Although AUGE legislation guaranteed that waiting periods for mandated services would not exceed certain limits, over half of AUGE beneficiaries report waiting periods beyond the stated threshold.[75] The availability of services negatively affects an individual's decision to use the AUGE plan.[76] In fact, public insurance beneficiaries who live in areas with a low supply of public hospitals are less likely to use AUGE because of their inability to access services conveniently, and therefore, AUGE is not yet achieving its goals for some.[77] Additionally, in some cases, increased waiting periods can lead to a worsening of the chronic condition, thus undermining the benefit AUGE was enacted to attain.[78] The waiting period is worse for low-income beneficiaries than for higher-income beneficiaries,[79] meaning the gap that Chile's dual-system creates between the service received by public and private beneficiaries persists as well.[80]

AUGE has created a new gap in access, one between those services

74. *Id.* at §22.
75. *Id.*
76. Amanda Dawes & Felipe Gonzalez, *On the Importance of Hospital Supply in Health Reforms: the AUGE Plan in Chile*, POINTIFICIA UNIVERSIDAD CATOLICA DE CHILE 14 (Nov. 2010).
77. *Id.*
78. *Id.* at 1.
79. *Plan AUGE*, *supra* note 30, at §22.
80. Jean-Pierre Unger et al., *Chile's Neoliberal Health Reform: An Assessment and a Critique*, 5 PLOS MEDICINE 542, 546 (2008).

covered by AUGE and those that are not.[81] While waiting lists for AUGE-covered services are long, those for non-AUGE-covered services are even worse.[82] In fact, the problem became so worrisome that in 2008, the Minister of Health created a ninety-day plan to reduce the waiting lists.[83] The government was able to reduce the waiting lists considerably, but stated that a complete resolution of the problem would take several years.[84]

A second issue surrounding the successful implementation of AUGE is a lack of information available to Chilean citizens.[85] Surveys of Chilean citizens reveal that eighty percent of respondents did not know which diseases were covered by the plan.[86] Of those individuals surveyed who qualified for AUGE but did not use it, sixty-four percent blamed a lack of information about the benefits of the plan.[87]

The last major concern is the lack of valuable assessment of the program.[88] While AUGE has achieved major advances in health outcomes, there is little to no data to compare the achievements with the cost of the reform.[89] Without the ability to analyze cost-benefit data, it is difficult to determine whether the program's ability to achieve early intervention and detection actually saves Chile money. The government is eager to add more conditions to the list of prioritized diseases, and therefore it will be increasingly important to evaluate the system[90] in order to improve it and ensure that the most cost-effective services are used for the prioritized conditions.

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81. Bitran, Escobar & Gassibe, *supra* note 8, at 2164.
82. *Id.*
83. *Id.*
84. *Id.*
85. *Id.* at 2163.
86. *Plan AUGE*, *supra* note 30, at §21.
87. *Id.*
88. Bitran, Escobar & Gassibe, *supra* note 8, at 2168.
89. *Id.*
90. *Id.* at 2169.

V. THE UNITED STATES

The PPACA does not include an AUGE-like provision in the sense that the government has not identified certain conditions for which it will be mandating coverage. The PPACA does, however, attempt to achieve similar goals as AUGE; namely, greater equity in access and cost-effectiveness.[91] Cost-effectiveness is particularly important when it comes to treating the most expensive of conditions – chronic conditions. Thus, AUGE has achieved a valuable goal in making the receipt of care for those suffering from some of the most dangerous and difficult-to-control conditions more affordable. Unfortunately, an AUGE-like plan in the United States is likely politically infeasible. Given the difficulty in passing the PPACA, Congress is unlikely to take up further debates to create additional public health insurance programs.[92] Additionally, in times of economic recession, any program needing government funding or tax increases appears doomed to fail.

Nevertheless, there are provisions in the PPACA for which the Chilean government's experience with AUGE may be instructive. Certain provisions in the PPACA may face similar challenges to those faced by AUGE, most notably the Medicaid expansion and Accountable Care Organizations (ACOs). Medicaid expansion will vastly increase the number of individuals eligible to receive Medicaid assistance.[93] Many experts are already concerned that the increase in health coverage will not necessarily equate to an increase in ability to procure services due to a lack

91. Cutler, *supra* note 3, at 1131.

92. Charles Krauthammer, *Obamacare: The Reckoning*, WASH POST (March 22, 2010) available at: http://www.washingtonpost.com/opinions/obamacare-the-reckoning/2012/03/22/gIQALF1QUS_story.html

93. Patient Protection and Affordable Care Act, Pub. L. No. 111–148, 124 Stat. 271 (2010). PPACA extends coverage to all individuals with income levels at 133% of the federal poverty line or lower.

of providers.[94] As was the case in Chile, individuals with new health coverage will be more likely to access services if they are easily found. The PPACA attempts to address the issue of provider shortage in several ways, including increased funding to Federally Qualified Health Centers (FQHCs).[95] Ultimately, however, the Medicaid expansion will not improve the health outcomes in the United States unless people with chronic conditions actually have access to services. Further, the healthcare cost curve will remain similarly unchanged unless people with chronic conditions can access preventive services earlier. Based on the available evidence from Chile, even care to which individuals are entitled to receive will not be utilized in the face of waiting lists and overcrowded facilities. Even with a hypothetical surplus of providers of care, like Chileans, Americans will not seek care if it is not available in convenient places – in their communities.

Additionally, adequate information and education regarding eligibility and benefits will be the key to enrolling people in Medicaid and providing them care. In Chile, one of the major barriers to use of the AUGE plan was the lack of information available to Chilean patients. Similarly, in the United States some of the individuals who will have access to care through Medicaid expansion will be accessing the system for the first time, and therefore, information will prove crucial to enrolling individuals and providing them access to the care they need.

The PPACA emphasizes the creation of ACOs, which are perhaps the piece of the PPACA which most closely resemble AUGE. ACOs provide

94. Leighton Ku et al., *Strengthening Primary Care to Bend the Cost Curve: The Expansion of Community Health Centers Through Health Reform*, GEIGER GIBSON/RCHN COMMUNITY HEALTH FOUNDATION RESEARCH COLLABORATIVE POLICY RESEARCH BRIEF NO. 19 2 (2010).

95. *Id.* at 3.

coordinated care for patients in a team-based setting.[96] The team of providers is incentivized to provide efficient, cost-effective care.[97] ACOs promote primary care and control of chronic conditions in an effort to reduce costs and improve quality.[98] While ACOs differ from AUGE in several ways, including that they will not be mandated to treat certain conditions, there are lessons to be learned from AUGE in their implementation. For example, proper assessment and evaluation of ACOs will be critical to their success. One of the frustrations for policymakers trying to improve or refine AUGE is the lack of evidence relating to cost-effectiveness. In the United States, providers are beginning to create ACOs as pioneer organizations.[99] The Department of Health and Human Services believes that the pioneer ACO organizations can achieve $1 billion in savings over five years.[100] The government and the providers involved will need to carefully document and evaluate the entire process in order to analyze whether ACOs achieve this goal. Additionally, ACOs will likely need refining, just as AUGE does, and assessment will be pivotal to determining what form the refinement takes.

While the ACO initiative does not involve identifying the most costly diseases, this may be a useful exercise for the United States. Identifying those diseases which are most dangerous, yet most treatable, can help the United States to prioritize the conditions that, when more actively managed, could have the greatest impact on improving the health of its citizens and bending the cost curve. If this project were to be undertaken, the United States should be careful not to duplicate the efforts of Chile, but rather to

96. *Bending the Cost Curve*, *supra* note 1.
97. *Id.*
98. *Id.*
99. Press Release, U.S. Dep't of Health and Human Servs., Affordable Care Act Helps 32 Health Systems Improve Care for Patients, Saving up to $1.1 Billion (Dec. 19, 2011) , available at http://www.hhs.gov/news/press/2011pres/12/20111219a.html.
100. *Id.*

heed the lessons that the extensive process of implementing AUGE has already created.

VI. CONCLUSION

The United States is not the only country facing great challenges when it comes to caring for chronic illnesses. Additionally, no country's reform efforts look the same as another's. The United States and Chile have similarities in their reforms, but, overall, they differ vastly. Moreover, the United States and Chile differ economically, culturally, and politically. This does not mean, however, that the United States cannot learn from the health reform implemented in Chile. The PPACA promises to fundamentally alter the way healthcare is delivered in the United States to patients with chronic disease, and stakeholders have a challenging time ahead in implementing and refining healthcare. The Chilean health reform and AUGE can provide valuable lessons, including the need for easily accessible, convenient care; the reliance of individuals on information before they will access benefits; and the value of thorough assessment and data.

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Cost Control: What the United States Can Learn from Japan's Fee Schedule

Timothy M. Black∗

I. INTRODUCTION

Healthcare reform is a continuous process. Even when it looks like a nation has found an acceptable healthcare delivery system, factors such as a changing economy, changing demographics, or changes in the weather could influence people to become more satisfied, or more dissatisfied with the healthcare delivery system of their nation. The United States is no different.

In an attempt to effectively balance the needs of the people it serves, the needs of the special interest groups who support it financially and politically, and the needs of an economy in distress, the United States has taken on the task of significantly reforming its national healthcare system. While trying to find a system on which everyone can agree, it is important that standards such as quality of care are neither forgotten nor overlooked. During this process, legislators and pundits must examine what has worked and what has failed in other countries.

This article will explore the functionality of Japan's universal healthcare system, and expose some of the issues it now faces. Japan provides an excellent case study, as it has found success through its universal healthcare system. Pursuant to the Organisation for Economic Co-operation and Development (OECD) Health Data sheet, Japan spent less than half the amount of its Gross Domestic Product (GDP) on health care that the United

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States spent of its GDP on health care in 2008, but it also had the lowest infant mortality rate and the highest life expectancy of nearly all of the thirty-two OECD member countries.[1] With such a low percentage of GDP spent on healthcare, and such a healthy patient base, Japan makes the perfect place for this examination to start.

This article will first provide a background of Japan's universal healthcare system and what reforms have led to the current plan. Next, it will discuss the issues that Japan faces in maintaining that system. Finally, this article will analyze what can be gleaned from Japan's fee schedule to help the United States grow an effective and sustainable healthcare system.

II. HEALTHCARE IN JAPAN

In the aftermath of World War II, Japan was forced to undergo economic and social reconstruction.[2] In 1947, the Japanese Constitution was amended to guarantee "wholesome and cultured living" to every Japanese citizen.[3] By 1961, Japan launched *kaihoken*,[4] a universal healthcare system designed to meet that guarantee.[5] Since then, the system has undergone several changes.[6]

To meet Japan's goal of providing necessary and adequate medical care to all citizens at a low cost,[7] the government developed a system of healthcare that allows its citizens to choose any primary care physician or

1. OECD Health Data 2011, How Does Japan Compare, *available at* www.oecd.org/dataoecd/45/51/38979974.pdf.

2. *See* Naoya Ono, *Medical Insurance in Japan*, 1 THE J. OF KAMPO, ACUPUNCTURE & INTEGRATIVE MED. (SPECIAL EDITION) 105 (2010).

3. Comments, *U.S. Health Care Reform: Some Lessons from Japanese Health Care Law and Practice*, 9 TEMP. INT'L & COMP. L. J. 365, 374 (1995).

4. *Health Care in Japan: Not all Smiles*, THE ECONOMIST, Sep. 10, 2011, www.economist.com/node/21528660.

5. Ono, *supra* note 2, at 5.

6. *See, e.g.* Ono, *supra* note 2, at 106-07.

7. Randall S. Jones, *Health-Care Reform in Japan: Controlling Costs, Improving Quality and Ensuring Equity* 7 (OECD Econ. Department, Working Paper No. 739, 2009).

specialist from any hospital or clinic.[8] Essentially, both quality of treatment and scope of care are consistent, hospital-to-hospital and clinic-to-clinic.[9]

Participation in the healthcare system is both universal and mandatory.[10] All Japanese citizens have some form of medical insurance through one of 3,500 plans that are determined by factors such as age, employment, and location.[11] Those 3,500 plans come from one of the following four insurance programs endorsed by the government: Society-Managed Health Insurance (SMHI), Japan Health Insurance Association-Managed Health Insurance (JHIAHI), National Health Insurance (NHI), and Mutual Aid Associations (MAA).[12]

Funding for medical care comes from three sources: insurance premiums, government subsidies, and co-payments by patients.[13] Payment for outpatient services comes predominantly from a fee-for-service system, whereas payment for inpatient care comes from a combination of fee-for-service and *per diem* payments.[14] Each medical procedure or service is assigned a price by the government.[15] The fee schedule is then evaluated and updated every two years.[16] Similarly, insurance companies are heavily regulated by the government and are forbidden from earning a profit.[17]

Another characteristic of the Japanese healthcare system is the frequency

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8. Tadahiko Tokita, *The Prospects for Reform of the Japanese Healthcare System*, PHARMACOECONOMICS 2002, 20 Suppl. 3, 58 (2002).

9. Jones, *supra* note 7, at 7.

10. Blaine Harden, *Health Care in Japan: Low-Cost, for Now*, WASH. POST, Sept. 7, 2009, www.washingtonpost.com/wp-dyn/content/article/2009/09/06/AR2009090601630.html.

11. Kenji Shibuya et al., *Future of Japan's System of Good Health at low Cost With Equity: Beyond Universal Coverage*, THE LANCET 68, 69 (September 1, 2011); *see also* Ono, *supra* note 2, at 105.

12. Jones, *supra* note 7, at 8.

13. Harden, *supra* note 10.

14. Yutaka Imai, *Health Care Reform in Japan* 5 (OECD Economics Department, Working Paper No. 321, 2002).

15. *Id.*

16. *Id.*

17. Jones, *supra* note 7, at 9.

with which Japanese citizens visit the doctor, and their length of stay in hospitals and inpatient clinics. A typical Japanese patient visits the doctor fourteen times per year, which is more than four times the amount of visits a typical American patient makes.[18] Similarly, the average hospital stay in Japan is nearly four times as long as the average hospital stay in the United States.[19] Whether the difference in length of stay is beneficial or detrimental to Japan's healthcare system is a topic of debate in the medical community.[20]

III. ISSUES CREATED BY THE JAPANESE SYSTEM OF UNIVERSAL HEALTHCARE

Japan's universal healthcare system is often lauded for its ability to maintain a high level of collective health without draining money from the people who use the system. The problems that the *kaihoken* model poses, however, are beginning to rear their collective head. There are two broad issues that need to be addressed to maintain the level of satisfaction with *kaihoken* that is seen today: a) rising healthcare costs; and, b) substandard quality of care.

A. Rising Healthcare Costs

The cost of healthcare in Japan is rising due mostly to low economic growth rates and an unstable political climate, combined with structural inefficiencies and population aging.[21] As is true with most of the global

18. Harden, *supra* note 10.

19. *Id.*; Imai, *supra* note 14, at 7; Jones, *supra* note 7, at 12.

20. *Compare* Jones, *supra* note 7, at 12 ("One exceptional feature of the Japanese health care system is the number of hospital beds and the length of the average stay, which are both about four times longer than the OECD average.") *with* Imai, *supra* note 14, at 7 ("But the average length of stay is about four times more than the OECD average reflecting the fact that many acute care beds have taken on the long-term care function for the elderly, the phenomenon known as 'social hospitalization.'")

21. Shibuya, *supra* note 11, at 69.

economy, the Japanese economy is struggling.[22] It has been suggested that the biggest challenge to solving the nation's fiscal situation is the financing of healthcare.[23] Many of the issues that are created by the universal healthcare system were overlooked during periods of economic success, but can no longer be tolerated in the current economic climate.[24] In fact, without a commitment to structural reform, it is predicted that costs could double within the next decade.[25]

The rise in health spending is due in large part to the following four factors: population aging, population growth, changes in the fee schedule, and other factors such as changes in technology.[26] Japan, as a nation, is aging more rapidly than any other country.[27] The aging of the Japanese society continues to drive up healthcare spending.[28] Spending on citizens ages seventy and over is five times the level of spending on the remaining citizens, which is high as compared to other nations.[29] Much of the blame falls on a combination of the fee-for-service model of payment and the insurance policies that pay for care of the elderly.[30] As the nation continues to age, the fee-for-service model and the insurance structure continue to place a heavy burden on younger generations, and more specifically, the working population.[31] Under the current Japanese insurance structure, inequities amongst the various insurance plans are addressed by imposing "cross-subsidies" between the different insurance plans to account for the

22. CIA World Factbook – Japan (Feb. 24, 2012 10:32 AM), www.cia.gov/library/publications/the-world-factbook/geos/ja.html.
23. Shibuya, *supra* note 11, at 70.
24. *Supra* note 4, at 2.
25. Harden, *supra* note 10.
26. Jones, *supra* note 7, at 6.
27. Tokita, *supra* note 8, at 58.
28. Imai, *supra* note 14, at 9.
29. *Id.*; Ono, *supra* note 2, at 106.
30. *See, e.g.* Hideki Nomura & Takeo Nakayama, *The Japanese healthcare* system, 331 BRIT. MED. J. 648, 648 (Sept. 24, 2005).
31. *Id.*

number of elderly people enrolled in the various plans.[32]

In 1973, the government passed legislation that abolished the co-pay for the nation's elderly,[33] which had the unintended consequence of growing the rate of long-term care patients in hospital beds, "turning hospitals into *de facto* nursing homes."[34] This trend – known as "social hospitalisation" – reflects a number of factors.[35] Those factors include: 1) a shortage of formal long-term care facilities, such as nursing homes; 2) the trend among the Japanese population of going to large medical centers as opposed to small hospitals, giving small hospitals an incentive to fill their beds with long-term care patients; 3) healthcare costs for the nation's elderly, including long-term care costs, which are not capped by the budget like other social welfare programs; and 4) the aging population.[36]

B. Substandard Quality of Care

The second major problem that needs to be addressed with regard to Japan's healthcare system is the issue of quality of care. As the global community has become interconnected, Japanese expectations regarding the quality of healthcare have risen.[37] The healthcare system, vis-a-vis the government, however, has been too slow in its response.[38] Specific complaints include: long wait times coupled with short consultation time with a doctor; insufficient explanation of procedures and maladies, including a lack of availability of medical information; and an overall poor level of care in hospitals.[39] The "blame" for the lack of quality of care in

32. Shibuya, *supra* note 11, at 69.
33. Ono, *supra* note 2, at 106; Tokita, *supra* note 8, at 56.
34. Jones, *supra* note 7, at 13.
35. Imai, *supra* note 14, at 7; Jones, *supra* note 7, at 14.
36. Jones, *supra* note 7, at 14.
37. Shibuya, *supra* note 11, at 71; Imai, *supra* note 14, at 10.
38. Shibuya, *supra* note 11, at 71.
39. Imai, *supra* note 14, at 7-8.

Japan can be attributed to three different aspects of the healthcare system: doctors, pharmaceuticals, and equality.

1. Doctors

In an increasingly globalized world, patients in Japan are becoming increasingly aware of quality standards and physician standards.[40] The current healthcare system has not allowed doctors to keep up with those changes.[41] The barriers stem from a) the fee-for-service model, and the effects it has on physician incentives; and, b) the lack of differentiation between general care and specialty care.[42]

a. Fee-for-service model

As previously stated, one of the main objectives of the Japanese government is to provide "necessary and adequate" healthcare to its citizens.[43] An unintended consequence of the fee-for-service payment method with regard to providing "necessary and adequate" care is that the definition of "necessary" changes over time.[44] In other words, the fee-for-service model creates a culture where treatment that is considered "necessary" is determined less by its medical effectiveness and more by the price point of that treatment, which leads to a higher volume of prescription of higher-priced services.[45] A higher volume of services leads to higher reimbursement for providers, thus it creates a system that values quantity over quality.[46]

Most Japanese doctors earn significantly less than doctors in the United

40. Hideki Hashimoto et al., *Cost Containment and Quality of Care in Japan: Is there a Trade-off?*, 378 THE LANCET 1174, 1179-80 (2011).
41. Shibuya, *supra* note 11, at 71.
42. Imai, *supra* note 14, at 6.
43. Jones, *supra* note 7.
44. *Id*. at 19.
45. Imai, *supra* note 14, at 7.
46. *Id.*

States.[47] The government keeps strict control over the amount of doctors in the market, and the average Japanese patient visits the doctor fourteen times per year.[48] This combination of fewer doctors and more frequent patient visits leads to very long working hours for the already underpaid physicians, severely diminishing the quality of care.[49] As a result, the most skilled doctors in Japan tend to leave the long hours and low wages of hospitals for the predicable schedule and higher income of private clinics.[50] Indeed, most doctors in Japan who make the switch from hospital to private clinic double their income.[51] When the more skilled doctors leave the hospitals for private clinics, the quality of care at the hospitals suffers. In fact, one of the most common complaints among Japanese patients is that they spend as long as three hours waiting for three minutes of face time with a doctor, and quality and depth of service suffers as a result.[52]

b. Accreditation

The flight of doctors from hospitals to clinics has led to a disparity of trust between clinic doctors and hospital doctors, which reflects the lack of accreditation standards in Japan.[53] Physicians in Japan are allowed to represent themselves as specialists without extra training in the area in which they claim to specialize.[54] Specifically, roughly two-thirds of doctors in Japan claim a specialty, although as few as half have undergone formal training in that specialty.[55]

In addition to the distrust in doctors that spreads as a result of the lack of

47. Harden, *supra* note 10.
48. *See generally*, Imai, *supra* note 14; s*ee also*, Harden, *supra* note 10.
49. Jones, *supra* note 7, at 11.
50. Harden, *supra* note 10.
51. *Id.*
52. Jones, *supra* note 7, at 11.
53. *Id.* at 24.
54. *Id.* at 24.
55. *Id.* at 25.

accreditation, there is a shortage of doctors to fulfill certain specialties.[56] These shortages are most prevalent in the areas of obstetrics, emergency care, pediatrics, and surgery.[57]

2. Pharmaceuticals

The pharmaceutical industry also weighs heavily against the quality of healthcare in Japan. Unlike in the United States, there are no laws in Japan mandating the separation of prescribing drugs and dispensing drugs.[58] Consequently, physicians are selling pharmaceutical drugs to supplement their incomes.[59] Under the current fee schedule, physicians are compensated for each prescription they write and each test they perform, not the amount of time or the quality of care given to a patient.[60] This system has resulted in an increase in the number of drugs and tests prescribed and consumed, with little regard for quality,[61] making Japan the highest among OECD nations in prescription and consumption of drugs and administration of tests.[62]

IV. HEALTHCARE IN THE UNITED STATES COMPARED TO HEALTHCARE IN JAPAN

As detailed above, Japan has very good reason to be proud of its healthcare system. The Japanese government has been able to find a delicate balance between keeping consumer costs down, while maintaining impressive health outcomes. To that end, the aspect of *kaihoken* that is most helpful for the United States is the strict fee schedule set by the

56. *Id.* at 7; Shibuya, *supra* note 11, at 71.
57. Jones, *supra* note 7, at 7; Shibuya, *supra* note 11, at 71.
58. Imai, *supra* note 14, at 6.
59. Jones, *supra* note 7, at 11-12.
60. Nomura, *supra* note 30, at 648.
61. *See* Jones, *supra* note 7, at 12; *see also* Nomura, *supra* note 30, at 648; *see also* Tokita, *supra* note 8, at 62.
62. Jones, *supra* note 7, at 20.

Japanese government.[63] The tight control of healthcare in Japan is a double-edged sword, however; while it allows the government to keep costs at a minimum, it also limits the quality of care in the country.[64]

The Japanese government keeps tight control over the cost of medical goods and services by setting a fee schedule.[65] This fee schedule has been integral for Japan in limiting the cost of care for its patient population.[66] The process of setting the fee schedule begins every two years, when members of the Japanese government decide on a global revision rate, which is the rate by which the entire budget for healthcare spending is increased or decreased.[67] After the global revision rate is set, the Central Social Insurance Medical Council[68] works within that guideline to revise the price for each drug, device, and service on an item-by-item basis.[69] Those numbers are, then, negotiated between provider groups and the Ministry of Health, Labour and Welfare.[70] When they come to an agreement on the price of each drug, device, and service offered, those are the numbers that are used for the following two years, until the entire process begins again.[71]

Like the system in the United States, *Kaihoken* is a multi-payor system that charges for medical care on a fee-for-service basis; but, unlike the

63. *See, e.g.* Hashimoto, *supra* note 40, at 1181.

64. *See generally* Jones, *supra* note 7 (explaining that the Japanese government has struggled to balance quality and cost throughout its fifty year history of providing universal healthcare).

65. *See* Harden, *supra* note 10.

66. Naoki Ikegami & John Creighton Campbell, *Japan's Health Care System: Containing Costs and Attempting Reform*, 23 HEALTH AFF. 26, 26 (2004).

67. Hashimoto, *supra* note 40, at 1175.

68. Committee consisting of payers, providers, and public interest appointed by the Minister of Health, Labour and Welfare.

69. Hashimoto, *supra* note 40, at 1175-76.

70. *Id.* at 1176.

71. Mark J. Ramseyer, *The Mortality Effects of Cost Containment Under Universal Health Insurance: The Japanese Experience*, HARVARD L. SCH. JOHN M. OLIN CENTER FOR L., ECON. & BUS. DISCUSSION PAPER SERIES, Paper 619, 4 (2008), *available at* http://lsr.nellco.org/harvard_olin/619.

United States, it uses the fee schedule to maintain one single payment system.[72] The effect of this single payment system is equality of care across the entire nation because every insurance plan is essentially the same in what is covered, and all procedures cost the same throughout the country.[73] Furthermore, the strict regulation of costs allows the Japanese government to promote specific technologies and procedures by lowering their costs, while deterring other technologies and procedures by raising their costs.[74]

As discussed in depth above, the strict regulation of the fee schedule does not achieve low-cost healthcare without consequences, which come mostly in the form of diminished quality of care. Because of the fee schedule and its highly regulated costs, most Japanese doctors make less money than their American counterparts.[75] In an effort to subsidize their income, Japanese doctors maximize the number of patients they see each day, which limits the amount of time spent with each patient.[76] The result is "assembly line medicine."[77]

Additionally, while strict adherence to the fee schedule keeps costs at a low, standard level for the consumer, it simultaneously dissuades doctors from specializing.[78] In other words, because doctors are being paid a set amount for each procedure, regardless of their level of expertise in that procedure, there is no incentive to gain extra training in a particular field of medicine.[79]

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72. Hashimoto, *supra* note 40, at 1175; Karen Davis, *Slowing the Growth of Health Care Costs – Learning from International Experience*, 359 NEW ENG. J. MED. 1751, 1753 (2008).
73. Hashimoto, *supra* note 40, at 1175.
74. Davis, *supra* note 72, at 1753.
75. Harden, *supra* note 10.
76. Ramseyer, *supra* note 71, at 5.
77. Michael Tanner, *The Grass is Not Always Greener: A Look at National Health Care Systems Around the World*¸ POLICY ANALYSIS NO. 613 (CATO Inst.) 17 (2008).
78. Ramseyer, *supra* note 71, at 6.
79. *Id.*

Similarly, the heavy regulation of the health insurance firms enhances the equality of care, but limits incentives to increase quality and efficiency or to develop innovative techniques and procedures.[80] It achieves this goal by completely banning insurance companies from turning a profit, which arguably would never be permissible in the United States.[81]

The fee schedule may not be the sole reason for the diminished quality of care in Japan, however, which comes as good news to those responsible for restructuring the American healthcare system.[82] The seemingly poor quality of care in Japan is likely rooted more in the physician and hospital culture in Japan, than in the fee schedule component of Japanese healthcare.[83] To that end, studies show that levels such as the postsurgical mortality rate are consistently on the low end as compared to other developed countries.[84] Additionally, as noted at the outset of this article, the overall health outcomes of Japanese people are excellent according to the global indices of health.[85]

The fact that the quality issues that Japan faces as a result of their fee schedule seem to be more systematic and cultural than resultant of the government's tight grip on medical costs is encouraging for the United States. It would logically follow that a country such as the United States, which already has a culture of high-quality medical care, would be less vulnerable to many of the quality concerns that Japan faces. Thus, experimentation with greater government regulation of healthcare in America could prove to be the answer to the crisis of rising healthcare costs.

Finally, based on the lessons that can be learned from Japan's struggle to maintain a high-quality, low-cost universal healthcare system, it may be

80. Jones, *supra* note 7, at 9.
81. Harden, *supra* note 10.
82. Hashimoto, *supra* note 40, at 1174, 1177.
83. *Id.*
84. *Id.* at 1178.
85. *Id.* at 1180.

wise for the United States to place a priority on delivering care to everyone before it perfects the quality and efficiency aspects of its healthcare delivery system.[86]

V. CONCLUSION

Japan serves as a great model for the United States because it has a system of universal healthcare that has been in place for over a half-century. The factors that frustrate healthcare spending and quality in the United States are many of the same factors that frustrate Japan's healthcare spending and quality. In the end, it is very difficult to balance the need for equality with the need for quality, and one is sure to suffer at the behest of another.[87]

However, we can learn a lot from Japan's artful balance of low-cost healthcare and effective healthcare outcomes. Specifically, Japan's use of strict government control over healthcare costs has provided a useful example of a system that has curbed spending without affecting the bottom line of health care quality. While the day-to-day aspects of quality to which we have become accustomed in America are not always present in Japan, the Japanese people enjoy longer lives and lower infant mortality rates than most of the developed world.[88] Combining some of the high quality of care aspects that the United States already has in place with aspects of the Japanese fee schedule could prove to be the answer the United States has been looking for all along.

86. Hashimoto, *supra* note 40, at 1180-81.

87. Jones, *supra* note 7, at 7 ("According to the landmark study by Campbell and Ikegami (1998), 'The underlying principle of the Japanese healthcare system is equality, among patients and providers, and equality and quality tend to conflict.'").

88. OECD Health Data, *supra* note 1, at 1.

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Addressing the Unacceptable State of Health Care in the U.S.: Lessons to be Learned from Spain's Focus on Primary Care

Sean R. Walter ∗

I. INTRODUCTION

It is well known that the health care system in the United States, the most expensive in the world, performs poorly in comparison to other developed countries.[1] Among the thirty-four member countries of the Organization for Economic Cooperation and Development (OECD), the U.S. has the highest prevalence of adult obesity and the second highest prevalence of diabetes.[2] In terms of medical care needs which are unmet due to financial reasons, the U.S. ranked worst among a representative sample of eleven OECD countries,[3] and also ranked worst among fifteen of these countries in "horizontal inequity for probability of a doctor visit," a measure of inequality in health care use (the U.S. system favoring high income groups).[4] According to a 2006 report from the Agency for Healthcare Research and Quality, "disparities related to race, ethnicity, and socioeconomic status still pervade the American health care system."[5] A calculation of efficiency based on health care spending versus life

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1. Glen Cheng, *The National Residency Exchange: A Proposal to Restore Primary Care in an Age of Microspecialization*, 38 AM. J. L. & MED. 158, 160 (2012).

2. OECD, *Health at a Glance 2011: OECD Indicators*, OECD PUBLISHING 1, 43, 55 (2011), *available at* http://dx.doi.org/10.1787/health_glance-2011-en.

3. *Id.* at 131.

4. *Id.* at 139.

5. Ellen Nolte & C. Martin Mckee, *Measuring the Health of Nations: Updating An Earlier Analysis*, 27 HEALTH AFF. 1, 58 (2008).

expectancy found that the U.S. ranked worst among thirty countries.[6]

The U.S. could learn a great deal from studying the health care systems of best-performing countries. Countries such as Spain, Italy, France, and Australia have many lessons to teach regarding efficiency, effectiveness, and prioritization in health care delivery.[7] Above all, the U.S. can learn from other countries about the importance of equitable access and a strong primary care system in promoting healthy lives.[8] Spain, one of the leading health systems in the world, is especially instructive because of its remarkable success in establishing a robust and equitable primary care system over the past thirty years.[9] Spain possesses several successful features applicable to the U.S., which could help the U.S. re-focus and revitalize its struggling health care system.

First, this article will discuss the role of primary care in determining a country's health status. Second, it will explore select features of the Spanish health care system, focusing on Spain's sustained political commitment to universal coverage and primary care, the evolution to a decentralized system, the accessibility of its primary care network, its use of primary care teams, and an overview of the Spanish system's challenges and achievements. Finally, this article will suggest what the U.S. can learn from Spain and how these lessons might be implemented.

II. THE ROLE OF PRIMARY CARE IN DETERMINING A COUNTRY'S HEALTH STATUS

The U.S. Institute of Medicine defines primary care as "'the provision of integrated, accessible health care services by clinicians who are accountable

6. Sandra Garcia-Armesto et al., *Spain: Health System Review*, 12 HEALTH SYSTEMS IN TRANSITION 1, 254 (2010).

7. *See generally* OECD, *supra* note 2.

8. *Id.*

9. *See* Jeffrey Borkan et al., *Renewing Primary Care: Lessons Learned From the Spanish Health Care System*, 29 HEALTH AFF. 1432, 1432-41 (2010).

for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.'"[10] The main features of primary care include accessibility (especially to vulnerable populations), continuity, comprehensiveness, and coordination, as well as an emphasis on screening, prevention, health education, and the care of patients with chronic illness.[11]

The effectiveness of primary care has been extensively documented. The World Health Organization (WHO) has shown that countries organized around primary care experience better health outcomes.[12] Many mechanisms account for the benefit of primary care, including greater access to needed services, its emphasis on prevention and education, the provision of care early in the course of a disease, and its role in preventing fragmented specialty-based care.[13] The outcomes associated with a strong primary care infrastructure are now undeniable: (1) the number of primary care physicians per population is consistently related to better health outcomes;[14] (2) the stronger the primary care orientation of a country, the lower its all-cause mortality;[15] (3) the higher the primary care physician to specialist ratio, the greater the cost savings;[16] and (4) countries that have built their health care systems on primary care in general enjoy better health outcomes, more equitable access to care, lower health disparities, and lower costs.[17] Spain is an excellent example of what on emphasis on primary care can achieve.

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10. Cheng, *supra* note 1, at 162.
11. Kristine Marietti Byrnes, *Is There a Primary Care Doctor in the House? The Legislation Needed to Address a National Shortage*, 25 RUTGERS L. J. 799, 801-02 (1994).
12. Cheng, *supra* note 1, at 166.
13. Barbara Starfield, Leiyu Shi & James Macinko, *Contribution of Primary Care to Health Systems and Health*, 83 THE MILBANK QUARTERLY 457, 474 (2005).
14. Barbara Starfield & Leiyu Shi, *The Medical Home, Access to Care, and Insurance: A Review of Evidence*, 113 PEDIATRICS 1493 (May 2004).
15. *Id.* at 1494.
16. Cheng, *supra* note 1, at 163.
17. *See* Starfield et al., *supra* note 13, at 466-75.

III. FEATURES OF THE SPANISH HEALTH CARE SYSTEM

A. Sustained Political Commitment to Universal Access and Primary Care

Since 1975, Spain has demonstrated a sustained commitment to primary care.[18] As a result, health disparities have decreased, patient-centered care has become increasingly available and affordable for its citizens, and health outcomes have improved.[19] A brief review of the evolution of this process is instructive.

The end of Francisco Franco's dictatorship led to a new Spanish Constitution in 1978 and the adoption of a democratic style of government.[20] The new Constitution created a universal and free national health system, which guaranteed equal access to preventive, curative, and rehabilitative services for all Spanish citizens.[21] This marked the beginning of Spain's progression to one of the strongest primary care systems in the world.[22] Coincidentally, 1978 was also the year of the Alma-Ata Declaration of the WHO identifying primary health care as the key to achieving the goal of "health care for all."[23]

After the Constitution, the General Health Law of 1986 was the first major health legislation reform enacted.[24] This new law extended coverage to the remaining uninsured population, provided the basis for the transfer of health care management from the central government in Madrid to Spain's seventeen regions ("autonomous communities"), and led to the

18. Borkan et al., *supra* note 9, at 1438.
19. *See id.* at 1433-35.
20. *Id.* at 1432.
21. R.J. Blendon et al., *Spain's Citizens Assess Their Health Care System*, 10 HEALTH AFF. 216, 217 (1991).
22. *See* Borkan et al., *supra* note 9, at 1433-34.
23. Francisco J. Mirando et al., *Assessing Primary Healthcare Services Quality in Spain: Managers vs. Patients Perceptions*, 30 THE SERVICE INDUSTRIAL J. 2137, 2137 (2010).
24. Guillem Lopez-Casasnovas, Health Care and Fiscal Decentralization in Spain 1, http://www.upf.edu/pdi/cres/lopez_casasnovas/_pdf/health_care.pdf.

establishment of a national program of primary health centers.[25] The 1986 law affirmed Spain's commitment to universal access and a decentralized national health service.[26]

Throughout the late 1980s and 1990s, Spain further strengthened its primary care system by adopting a tax-based financing system, improving the geographic allocation of funds, and increasing the supply of family physicians.[27] The decentralization process was completed in 2002.[28]

The Act on Cohesion and Quality in the National Health System, passed in 2003, was an additional major legislative action in support of the health care system.[29] This law further articulated the goals of improving the quality and coordination of health care, ensuring geographic equality, and defining a common benefits basket.[30]

This unwavering political commitment to health care for all and to the central role of primary care has been effective. Before the start of health care reform in the late 1970s, Spain's primary care structure consisted of a sparse network of doctors' offices and few primary care centers.[31] By 2008, there were almost 3,000 primary care centers, as well as over 10,000 basic medical centers in small rural towns.[32] The initial vision of free access to medical care for everyone has been achieved, with health coverage now provided to over 99.5% of Spain's citizens,[33] while

25. Blendon et al., *supra* note 21, at 218.
26. Lopez-Casasnovas, *supra* note 24, at 1.
27. Marisol Rodriquez et al., *An Update on Spain's Health Care System: Is It Time for Managed Competition*?, 51 HEALTH POL'Y AND PLAN. 109, 111 (2000); Garcia-Armesto et al., *supra* note 6, at xxvii; Borkan et al., *supra* note 9, at 1433-35.
28. Lopez-Casasnovas, *supra* note 24, at 1.
29. Rosa Rodriguez-Monguio & Fernando Antonanzas Villar, *Healthcare Rationing in Spain: Framework, Descriptive Analysis and Consequences*, 24 PHARMACOECONOMICS 537, 540 (2006).
30. Lopez-Casasnovas, *supra* note 24, at 2; Garcia-Armesto et al., *supra* note 6, at xxvii.
31. Borkan et al., *supra* note 9, at 1434.
32. *Id.* at 1435.
33. International Health Systems, KAISER EDU, *available at* http://www.kaiseredu.org/

maintaining health expenditures at less than 10% of the Gross Domestic Product (compared to 17% in the U.S.).[34]

B. Decentralization

From the onset of the health care reform process, Spain was committed to a decentralized system, a goal that was fully achieved by 2002.[35] Spain is now one of the most decentralized health care systems in Europe,[36] a structure aimed at improving responsiveness to local needs and managerial efficiency.[37] Spain's seventeen "autonomous communities" now have primary jurisdiction for planning and coordinating their own regional health care system, from the provision of primary care in small rural medical centers to broader public health initiatives.[38] The central government retains an oversight function, establishing basic principles, ensuring coordination of services, and managing the National Institute of Health.[39]

This decentralized system is not without its shortcomings, but has advantages over a central monolithic bureaucratic structure.[40] It allows for local voices, including those of patients, health care providers, and community leaders, to be heard; ensures that the system is responsive to local needs;[41] and fosters needed capacity building at a local level.[42] A Catalán health economist advises other health care systems in evolution to "not be afraid of diversity," but to embrace decentralization as a way to

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Issue-Modules/International-Health-Systems/Spain.aspx.

34. OECD, *supra* note 2, at 151.
35. Garcia-Armesto et al., *supra* note 6, at 37.
36. Kevin Brekke, *Three Off-Balance Sheets to the Wind*, FIN. SENSE (May 24, 2011), *available at* http://www.financialsense.com/contributors/kevin-brekke/three-off-balance-sheets-to-the-wind.
37. Lopez-Casasnovas, *supra* note 24, at 4-5.
38. Borkan et al., *supra* note 9, at 1433.
39. *Id*.
40. Lopez-Casasnovas, *supra* note 24, at 8.
41. Borkan et al., *supra* note 9, at 1437.
42. Garcia-Armesto et al., *supra* note 6, at 44.

foster "differentiation and experimentation."[43]

C. Convenient and Accessible Primary Care Centers

The process of decentralization went hand-in-hand with the development of a geographic organizational structure to ensure convenient and accessible health centers for the entire population. Health care reform envisioned each autonomous community being organized into "Health Areas" and "Basic Health Zones."[44] The "Basic Health Zone" is the smallest unit of health care organization, made up of 5,000 to 25,000 people, with services generally provided by a single primary care team.[45] By 2008, the goal of having a primary care center within fifteen minutes of every Spanish citizen had nearly been met.[46]

As noted above, there are now over 13,000 primary care and basic medical centers in Spain, each serving approximately 3,500 patients on average.[47] Given the convenience of these centers, there is a high rate of utilization. Visits to a family physician average approximately six per year per inhabitant,[48] while the overall outpatient contacts per year is among the highest in the WHO European Region.[49]

D. Primary Care Teams

A final key feature of Spain's health care system is the use of primary care teams based in the health centers and serving the citizens of the Basic Health Zones.[50] The teams are multidisciplinary and comprised of general practitioners, pediatricians, nurses, social workers, and administrative

43. Lopez-Casasnovas, *supra* note 24, at 16.
44. Borkan et al., *supra* note 9, at 1433.
45. *Id.*
46. *Id.* at 1435.
47. Garcia-Armesto et al., *supra* note 6, at xxvi.
48. *Id.* at 193.
49. *Id.* at 195.
50. Borkan et al., *supra* note 9, at 1434-35.

staff.[51] Their focus is to provide a wide range of services, emphasizing health promotion, education, prevention, and the care of acute and chronic illnesses.[52] These primary care teams now serve nearly all of the population and handle more than seventy percent of all health care visits in the country.[53] A recent article from the United Kingdom showed that Spain ranked very highly compared to other developed countries in the domain of interpersonal qualities in the health care relationship (e.g. dignity, communication), a likely reflection of the work of these primary care teams.[54]

E. The Spanish Health Care System's Problems and Achievements

None of the above is meant to glorify Spain's health care system or minimize its problems. There is no doubt that Spain's system faces a vast number of challenges and difficulties. There remains an unbalanced distribution of resources across the country's diverse regions, as well as a range of managerial competence at the regional level.[55] Although the regional approach provides variety and creativity, there is also the danger that regions will lose "the wider perspective necessary in a national health system."[56] There are concerns about some vital services being less available, e.g. mental health services, dental specialties, long-term care of the elderly, and community outreach. Additionally, it is unclear whether there will be a sufficient number of primary care physicians in the future, and concerns have been raised about the relatively low status and pay of

51. *Id.*
52. *Id.* at 1435.
53. *Id*.
54. Andrew M. Jones et al., *Inequality and Polarization in Health Systems' Responsiveness: A Cross-Country Analysis*, 30 J. OF HEALTH ECON. 616, 624 (2011).
55. Eunice Rodriguez et al., *The Spanish Health Care System: Lessons From Newly Industrialized Countries* 14 HEALTH POL'Y AND PLAN. 164, 166 (1999).
56. Garcia-Armesto et al., *supra* note 6, at 44.

these physicians.[57] There is still some residual inequity within the system, e.g. richer people have more visits with specialists.[58] There are also continuing problems with wait times to see a primary care physician or specialist, problems which account for one-third of all complaints of health system users.[59] Financial sustainability is likewise problematic.[60] Spain has a twenty percent rate of poverty,[61] rising costs, increasing competition for financial resources, and an aging population.[62] A recent editorial even raised the issue of abuse among Spain's regions in breaching their imposed budget targets and under-reporting their debt.[63]

Notwithstanding all of the above serious concerns, the Spanish National Health Service remains a remarkable success story. Comparing their health statistics and outcomes to those of the U.S. is a worthwhile exercise. Among thirty-four OECD countries, Spain ranks fourth in life expectancy and fourth in "potential years of life lost," while the U.S. ranks twenty-seventh and thirtieth, respectively, in those measures.[64] When last analyzed, the U.S. was also the worst performer among nineteen OECD countries regarding "amenable mortality" (i.e. deaths that could be avoided by timely and effective health care), while Spain ranked fourth.[65]

Among thirty-four OECD countries, Spain ranked eighth in doctor

57. Borkan et al., *supra* note 9, at 1438.
58. Lourdes Lostao et al., *Socioeconomic Patterns in Health Services Use in Great Britain and Spain Before and After the Health System Reforms of the 1990's*, 17 HEALTH & PLACE 830, 834 (2011).
59. Rodriguez-Monguio & Villar, *supra* note 29, at 543-44; Garcia-Armesto et al., *supra* note 6, at 70-71 (stating that the average waiting time for surgery was sixty-three days in 2009, with five percent of patients waiting more than six months, and that only twenty percent of patients think waiting times are improving).
60. Borkan et al., *supra* note 9, at 1438.
61. Garcia-Armesto et al., *supra* note 6, at 5.
62. Borkan et al., *supra* note 9, at 1438.
63. Brekke, *supra* note 36.
64. OECD, *supra* note 2, at 25, 27.
65. Nolte & Mckee, *supra* note 5, at 59-62.

consultations per capita, while the U.S. ranked thirtieth.[66] In ischemic heart disease mortality, which at least in part reflects a country's attention to primordial and primary prevention, Spain ranked sixth, and the U.S., in spite of its impressive technology, ranked twenty-fifth.[67]

IV. APPLYING LESSONS FROM SPAIN'S HEALTH CARE SYSTEM TO THE U.S.

A. Recognizing the Importance of Primary Care

The U.S. health care system has great strengths. U.S. technological advancements in medical and surgical care are unsurpassed, leading wealthy people from around the world to come to this country for highly specialized care. U.S. medical schools are among the finest in the world, and U.S. contributions to medical science are probably second to none. The U.S. performs well in the use of clinical guidelines and in some aspects of preventive care,[68] and outperforms Spain in terms of all-cancer mortality and screening for cervical and breast cancer.[69] But, given the wealth of the U.S., its shortcomings in health care seem as remarkable as its achievements.

The U.S. is the only major industrialized country in the world without universal health coverage.[70] As a result, the U.S. system is noted for its "unethical disparities in health and health care,"[71] and ranks "dead last" on almost all measures of equitable care.[72] The lack of care provided to uninsured patients is seen as a major reason for the U.S.'s poor global

66. OECD, *supra* note 2, at 81.
67. *Id.* at 29.
68. Editorial, *World's Best Medical Care?*, N.Y. TIMES, Aug. 12, 2007, *available at* http://www.nytimes.com/2007/08/12/opinion/12sun1.html?pagewanted=all.
69. OECD, *supra* note 2, at 119, 121.
70. *World's Best Medical Care?*, *supra* note 68.
71. Robert L. Phillips, *Primary Care in the United States: Problems and Possibilities*, 331 BMJ 1400, 1400 (Dec. 2005).
72. *World's Best Medical Care?*, *supra* note 68.

standing.[73] In comparison to five other developed countries, the U.S. ranks last on an aggregate score of quality, access, efficiency, and equity, performing especially poorly on its ability to promote healthy lives and on the provision of care that is safe and coordinated.[74] One author chides the U.S. for operating a health care system that is a "marketplace darling," consuming [seventeen] percent of the overall economy, but failing to decide the purpose of its health care system beyond some market imperative to expand lucrative services.[75] According to this author, "[f]or all the U.S. fiscal largesse, there is a relative underinvestment in primary care" – a platform focused on "improving population health, not wealth."[76]

The U.S. has been rated the lowest among groups of industrialized countries in terms of its primary care orientation.[77] The U.S. possesses roughly twice the MRI and CT scanners as Spain,[78] but trails Spain and many other countries in health outcomes and equitable care because it has refused to make primary care a cornerstone of its health care system.[79] With regards to general practitioners as a percentage of the total number of physicians, the U.S. ranks twenty-eight out of thirty-one OECD countries, affecting its ability to provide health education, health promotion, and ongoing care to the forty-five percent of Americans with chronic illness.[80]

In spite of the considerable strengths of the U.S., its current situation is untenable: the country's health care is driven by financial incentives and

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73. *Id.*

74. Karen Davis et al., *Mirror, Mirror on the Wall: An International Update on the Comparative Performance of American Health Care*, 59 THE COMMONWEALTH FUND (May 15, 2007), *available at* http://www.commonwealthfund.org/Publications/Fund-Reports/2007/May/Mirror—Mirror-on-the-Wall—An-International-Update-on-the-Comparative-Performance-of-American-Healt.aspx.

75. Phillips, *supra* note 71, at 1400.

76. *Id.*

77. Starfield & Shi, *supra* note 14, at 1494.

78. OECD, *supra* note 2, at 83.

79. Starfield et al., *supra* note 13, at 457.

80. OECD, *supra* note 2, at 63.

technological imperatives, while failing to address profound cost inefficiencies, disparities of care, and poor health outcomes. Learning from Spain's experience could help address these problems.

B. Four Lessons from Spain

First, Spain's steady evolution for more than three decades to a system of universal coverage and accessible primary care demonstrates that a sustained and effective political process in support of high quality health care for all citizens is possible. A study of eleven industrialized countries found that the adequate delivery of primary care services was associated with supportive government policies, proving that a cohesive, enabling political process is possible.[81] Spain serves as a model of what is required to start along this path: a country needs to look honestly at its health care system and health outcomes, decide that it wants to be one of the best health care systems in the world, and develop a shared vision of what it will take to get there. Unfortunately, that has not yet occurred in the U.S.

Second, Spain, a quasi-federalist state, also pursued a shared vision of how responsibility for the health care system would be divided between the central government and its "autonomous communities," choosing a highly decentralized system that took over twenty years to realize. It is too soon to tell whether this model will prove to be optimally effective or whether a different balance between Madrid and the regions will need to be found; however, what is again noteworthy is the consensus approach that sustained the process since the new Spanish Constitution's inception. In the U.S., there is a similar need to determine the correct balance of responsibility and control between the federal and state governments for better health outcomes. It has been noted that the "commitment to remedying health care

81. Starfield et al., *supra* note 13, at 466-67.

imbalances has been much more pronounced on the state level."[82] On the other hand, health determinants and health outcomes vary significantly by state, with some states far more successful than others. A yearly report by the United Health Foundation calculates detailed health rankings for each of the fifty states and reveals striking differences in performance and outcome between states.[83] Looking carefully at the features of the best performing states would be enlightening.

Third, Spain's plan, now almost fully achieved, was to have primary care services located within fifteen to thirty minutes of every citizen, including those living in remote rural areas and, consequently, their outpatient visits per capita are now among the highest in the world. Community health centers in the U.S. are analogous to the primary care and basic medical centers of Spain because both are focused on providing preventive services to vulnerable populations as well as managing acute and chronic illness.[84] However, U.S. community health centers currently are poorly resourced and have not been strategically placed to ensure accessibility for the entire population. In fact, sixty-five million Americans, about one in five, live in areas without adequate primary care.[85] A "master plan" for convenient and accessible medical care, modified at the state level, should be developed so

82. Byrnes, *supra* note 11, at 819-829 (outlining interventions by state legislatures which have included putting pressure on medical schools to produce more primary care physicians, requiring the creation of primary care centers, offering financial incentives to medical students to work in underserved areas, and establishing state-run Health Service Corps to improve services to needy populations).

83. United Health Foundation, *America's Health Rankings: A Call to Action for Individuals and Their Communities*, 49-99, *available at* http://www.americashealthrankings .org. Comparing the average of the five best performing states with the average of the five worst performing ones shows marked differences: percent obese (twenty-four vs. thirty-two), percent lacking health insurance (nine vs. eighteen), number of primary care physicians per 100,000 population (one hundred and sixty-one vs. ninety-six), preventable hospitalizations per 1,000 Medicare enrollees (fifty-five vs. eighty-seven), and number of years of potential life lost prior to age seventy-five per 100,000 population (5,740 vs. 10,351), respectively.

84. Vivek S. Kantayya & Steven J. Lidvall, *Community Health Centers: Disparities in Health Care in the United States 2010*, 56 DIS. MON. 681, 686 (2010).

85. Susan Dentzer, *Reinventing Primary Care: A Task That is Far "Too Important to Fail"*, 29 HEALTH AFF. 757, 757 (2010).

that all U.S. citizens, like Spanish citizens, are within a reasonable distance from a health center.

Finally, the backbone of the Spanish system has become the multidisciplinary primary care team, which is now involved in the majority of health care visits in the country.[86] This model aligned with the WHO's 2008 report "Primary Care Now More Than Ever" which emphasized the importance of adequately resourced team-based care,[87] and is also in accord with the model of "patient-centered medical care homes" characterized by "relationships between patients and teams of providers that endure over time."[88] In the U.S., however, the proportion of physicians involved in direct primary care is in decline.[89] In fact, only about one in fourteen medical students plan to pursue a career in primary care,[90] and many state laws forbid nurse practitioners and other mid-level primary care providers from "practicing to the extent their training warrants."[91] The failure to support primary care and patient-centered medical homes continues to be cited as a key reason that the U.S. is falling farther behind in so many measures of health outcomes.[92]

V. CONCLUSION

This article has explored the fundamental role of primary health care in determining a country's health status and has discussed select features of the Spanish health care system which may be of special interest, including their sustained political commitment to universal coverage and primary care, their decentralized approach, the promise they fulfilled regarding

86. Borkan et al., *supra* note 9, at 1434-35.
87. Robert L. Phillips, Jr. & Andrew W. Bazemore, *Primary Care and Why It Matters For U.S. Health System Reform*, 29 HEALTH AFF. 806, 807 (2010).
88. *Id.* at 808.
89. *Id.*
90. Dentzer, *supra* note 85, at 757.
91. *Id.*
92. Phillips, Jr. & Bazemore, *supra* note 87, at 807.

accessible and convenient health care for all citizens, and their use of multidisciplinary primary care teams. Spain serves as a particularly instructive country for the U.S. because they reengineered their entire health care system around primary care,[93] and, in so doing, have become one of the world's best performing systems, with far better outcomes and at far less cost than the U.S.

In contrast to Spain, health policy experts have described the U.S. as a specialist-dominated health care system that produces "care of mediocre quality, with excessive costly services that have little marginal benefit."[94] The editor-in-chief of *Health Affairs* notes that the U.S.'s system of primary care is "horribly broken – the victim of underinvestment, misaligned incentives, and malign neglect."[95] The challenges of redesigning the health care system in the U.S. are enormous, but what is most enlightening about Spain's long journey is the way they implemented their system: they developed a shared vision, focused on the common good, and agreed upon their goals (equal access, an emphasis on primary care and prevention, and improved health outcomes). This vision has been sustained since 1978, in the face of several exchanges between socialist and conservative governments. This stands in sharp contrast to the rancorous, partisan debate and lack of consensus that unfortunately characterized the U.S.'s recent discussion of a pathway to affordable health care. U.S. primary health care can be invigorated and can pursue new and innovative approaches such as patient-centered medical homes embedded in integrated networks,[96] but, as Spain has taught the U.S., it has to begin and continue with a shared vision.

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93. *Id.*

94. Bruce E. Landon et al., *Prospects for Rebuilding Primary Care Using the Patient-Centered Medical Home*, 29 HEALTH AFF. 827, 827 (2010).

95. Dentzer, *supra* note 85, at 757.

96. Phillips Jr. & Bazemore, *supra* note 87, at 809.

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Health Information Technology and Primary Care: Health Care Lessons from Denmark

*Alissa Bugh**

According to most Danes, there is nothing rotten with the state of Denmark's healthcare system.[1] Denmark consistently has a notably high rating of patient satisfaction.[2] A 2009 survey showed that ninety percent of hospitalized patients rated their experience as good or very good and eighty-nine percent of patients were somewhat or very satisfied with their general practitioner (GP).[3] This is not the result of higher health spending. The percentage of gross domestic product (GDP) spent on health care in Denmark was 7.3%, while in the United States that number is currently about 15.3%.[4] With a high rate of satisfaction and lower health care spending, the U.S. could benefit from a review of certain cost-effective elements of the Danish health care system.

I. INTRODUCTION

Health reform in the U.S., through the recent Patient Protection and Accountable Care Act (PPACA) aims to overhaul a health system with glaring structural defects. Although it is difficult to compare a country of

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1. Kjeld Moller Pedersen, *The Danish Health Care System: Evolution – Not Revolution – in a Decentralized System* 14 HEALTH ECON. 541, 541 (2005).

2. *Id.*

3. Kjeld Moller Pedersen et al., *The Danish Health Care System: An Analysis of Strengths, Weaknesses, Opportunities and Threats (SWOT analysis)* 8 (Institute of Public Health – Health Economics University of Southern Denmark, Health Economic Papers 2, 2011).

4. ELIZABETH G. ARMSTRONG ET AL., THE HEALTH CARE DILEMMA: A COMPARISON OF HEALTH SYSTEMS IN THREE EUROPEAN COUNTRIES AND THE US 15 (2011).

5.4 million people with a country of over 300 million current or future patients,[5] there are certain significant lessons that the U.S. can take from Denmark regarding specific elements of the proposed reform. First, Denmark is known as a leading nation in its effective use of health information technology (HIT).[6] Second, Denmark has structured its health system around general practitioners who act as "gatekeepers,"[7] a system the United States is looking to implement via patient-centered medical homes (PCMHs) provided for in the PPACA.[8] Both of these elements contain the possibility of savings and higher patient satisfaction.

II. THE STRUCTURE OF THE DANISH HEALTH CARE SYSTEM

The Danish health care system is fundamentally different from the U.S. system. According to the Chief Financial Officer of the Copenhagen Hospital, the essential premise of the Danish health care system "is to provide free access to most health services for all people regardless of their economic situation."[9] Thus, health coverage in Denmark is universal and free at the point of access.[10] The system is publicly funded through taxes, primarily with a centrally collected income tax of eight percent.[11] The priorities of the health care sector stem naturally from Denmark's overall political structure, which is a welfare-based system.[12]

Danish health care is characterized by its decentralized structure. While

5. *Id.*

6. Denis Protti & Ib Johansen, *Widespread Adoption of Information Technology in Primary Care Physician Offices in Denmark: A Case Study*, 80 THE COMMONWEALTH FUND 1 (March 2010).

7. Pedersen, *Evolution – Not Revolution*, *supra* note 1, at 542.

8. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3502, 124 Stat. 119, 124 (2010). (Section 3502 provides for community health teams to support PCMHs).

9. ARMSTRONG, *supra* note 3, at 3.

10. Karsten Vrangbaek, *The Danish Health Care System*, *in* INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS 32, 32 (2011).

11. *Id.*

12. Karsten Vrangbaek & Terkel Christiansen, *Health Policy in Denmark: Leaving the Decentralized Welfare Path?* 30 J. HEALTH POL., POL'Y & L. 29, 33 (2005).

the state is generally in charge of legislation, supervision, monitoring, and the overall framework, the primary responsibility for delivery of care rests with the regions and municipalities.[13] Delivering care at the lowest administrative level ensures that services are "provided as close to the users as possible."[14] On January 1, 2007, legislation came into effect that reduced the number of counties from fifteen to five, and the number of municipalities from 271 to 98.[15] The central government meets with the regions and municipalities in annual negotiations where they collectively decide levels of taxation and expenditure.[16]

Within each municipality there are self-employed GPs who are paid a combination of capitation, based on the number of patients they serve, and fee-for-service.[17] Danes must register with a GP within fifteen kilometers of their home and GPs average about 1,400 to 1,500 patients.[18] Patients must receive referrals to specialists through their GP, thereby creating a "gatekeeper" function and ensuring that patients do not visit specialists unless it is necessary.[19] Visits with GPs are entirely free, though copayments do exist for some services such as pharmaceuticals, dentistry, and physiotherapy.[20] Private insurance is available (and is utilized by about thirty percent of the population) to cover such services as dental care and physiotherapy, as well as coverage for prescription drug cost sharing.[21] All citizens have been guaranteed choice of hospital since the 1990s, and wait

13. MINISTRY FOR HEALTH PREVENTION, HEALTH CARE IN DENMARK 9 (2008).
14. *Id.* at 7.
15. *Id.* at 8.
16. Vrangbaek, *Danish Health Care System*, *supra* note 10.
17. Protti & Johansen, *supra* note 6, at 3.
18. Background Briefing: Health Care Lessons from Denmark, CIVITAS (2002).
19. Dorte Sindbjerg Martinsen & Karsten Vrangbaek, *The Europeanization of Health Care Governance: Implementing the Market Imperatives of Europe*, 86 PUB. ADMIN. 169, 174 (2008).
20. *Id.*
21. Sarah Thomson & Elias Mossialos, *Primary and Prescription Drugs: Coverage, Cost-Sharing, and Financial Protection in Six European Countries*, 82 COMMONWEALTH FUND 3 (March 2010).

times are capped at one month.[22] If a patient has been recommended for a treatment or an operation, they must receive it within thirty days at any public hospital in Denmark or any private hospital that has an agreement with their region.[23] By legislating this right, Denmark has provided a tool to empower patients and combat one of the stigmas of nationalized healthcare.[24] However, this solution is still subject to complaint because the provision does not apply to waiting times for elective surgeries, which can be a source of patient dissatisfaction.[25] Overall, the general structure of the national coverage plan has been in place since the 1970's, and any slight reforms have maintained the goals of equal access and limited public expenditure.[26]

III. WHAT THE UNITED STATES CAN LEARN FROM DENMARK'S USE OF HEALTH INFORMATION TECHNOLOGY

In Denmark, all GPs use electronic medical records (EMRs) and ninety-eight percent are able to electronically manage patient care.[27] Studies have estimated that the Danish information system saves doctors an average of fifty minutes per day in administrative work.[28] Reports have also found that Denmark's use of EMRs saves the health system as much as $120 million a year.[29] Recent legislation has made health information technology (HIT) a

22. Denis Protti et al., *Adoption of Information Technology in Primary Care Physician Offices in New Zealand and Denmark, part 1: Healthcare System Comparisons*, 16 INFORMATICS IN PRIMARY CARE 183, 187 (2008).

23. Ulrika Winblad, Karsten Vrangbaek, & Katarina Ostergren, *Do the Wating-Time Guarantees in the Scandinavian Countries Empower Patients?* 23 INT'L J. PUB. SECTOR MGMT. 353, 354 (2010).

24. *Id.* at 361.

25. Armstrong, *supra* note 4, at 9.

26. Vrangbaek & Christiansen, *supra* note 12, at 36-37.

27. Protti & Johansen, *supra* note 6, at 1.

28. Sindya N. Bhanoo, *Denmark Leads the Way in Digital Care*, N.Y. TIMES, Jan. 11, 2010, *available at* http://www.nytimes.com/2010/01/12/health/12denmark.html.

29. *Id.*

priority in the U.S. as well.[30] With a new emphasis on HIT implementation, the U.S. could benefit from considering how Denmark has successfully utilized this cost-saving measure.

Widespread adoption of HIT came about in Denmark partly because it was mandated but also through peer pressure, technical assistance, and MedCom, a national health system integrator.[31] MedCom was created in the 1990's and has evolved as an independent organization that is part of the Danish national IT strategy.[32] A centralized integrator such as MedCom provides established standards for electronic communication and promotes seamless care across care settings.[33] The Danish dependence on MedCom, an independent company, is a concept that would be palatable to Americans who prioritize maintaining elements of a free market system within the health care sector.[34] Although the Danish government set the overall policy agenda regarding HIT, they ultimately stood aside and let the private sector use their expertise to create and implement a high-functioning system.[35]

The most functional implementation of HIT allows Danish GPs to "electronically manage medication lists, generate problem lists, enter clinical progress notes, access image archives, use external decision-support programs, and send patients automatic reminders for preventive care."[36] Additionally, GPs can use an electronic messaging system to communicate with specialists, hospitals, laboratories, and pharmacies.[37] Over ninety percent of all clinical communication between various areas of the health

30. David Blumenthal & Marilyn Tavenner, *The "Meaningful Use" Regulation for Electronic Health Records*, 363 N. ENG. J. MED. 501, 501 (2010).
31. Protti & Johansen, *supra* note 6, at 3.
32. *Id.* at 4.
33. *Id.*
34. Denis Protti et al, *Adoption of Information Technology in Primary Care Physician Offices in New Zealand and Denmark, Part 5: Final Comparisons*, 17 INFORMATICS IN PRIMARY CARE 17, 19 (2009). *See generally* http://www.medcom.dk.
35. *Id.*
36. Protti & Johansen, *supra* note 6, at 1.
37. *Id.* at 2.

care sector occurs electronically.[38]

In part, the purpose of investing in HIT is to lower costs and improve quality of care,[39] both of which are documented results of the digital system in Denmark. Studies have demonstrated that comprehensive adoption of HIT in the United States could save $142 billion in physician offices and $371 billion in hospitals over the next fifteen years.[40] The current administration has flagged HIT as a priority by expressly providing for its implementation in recent legislative measures.[41]

In 2009, Congress passed the Health Information Technology for Economic and Clinical Health Act (HITECH)[42] as a part of the American Recovery and Reinvestment Act (ARRA).[43] The federal government designed this Act to incentivize clinicians and hospitals to use EMRs by authorizing payments for improvements in care delivery.[44] Toward these incentive payments, Congress has earmarked up to $27 billion over ten years to be paid out through Medicaid and Medicare.[45] HITECH regulations require that providers demonstrate "meaningful use" of HIT by meeting certain benchmarks.[46] The purpose of the benchmarks is to ensure that providers prove they are not merely implementing HIT but actually using it in such a way that improves quality of care.[47] A broad review of studies on healthcare groups that have already implemented some elements

38. *Id.*
39. David Blumenthal, *Launching HITECH*, 362 N. ENG. J. MED. 382, 382 (2010).
40. Gerard F. Anderson et al., *Health Care Spending and Use of Information Technology in OECD Countries*, 25 HEALTH AFFAIRS 819, 821 (2006).
41. Blumenthal & Tavenner, *supra* note 30.
42. *Id.*
43. American Recovery and Reinvestment Act, Pub. L. No. 111-5, §§ 13001-13424, 123 Stat. 115 (2009).
44. Blumenthal & Tavenner, *supra* note 30, at 501.
45. *Id.*
46. Sean O. Hogan & Stephanie M. Kissam, *Measuring Meaningful Use*, 29 HEALTH AFFAIRS 601, 601 (2010).
47. Blumenthal, *supra* note 39.

of HITECH indicate generally positive outcomes.[48]

Although the sheer size of the U.S. means that widespread adoption of HIT will be a more complex undertaking than it was for Denmark, some lessons still carry over. Through HITECH, the U.S. has set an agenda for implementing HIT, and some of the objectives are services that Denmark is currently providing patients.[49] Among other items, meaningful use objectives require providing patients with electronic versions of their medical records, generating prescriptions, and using clinical-decision making.[50] In Denmark, all pharmacies are able to receive electronic prescriptions, and GPs enter the prescriptions for medications themselves.[51] The electronic system provides decision support in the form of alerts on potential drug interactions.[52] Additionally, in 2003, Denmark launched a national e-health portal.[53] This successful system provides patients with access to services such as viewing their medication and health data, making GP appointments, general and disease-specific information, and the opportunity to make a Living Will or indicate their wishes to be an organ donor.[54] Among other HIT items, these services are objectives specifically delineated in HITECH.[55] Denmark's success in implementing these practices, and their commitment to continually improving their system, offer a useful model for the U.S.

48. Melinda Beeuwkes Buntin et al., *The Benefits of Health Information Technology: A Review of The Recent Literature Shows Predominately Positive Results*, 30 HEALTH AFFAIRS 464, 470 (2011).
49. Blumenthal & Tavenner, *supra* note 30, at 503.
50. *Id.*
51. Protti & Johansen, *supra* note 6, at 6.
52. *Id.*
53. MINISTRY OF HEALTH PREVENTION, *supra* note 13, at 37.
54. *Id.* at 37-38.
55. Blumenthal & Tavenner, *supra* note 30, at 502-03.

IV. WHAT THE UNITED STATES CAN LEARN FROM THE CENTRALITY OF PRIMARY CARE IN DENMARK

Health Information Technology is just one aspect of Denmark's overall commitment to patient-centered, coordinated care.[56] While most industrialized countries have experienced an increase in health care spending during recent decades, per capita spending in the United States has outstripped that of other comparable countries.[57] One frequently cited factor is the fragmented nature of the U.S. system, which leads to misuse of resources and poor coordination of specialists.[58] To confront this problem, a central theme in the recent health care reform is patient-centered medical care, refocused around primary care.[59] The goal of this care structure is to increase quality of care and contain costs.[60] Specifically, many hope that patient-centered medical homes (PCMHs) will be a vehicle for reform.[61] The general principle behind PCMHs is that patients will have close, ongoing contact with a physician who will take the lead in referring the patient to specialists as necessary.[62] Estimates indicate that the Medicare system alone could save $194 billion over ten years by moving to a PCMH system.[63] To test this concept, the American Academy of Family Physicians launched the National Demonstration Project (NDP) in 2006.[64]

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56. Martin Strandberg-Larsen & Allan Krasnik, *Does a Public Single Payer System Deliver Integrated Care? A National Survey Study Among Professional Stakeholders in Denmark*, 8 INT'L J. OF INTEGRATED CARE 1, 1 (JULY 2008).

57. David A. Squires, *The U.S. Health System in Perspective: A Comparison of Twelve Industrialized Nations*, 16 COMMONWEALTH FUND 1, 11 (July 2011).

58. *Id.*

59. Amanda Cassidy, *Health Policy Brief: Patient-Centered Medical Homes*, HEALTH AFFAIRS (September 14, 2010).

60. *Id.*

61. *Id.*

62. *Id.*

63. Karen Davis, *Slowing the Growth of Health Care Costs – Learning from International Experience*, 359 N. ENG. J. MED. 1751, 1762 (2008).

64. Paul A. Nutting et al., *Initial Lessons from the First National Demonstration Project on Practice Transformation to a Patient-Centered Medical Home*, 7 ANNALS FAM. MED. 254, 254 (2009).

While the NDP provided many recommendations, the ultimate result was a determination that a transformation to PCMHs is feasible, but will require tremendous effort and additional resources.[65] Although the results were inconclusive as to perceived impact on quality of care, the likely explanation for this is that the benefits of this concept cannot be fully realized without system-wide reform integrating primary care with the larger health care system.[66]

A 2008 European Union survey found Denmark to be leading the way in integrating care.[67] In Denmark, the use of primary care providers as gatekeepers "is the key systemic control on costs."[68] The combination fee-for-service and capitation payment system, coupled with the well-organized patient-list system provides quick access to primary care services and ensures that treatment is delivered at the lowest cost possible.[69] The patient-list system and the defined set of patients assigned to each GP encourage rights and responsibilities for both physicians and patients.[70] GP practices are structured so that they can handle same-day appointments and walk-ins.[71] This concept provides an example for those who advocate the implementation of PCMHs. Mimicking the Danish style medical home would facilitate continuity of care and potential reduction of emergency room care.[72] In this regard, Denmark effectively uses after-hours care.[73] In 1992, Denmark moved to a system whereby after-hours primary care is

65. Benjamin F. Crabtree, *Summary of the National Demonstration Project and Recommendations for the Patient-Centered Medical Home*, 8 ANNALS FAM. MED. 580, 580 (2010).

66. *Id.* at 583.

67. MARGARET MACADAM, FRAMEWORKS OF INTEGRATED CARE FOR THE ELDERLY: A SYSTEMIC REVIEW, CANADIAN POLICY RESEARCH NETWORKS 14-15 (APRIL 2008).

68. Armstrong et al., *supra* note 4, at 18.

69. Pedersen et al., *supra* note 3, at 39.

70. Karen Davis, PhD, et al., *A 2020 Vision of Patient-Centered Primary Care*, 20 J. GEN. INTERNAL MED. 953, 955 (2005).

71. *Id.*

72. *Id.* at 956.

73. Davis, *Slowing the Growth of Health Care Costs*, *supra* note 63, at 1752.

provided by large organizations covering an entire region.[74] Through a triage system, patients are guaranteed access to a GP at any hour to determine whether the patient needs a home visit, a consultation, or advice over the phone.[75] This system has greatly decreased the workload for individual GPs while maintaining patient satisfaction at a relatively stable rate.[76] Because GPs are available at any time, this aspect of Denmark's primary care lends itself to continuity of care and a reduction in the unnecessary use of emergency care, a result that is a primary goal of PCMHs.

V. CONCLUSION

Structurally, the U.S. is significantly different from Denmark. The U.S. does not have the long-standing emphasis on egalitarianism and social welfare found in Denmark that logically leads to a universal health care system. However, recent health reform in the U.S. opens the path to mimicking certain aspects of the Danish health system that are not strictly tied to a nationalized system. Denmark's effective use of primary care physicians as gatekeepers and related use of HIT provide interesting case studies for priorities that are delineated in the PPACA. The U.S. has already taken steps to encourage the use of HIT. Widespread adoption will require considerable time and effort, and in order for physicians to convert to a digital system, they must be convinced of the benefits. Denmark provides an example of an effective HIT system that has resulted in high patient satisfaction and improved efficiency for providers. This digital system is effective at all levels of care, and will be particularly necessary if

74. Richard Grol et al., *After-Hours Care in the United Kingdom, Denmark, and The Netherlands: New Models*, 25 HEALTH AFFAIRS 1733, 1735 (2006).

75. Morten Bondo Christensen & Frede Olsen, *Out of Hours Service in Denmark: Evaluation Five Years After the Reform*, 316 BRITISH MED. J. 1502, 1502 (1998).

76. *Id.* at 1504.

the U.S. embraces the PCMH model. The PCMH model acknowledges the importance of primary care physicians in reducing the fragmentation of the current system. The PPACA and other initiatives emphasize the implementation of PCMHs in order to improve the quality of care for patients. The PCMH care structure is largely dependent upon HIT and primary care physicians in a gatekeeper role. As the U.S. continues to look to demonstration projects to determine the benefits and feasibility of this undertaking, Denmark provides an effective example. Investment in these efforts to improve health care could prove beneficial despite the risks.

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Advantages and Limitations of EHRs: A Global Perspective

Andrew Holmstrom ∗

I. INTRODUCTION

Electronic health records (EHRs), also known as electronic medical records (EMRs), are computerized medical documents.[1] Perhaps more appropriately, they are also referred to as a "repository of electronically maintained information about an individual's lifetime health status and health care."[2] Advocates of EHRs believe that the coordination of care can be improved through their use.[3] There is, however, debate as to whether the current use of EHRs improves health care and better facilitates coordination.[4] By taking a comparative view of EHRs in a global context, better arguments can be made as to their effectiveness.

Despite the fact that American patients have better access to medical care than many other countries, physicians in the United States lag on EHR use.[5] Particularly telling is that "[a]mong all major segments of the U.S. economy, health care has lagged in realizing benefits from information technology," and unlike other industries, such as manufacturing, finance,

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1. Menachem M. Meller,, *EMRs: Confronting the Challenge*, AAOSNOW, Feb. 2011, at 38 [hereinafter Meller].

2. Sharona Hoffman, *Employing E-Health: The Impact of Electronic Health Records on the Workplace*, KAN. J. L. & PUB. POL'Y, 409, 412 (2010).

3. Ann S. O'Malley et al., *Are Electronic Medical Records Helpful for Care Coordination? Experiences of Physician Practices.* 25 J. GEN. INTERNAL MED. 177, 177 (2009).

4. *Id.*

5. Doug Trapp, *U.S. physicians lag on EMR use*, AMERICAN MEDICAL ASSOCIATION (2009), http://www.ama-assn.org/amednews/2009/11/16/gvsd1119.htm.

and retail that have been automated through information technology, health care disproportionately relies on paper flowing through and being stored within organizations.[6]

During a 2009 survey of doctors in Australia, Canada, France, Germany, Italy, the Netherlands, New Zealand, Norway, Sweden, the United Kingdom, and the U.S., the U.S. reported the second lowest use of EHR systems for more than just billing purposes.[7] In contrast, the Scandinavian countries have nearly 100% adoption of EHRs.[8] Because Sweden, Finland, the Netherlands, and Denmark utilize EHRs at rates of 100%, 99%, 98%, and 95%, all of these countries are referenced for the purpose of this study.[9] In addition, the U.K. has a current EHR adoption rate of 90%, due to its National Health System.[10]

Although social, economic, and political differences may exist between these countries and the U.S., a study of EHRs in these foreign countries can help identify ways of overcoming barriers and other strategies that may aid in the adoption of EHRs in the U.S. With this in mind, this article will first explore the benefits and address the concerns of EHRs. In an effort to identify best practices, it will then look at the success and failure of EHR utilization in the Scandinavian countries and the U.K. This article will then address the state of EHRs in the U.S. and possible improvements.

II. OVERVIEW OF EHRS

Before beginning to discuss how EHRs are better utilized, a discussion of the reasons for and against their presence in U.S. healthcare is needed.

6. Greg R. Vetter, *Slouching Toward Open Innovation: Free and Open Source Software for Electronic Health Information*, 30 WASH. U. J.L. & POL'Y 179, 199 (2009).
7. Trapp, *supra* note 5.
8. Daniel Castro, THE INFO. TECH. & INNOVATION FOUND, EXPLAINING INTERNATIONAL IT APPLICATION LEADERSHIP: HEALTH IT 9 (2009) [hereinafter Castro].
9. *Id.*
10. *Id*.

During the initial development of EHRs, the Institute of Medicine hoped that EHRs would be "an electronic patient record that resides in a system specifically designed to support users through availability of complete and accurate data, practitioner reminders and alerts, clinical decision support systems, links to bodies of medical knowledge, and other aids."[11] These qualities are striving to make EHRs a tool to reduce practice costs, limit clutter, and accelerate transfer of medical charts between practices.[12]

Proponents of EHRs also argue that this technology may significantly reduce clinician workload and limit medical errors.[13] As of 1999, an estimated 44,000 to 98,000 people die each year in the U.S. due to medical errors.[14] As a result of EHR implementation, some believe that their use can lead to an improvement in the coordination of care.[15] Unlike paper-based medical records, EHRs allow more than one doctor or specialist to view a medical record at any given time.[16] Improved coordination of care can also be achieved, as health care providers are able to electronically access the entirety of a patient's electronic medical history.[17] Perhaps most importantly, EHR systems can directly limit medical errors through automatic alerts for "patient allergies, appropriate diagnostic tests, potential drug interactions, and other matters."[18]

Despite the benefits that EHRs can provide, they are not perfect. Chief among the concerns about EHRs are the cost of implementation. While the

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11. *Id.*
12. *See* Meller, *supra* note 1.
13. *See* Sameer Kumar & Krista Aldrich, *Overcoming Barriers to Electronic Medical Record (EMR) Implementation in the US Healthcare System: A Comparative Study*. HEALTH INFORMATICS J., 16(4), 306-318 (2010).
14. Castro, *supra* note 8, at 11.
15. O'Malley, *supra* note 3, at 177.
16. Vetter, *supra* note 6, at 201.
17. Ortega v. Colorado Permanente Grp, P.C., 265 P.3d 444, 447 (Colo. 2011), *reh'g denied* (Dec. 5, 2011).
18. Sharona Hoffman, *Employing E-Health: The Impact of Electronic Health Records on the Workplace*, 19 KAN. J. L. & PUB. POL'Y 412 (2010).

belief is that EHRs will eventually decrease the costs of medical treatment, implementing the system is very costly. Cedars Sinai Medical Center in Los Angeles recently implemented a $34 million physician order entry order system.[19] Despite this large cost, physicians were overwhelmed with the daily electronic alerts and several hundred refused to even utilize the system; as a result, the EHR program was canceled by the hospital administration.[20]

Because EHRs are a developing technology, physicians have expressed concerns about their functionality. The software requires mastering new technology, time-consuming data entry, and expensive computer programming.[21] This problem is exacerbated, however, due to evolving software technology. Specifically, EHR software involves "preexisting technologies, evolving hardware and software platforms, user requirements, business process demands, interoperability and availability needs, standards entanglements, and licensing methods."[22]

Another complaint by physicians is that EHRs currently increase the daily workload. A study at Oakland-based Kaiser Health Plan found that doctors had to spend an extra thirty to seventy-five minutes per day after the implementation of the Clinical Information System.[23] Specifically, doctors have complained that the systems are "over-engineered."[24] Even with a training program, doctors complain that EHR programs are not natural and require clicking and scrolling through unneeded screens and windows.[25] "A typical EHR system contains hundreds and hundreds of screens that need to

19. John B. Smelcer, Hal Miller-Jacobs, & Lyle Kantrovich, *Problems with Electronic Medical Records*, 2 J. USABILITY STUD. 72 (2009).
20. *Id.*
21. Meller, *supra* note 1, at 38.
22. Vetter, *supra* note 6, at 181.
23. Smelcer, *supra* note 22, at 72.
24. *Id.*
25. *Id.*

be accessed through the system's navigational scheme using tabs, buttons, and hyperlinks. Learning the right path takes time."[26] Like all software, EHRs also include delayed system response time, the requirement to log in and out when changing workstations (or in this case, exam rooms), and screens packed with information.[27]

EHRs are also limited if they cannot adapt to a specialist's needs. If an EHR system relies on text, specialists that require drawings or different forms of inputting are restricted.[28] Despite the belief that EHRs will reduce errors, there is also the possibility that other types of errors may develop. Depending upon the physician's usual task flow, a physician may enter notes into the EMR software while the patient is present.[29] This results in longer and unnecessary use of the patient's time. On the other hand, a physician with a demanding workload may wait until the end of the day to input data into an EHR, thereby relying on human memory.[30] Additional errors occur when a clinic's standing orders and EHRs contradict each other. For example, one observation found that errors occurred when nurses were required to log into an EHR system and order labs and procedures, because those labs and procedures were then sent to the ordering nurse instead of the physician.[31] Additionally, until a complete transition to EHR use occurs, physicians also have the burden of dealing with "hybrid" record environments that include both paper and electronic records.[32]

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26. *Id.* at 73.
27. *Id.*
28. *Id.* at 77.
29. *Id.* at 75.
30. *Id.*
31. *Id.* at 74.
32. IRON MOUNTAIN, A SMOOTH TRANSITION TO AN EFFECTIVE TO AN EFFECTIVE ELECTRONIC MEDICAL RECORDS SYSTEM (2012) [hereinafter IRON MOUNTAIN], http://www.ironmountain.com/Knowledge-Center/Reference-Library/View-by-Document-Type/General-Articles/A/A-Smooth-Transition-to-an-Effective-Electronic-Medical-Records-System.aspx.

Like all medical records, there are privacy concerns when dealing with EHRs. Some doctors fear that their patients may not be as forthcoming due to privacy and security concerns of this technology.[33] Conversely, there are concerns that the use of EHRs may make it easier for employers to obtain personal health information and possibly lead to discriminatory decisions, privacy threats, and associated litigation.[34]

The Health Insurance Portability and Accountability Act (HIPAA) is designed to protect any and all medical information "whether oral or recorded in any form or medium" to regulate health information.[35] Despite concerns over patient record privacy, advocates of EHRs actually argue that records are more secure because "deploying EHR systems with robust technical controls, including encryption, electronic identification, and audit logs can improve the privacy and security of personal medical data."[36]

III. EHRS IN FOREIGN COUNTRIES

The rate of adoption of EHRs varies drastically between different countries, and there is the inference that "progress is not limited by the costs, quality or usefulness of the technology, but rather by other factors that nations can influence."[37] Scandinavian countries, such as Denmark, Finland, and Sweden, "are definitely ahead of the United States and most other countries in moving forward with their health IT systems."[38]

Unlike the U.S. approach of attempting to build the EHR network from the bottom up, "Denmark, Finland, and Sweden have all implemented

33. Meller, *supra* note 1, at 38.
34. Hoffman, *supra* note 2, at 410.
35. South Carolina Med. Ass'n v. Thompson, 327 F.3d 346, 353 (4th Cir. 2003) (quoting 42 U.S.C.A. § 1320d(4) (West 2010)).
36. Castro, *supra* note 8, at 3.
37. *Id.* at 1.
38. *Id.* at 7.

national-level strategies. . ."[39] These countries also have the benefit of single-payer health care systems and government-run hospitals.[40] Countries such as Denmark and Norway have also spurred EHR growth by mandating e-prescriptions.[41]

Developed countries such as Denmark, Sweden, and Finland also have an advantage of having a "relatively technologically sophisticated population. . ."[42] This aspect not only raises patient expectations, but also enables better access and care through networks.[43] Amplified by the sophisticated population, Swedish health professionals also have access to Sjunet to coordinate care. Sjunet, the national broadband network in Sweden, enables "the secure exchange of health information" among health centers.[44]

The United Kingdom also has an advanced system of EHR use.[45] Although EHRs are emerging technology, the idea of collective public heath care in the U.K. dates back to medieval times.[46] Needless to say, the cost of healthcare has increased dramatically since that time.

Compared to the per capita cost of $7,421 that the U.S. spends on healthcare, the U.K. system only spends $2,317 per person per year.[47] One advantage that the U.K. has to decrease per capita cost and more effectively utilize EHRs is the centralized health care system known as the National Health Service, thus creating an easier route for coordination.[48] Because

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39. *Id.* at 1.
40. *Id.* at 2.
41. *Id.*
42. *Id.* at 3.
43. *Id.* at 2-3.
44. *Id.*
45. *Id.* at 7.
46. John Middleton, *Healthy People, Healthy Lives. The English Public Health White Paper: Risks and Challenges for a New Public Health System*, 11 CLINICAL MED. 430, 430 (2011) [hereinafter Middleton].
47. Smelcer, *supra* note 19, at 71.
48. Castro, *supra* note 8, at 2.

the system is centralized, it does not have to face the many challenges of a fragmented health care industry. As "one of the world's largest employers with over 1.3 million individuals on its payroll," the NHS can also provide influential financial incentives.[49] The NHS National Programme for IT created a budget representing approximately 0.08% of the nation's entire GDP.[50]

Despite the presence of the NHS and extensive EHR utilization, the U.K. still has pressing health concerns. Specifically, the country has one of the "worst levels of obesity in the world."[51] Smoking-related deaths total 80,000 lives per year.[52] Additionally, British citizens who live in the poor areas are expected to live up to seven fewer years than those in affluent areas.[53]

Like the Scandinavian countries, the U.K. emphasizes "e-health" by providing patients with 24/7 health care information through the web or phone.[54] NHS Direct, the nation's e-health portal, "was designed to point people in the right direction for the most appropriate form of treatment and encourage the best use of health services."[55] Moreover, fifty percent of all of the NHS referral activity goes through another e-health portal known as NHS Choices where patients can obtain "information on medical conditions, treatment options, and drug information."[56] These tools also provide the resources for patients to research a variety of health care providers.[57] It is useful to keep these tools in mind when beginning to consider health care in the U.S.

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49. *Id.* at 28.
50. *Id.*
51. Middleton, *supra* note 46, at 430.
52. *Id.*
53. *Id.*
54. *Id.* at 15.
55. *Id.* at 17-18.
56. *Id.* at 18.
57. *Id.*

IV. THE STATE OF EHRS IN THE U.S.

Though it is well known that the United States spends more per capita on health care than other countries, "[w]hat may be less known is that the United States still has one of the highest growth rates in health care spending."[58] A 2009 survey by *The New England Journal of Medicine* found that just 1.5% of U.S. hospitals have a comprehensive electronic records system and only 7.6% have a basic system, with EMR present in at least one clinical unit.[59] The U.S. attempted to improve these numbers and facilitate the use of EHRs through the Health Information Technology for Economic and Clinical Health Act (HITECH Act).[60] The HITECH Act, enacted on February 17, 2009, expressed Congress's goal that health care providers would use EHRs by 2014.[61] The American Recovery and Reinvestment Act (ARRA) authorized $19.2 billion to spur the use and adoption of EHRs to help the "ultimate purpose of the legislation [to] improve the healthcare of patients."[62] Additionally, "financial penalties for non-compliance in the form of decreased Medicare reimbursement of anywhere from 1% in 2015 to a full 5% by 2019" may be assessed against any practice in the U.S. that is not fully digital by each yearly threshold.[63]

Before the HITECH Act was enacted in 2009, "only 1.5% of U.S. acute care general hospitals had comprehensive EHR systems and that an

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58. *See* KAISER FAMILY FOUNDATION, HEALTH CARE SPENDING IN THE UNITED STATES AND OECD COUNTRIES (2011), *available at* http://www.kff.org/insurance/snapshot/chcm010307oth.cfm.

59. A.K. Jha et al., *Use of Electronic Health Records in U.S. Hospitals*, 360 NEW ENG. J. MED. 16, (2009).

60. Heghmann v. Sebelius, No. 09 Civ. 5880 (BSJ), 2010 WL 2643301, at *1 (S.D.N.Y. May 13, 2010); HITECH Act, 42 U.S.C. §17931 *et seq.* (2009).

61. *Id*.

62. Ethan Katsh et. al., *Is There an App for That? Electronic Health Records (Ehrs) and A New Environment of Conflict Prevention and Resolution*, 74 L. & CONTEMP. PROBS. 31, 36 (2011).

63. Anthony Papillion, *Purchasing electronic medical records software with economic stimulus funds*, HELIUM (2009).

additional 7.6% had basic EHR systems in 2008."[64] The adoption of EHRs fail in countries like the U.S. because of the fragmentation of the health market.[65] In a comparison of EHR use in England, Scotland, and Denmark, it was noted that the use of EHRs had been consistent with the growth of EHRs in other European countries.[66] The very centralized health system in the European countries may be a contributing factor to the growth of EHRs in those countries.[67] In addition to the strong national network, there is an early emphasis on EHRs by health professionals and professional colleges.[68]

One way to promote a national health IT system in the United States, according to Daniel Castro, the author of the Informational Technology and Innovation Foundation Report, is the adoption of e-prescriptions.[69] E-prescriptions are prescriptions generated electronically through computers, digital assistants, or mobile phones.[70] As previously discussed, government mandates of e-prescriptions helped EHR growth in countries like Denmark and Norway.[71] Although the use of e-prescriptions has increased from two percent of all prescriptions in 2007 to seven percent in 2008, this is still a relatively small amount.[72] By increasing the use of e-prescriptions, EHRs not only become more familiar to health care providers, but it reduces demands on doctors and pharmacies. The traditional pen and paper, faxes, and telephones "account for up to 20 percent of the time of the staff at a

64. Dukyong Yoon,et al. *Adoption of electronic heath records in Korean tertiary teaching and general hospitals*, 81 INT'L J. MED. INFORMATICS 196, 197 (2012).
65. Denis Protti, et al., *Primary Care Computing in England and Scotland: A Comparison with Denmark*, 14 INFORMATICS PRIMARY CARE 93, 98 (2006).
66. *Id.*
67. *Id.*
68. *Id.*
69. *See* Castro, *supra* note 8, at 13-14.
70. *Id.* at 13.
71. *Id.* at 2.
72. *Id.* at 15.

doctor's office and 25 percent of the time of pharmacists."[73] It is the aim of e-prescriptions to reduce this time drain.

One factor of EHR implementation that has been argued as both an advantage and disadvantage of EHR implementation is the population of the country.[74] Economies of scale suggest that EHR implementation would be cheaper on a pro rata allocation.[75] Under this theory, the cost of EHR implementation can be spread across a larger pool of shareholders. On the other hand, smaller populations tend to result in easier coordination between health providers.[76] Given the advantages and disadvantages of each, it is difficult to argue population size for either position.

The financial incentive for health care providers to invest in EHR technology is also blurred. Because of the "asymmetrical relationship between costs and benefits" of EHR systems, some of the financial benefits pass over the health care provider who invested in the technology and end up in the hands of health insurers and patients.[77] As a result, additional financial incentives, such as payment bonuses for providers may need to be created by the U.S. government through efforts similar to the American Recovery and Reinvestment Act.[78]

V. CONCLUSION

Although evidence exists that "about 75% of information system implementations in health care have failed," case studies have been able to identify best practices to implement and expand the use of EHRs.[79] As seen in this article, Denmark, Finland, Sweden, and the U.K. have been able to

73. *Id.* at 14.
74. *Id.* at 2.
75. *Id.*
76. *Id.*
77. *Id.* at 28.
78. *Id.* at 29.
79. Marie-Pierre Gagnon et. al., *Implementation of an electronic medical record in family practice: a case study,* 18 INFORMATICS PRIMARY CARE, 31, 37 (2010).

implement successful EHR policies.

It is noteworthy, however, that no single metric of progress is determinative of the success for EHR utilization. Although Finland has no e-prescription technology, the country has the highest adoption rate of EHRs among all of the countries in the ITIF study.[80] A further illustration of this is that the U.S. has a "high 5-year cancer survival rate but a low 5-year kidney transplantation survival rate."[81]

Nonetheless, an exploration of policies in foreign countries can help the U.S. improve its own system by identifying best practices. This idea is supported by the Information Technology and Innovation Foundation recommendation that the United States borrow "policies from leading nations to help spur EHR adoption."[82] Because a strong correlation exists between EHR use and elements of effective clinical care, the U.S. has incentive to increase its use of the developing technology.[83]

If done properly, the U.S. will feel immediate benefits of "accurate medication lists, legible notes and prescriptions, immediately available charts, decreased chart pulls, lower transcription costs, medical error reduction and improvement in quality care and patient safety."[84] Implementing an EHR system, however, is challenging due to the planning, management, leadership, and training that is required.[85] Nonetheless, by gleaning information and techniques from foreign countries, it is believed that EHRs can improve U.S. healthcare.

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80. Castro, *supra* note 8, at 9.
81. *Id.*
82. Bob Brewin, *U.S. Lags Behind in Adopting Electronic Medical Records*, NEXTGOV (Sep 22, 2009), http://www.nextgov.com/ng_20090922_4329.php?oref=topstory.
83. *See* Smelcer, *supra* note 19.
84. Faustine Williams et. al., *The role of the electronic medical record (EMR) in care delivery development in developing countries: a systemic review*, 16 INFORMATICS PRIMARY CARE 139, 142 (2010).
85. *Id.*

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Turkish Pharmaceuticals: An Industry In Transition

By: Keshia Carswell ∗

I. INTRODUCTION

While the Turkish pharmaceutical industry holds a prominent status in the global pharmaceutical market,[1] it is beset with a variety of political and regulatory issues that affect and potentially threaten its operation, functionality, and international relations. A primary source of concern in all of these areas lies within Turkish patent law, or the lack thereof, with specific regard to patent protection in the pharmaceutical arena. These regulatory problems also extend to Turkey's problematic development of clinical trial procedures.[2] These issues in the Turkish pharmaceutical industry have remained a source of political contention with respect to Turkey's pending ascension into the European Union since membership negotiations began in 2005.[3]

The Turkish pharmaceutical industry is quite large and represents the principal pharmaceutical market in the Middle East.[4] In fact, Turkey ranks sixteenth among the world's thirty-five top pharmaceutical producing

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1. *See* AN OVERVIEW OF TURKISH PHARMACEUTICAL SECTOR, http://www.egonzehnder.com/global/knowledge/articleindex/article/id/11900260 (last visited Mar. 20, 2012).

2. *See* WAY TO A NEW ERA FOR CLINICAL TRIALS IN TURKEY, http://www.mondaq.com/404.asp?404;http://www.mondaq.com:80/x/144078/Healthcare/Way+To+A+New+Era+For+Clinical+Trials+In+Turkey&login=true (last visited Mar. 20, 2012).

3. HAVARD INTERNATIONAL REVIEW, http://hir.harvard.edu/turkey-s-membership-in-the-eu-realistic-or-merely-wishful?page=0,1 (last visited Mar. 20, 2012).

4. EGON ZEHNDER INTERNATIONAL, http://www.egonzehnder.com/us (last visited Jan. 5, 2012).

countries.[5] It is projected that by 2020, Turkey's pharmaceutical market, along with that of the other E7 countries, will account for twenty percent of global pharmaceutical sales.[6] E7 countries include China, Indonesia, Russia, Turkey, Brazil, India and Mexico, and are known for having fast-growing economies and aging populations that demand better healthcare.[7] Not surprisingly, the Turkish pharmaceutical market is the fastest growing in the Mediterranean region.[8]

This paper will address the regulatory issues Turkey's pharmaceutical industry overcame by implementing industry-wide reforms. Specifically, this paper will describe the patent concerns Turkey faced, followed by a discussion of clinical trial reforms, and their impact on the pharmaceutical industry. Finally, this paper will discuss Turkey's issue with Adverse Drug Reactions (ADE's) and how the implementation of a national drug policy will alleviate this problem.

II. GOVERNANCE AND PATENT CONCERNS

Turkey's pharmaceutical industry is governed by the Ministry of Health (MoH), within which lie The General Directorate of Pharmaceuticals and Pharmacies (GDPP).[9] The GDPP has sole authority for the registration, marketing approval and authorization, pricing, legal classification, and inspection of pharmaceuticals, manufacturers, wholesalers, and retail

5. *Id.*

6. Pharma 2020: The Vision: Which Path Will You Take? (last visited Jan. 3, 2012), http://www.pwc.com/gx/en/pharma-life-sciences/pharma-2020/pharma-2020-vision-path.jhtml.

7. Lesley J. Burgess & Marli Terblanche, *The Future of Pharmaceutical, Biological, and Medical Device Industry*, OPEN ACCESS JOURNAL OF CLINICAL TRIALS (2011), *available at* http://www.doaj.org/doaj?func=abstract&id=815417.

8. EGON ZEHNDER INTERNATIONAL, *supra* note 3.

9. Andreas Seiter, *Health, Nutrition and Population: Turkey: Pharmaceutical Sector Analysis*, WORLD BANK, 5 (2008), http://siteresources.worldbank.org/INTHSD/Resources/376278-1250623752714/Turkeypharmaceuticalsectoranalysis.pdf.

pharmacies.[10] In carrying out these functions, the GDPP is assisted by a number of committees whose functions are primarily consultative in nature.[11] Additionally, as a member of the World Trade Organization (WTO), Turkey is subject to certain trade agreements,[12] which play a large part in the current patent issues facing Turkey's drug industry. One such agreement is the Trade-Related Aspects of Intellectual Property Rights (TRIPS), which introduced minimum protection standards for protecting and enforcing most forms of intellectual property rights, including patent protection for pharmaceutical products.[13]

In general, pharmaceutical companies rely heavily on patents for their products, and these intellectual property rights have been dubbed a "major international battlefield."[14] TRIPS protects data and production exclusivity, and WTO members benefit from reduced tariffs on their exports in exchange for granting patents on certain products and processes, including pharmaceuticals.[15] TRIPS mandates that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[16] Despite its WTO membership, historically, Turkey employed policies that failed to grant pharmaceutical patent protections.[17] As a result, until approximately 2005, when new licensing

10. Directorate, General for Trade, *Commission Report to the Trade Barriers Regulation Committee: TBR Proceedings Concerning Turkish Practices Affecting Trade in Pharmaceutical Products*, at 16 (Sept. 13, 2004), *available at* http://trade.ec.europa.eu/doclib/html/119478.htm.

11. Seiter, *supra* note 9.

12. *See* David Henry & Joel Lexchin, *The Pharmaceutical Industry as a Medicines Provider*, 360 LANCET 1590, 1593 (2002).

13. *WTO and the TRIPS Agreement*, WORLD HEALTH ORG. (last visited Jan. 3, 2012), http://www.who.int/medicines/areas/policy/wto_trips/en/index.html.

14. Henry & Lexchin, *supra* note 13.

15. *Id.*

16. WORLD HEALTH ORGANIZATION, http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm (last visited Jan. 3, 2012).

17. *See* Office of the United States Trade Representative, TURKEY 622 (2006), *available*

regulations took effect, copies of patent protected drugs in the United States and European Union were legally introduced in the Turkish pharmaceutical market.[18] As such, Turkish pharmaceutical companies did not need to make any significant research and development investments, and consequently, the domestic sale of these drugs was a large source of profit.[19] Thus, Turkish pharmaceutical companies were able to make sizeable profits at the expense of the R&D investments of foreign pharmaceutical companies.[20] This lack of intellectual property protection was part of a complaint against Turkey by the European Federation of Pharmaceutical Manufacturers and Associates (EFPIA), which resulted in an investigation into Turkish pharmaceutical practices by the European Commission.[21] The investigation revealed that Turkey's lack of data exclusivity resulted in losses for "originator companies" between 128 and 135 million USD annually.[22] The EFPIA concluded that Turkey was in "clear violation" of the TRIPS agreement, and to fulfill its obligation, Turkey must provide data exclusivity for a "reasonable period of time."[23]

Today, while the pharmaceutical industry is not without problems, it has undergone several years of reform to bring the industry into compliance with international agreements.[24] In fact, Turkey already introduced several

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at http://www.ustr.gov/archive/assets/Document_Library/Reports_Publications/2005/2005_NTE_Report/asset_upload_file512_7503.pdf.

18. Seiter, *supra* note 11, at 7-8.

19. Seiter, *supra* note 11, at 8.

20. *Id.*

21. Mere Perez Pugatch, *Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio: Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access*, UNIVERSITY OF HAIFA, ICTSD UNCTAD (Oct. 12-16, 2004) *available at* http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf.

22. Directorate, General for Trade, *supra* note 10, at 48.

23. Directorate, General for Trade, *supra* note 10, at 46.

24. *An Uncertain Future for Pharmaceutical Companies in Turkey*, BUSINESS TURKEY TODAY (Mar. 15, 2011), *available at*, http://www.businessturkeytoday.com/an-uncertain-future-for-pharmaceutical-companies-in-turkey/.

regulations to align its patent laws with the EU.[25] Specifically, the Government of Turkey issued best practices[26] in a number of pharmaceutical sectors including manufacturing, drug research, product registration, and packaging and labeling.[27] Furthermore, Turkey instituted a requirement that pharmaceutical companies have data exclusivity over new molecules for a period of no less than six years after entering the Turkish pharmaceutical market for the first time.[28] Thus, while this waiting period could begin within the existing twenty-year international data exclusivity agreements, production of the generic form of a molecule new to Turkey could potentially have a waiting period of up to twenty-six years.[29] These reforms substantially impacted the pharmaceutical market and resulted in significant profit losses for Turkish drug companies. The MoH addressed this issue by increasing drug subsidies to Turkish pharmaceutical companies from 4% to 41%.[30] It seems that this solution was effective in light of the massive adjustment because drug manufacturers were able to sell their products to pharmacies at even cheaper prices than before.[31]

The sweeping reforms to Turkish patent law in the pharmaceutical context have certainly been successful; if only because they brought Turkey into compliance with international agreements, such as TRIPS.[32] However, more should be done to strengthen patent protections, particularly in light of

25. Rajesh Chhabara, *Transforming the Turkish Pharma Market* (Jan. 17, 2011), *available at*, http://social.eyeforpharma.com/marketing/transforming-turkish-pharma-market.

26. Best practices are guidelines that seek to identify the best or ideal practices in a sector or industry. USLEGAL, http://definitions.uslegal.com/b/best-practices/. (last visited Mar. 20, 2012).

27. Chhabara, *supra* note 25.

28. Interview with Seda Serin, Biologist, MN Pharmaceuticals, in Istanbul, Turkey (Mar. 5, 2012).

29. *Id.*

30. *Turkey: Pricing Dispute Between Government and Drug Manufacturers Resolved*, BUSINESS TURKEY TODAY (Dec. 19, 2011), *available at*, http://www.businessturkeytoday.com/turkey-pricing-dispute-between-government-and-drug-manufacturers-resolved.html.

31. *Supra* note 30.

32. *Supra* note 24.

Turkey's pursuit for EU membership. At a council debate in 2001, Turkish officials acknowledged "marketing exclusivity [is] not covered by Turkish legislation as it is the case in the EU and the US. Only patented product is protected by the patent law until the due date of the patent expires."[33]

In the EU, member countries provide said protection with Supplemental Protection Certificates (SPCs).[34] SPCs provide additional protection for a period of time to manufacturers whose patents have expired.[35] SPCs were introduced in the EU to compensate pharmaceutical companies for lengthy regulatory approval and authorization periods.[36]

While Turkey did institute the six-year data exclusivity protections mentioned *supra*,[37] that protection is narrow as it only applies to molecules new to Turkey, and was not applied retroactively.[38] Accordingly, should Turkey join the EU, it would have to implement additional patent protections inclusive of marketing exclusivity clauses and SPCs.[39]

III. CLINICAL TRIALS AND THE PHARMACEUTICAL INDUSTRY

In addition to the regulatory issues plaguing Turkish patent law, regulatory problems in the Turkish pharmaceutical industry also affected the development of clinical trials.[40] Clinical trials play an important role in the pharmaceutical industry, as they are vital to the development of new drugs.[41] Recent clinical trial legislation in Turkey has been the subject of

33. Directorate, General for Trade, *supra* note 10, at 37.
34. LONDON SCHOOL OF ECONOMICS, *Pharmaceutical Reimbursement Policy in Turkey* (Sept. 2005), *available at* http://www.suvak.org.tr/kitap-2ingilizce.pdf.
35. MPA BUSINESS SERVICES, EU SPC'S (2006), *available at* http://www.mpaservices.co.uk/eu-supplementary-protection-certificates.html.
36. *Id.*
37. *Supra* note 33.
38. LONDON SCHOOL OF ECONOMICS, *supra* note 33, at 13.
39. *Id.* at 44.
40. *Supra* note 2.
41. *See* Thomas Bodenheimer, *Uneasy Alliance—Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENGL. J. MED. 1539, 1539 (2000).

profound debates.[42] So much so that, in 2009, the Turkish Medical Association (TMA) filed an action against certain provisions of clinical trial regulations.[43] The 10th Chamber Council of State presided over the action and issued a stay of execution, which prevented the implementation of certain articles from the regulation until the court rendered a final decision.[44] The stayed articles provided that: volunteers participating in clinical trials could not be paid; a person independent of the research team must inform volunteers about the clinical trial proceedings; changes in clinical trial protocols required GDPP approval; and that the High Council of Health's authority could not establish Ethics Committees through regulation.[45]

During this time, the MoH and TMA filed a request for review with the Plenary Session of the Chambers for Administrative Cases (PSCAC), a branch within the 10th Chamber.[46] PSCAC held that the clinical trial regulations at issue were directly related to the "right to life and immunity of physical integrity," and as such, the regulations governed fundamental human rights.[47] Thus, the regulations intervened with the basic human right of physical integrity and could only be limited by law even with a volunteer's consent.[48] PSCAC explained that subjecting a person to scientific and medical experiments violated the Turkish Constitution, unless the experiments were authorized by law.[49] PSCAC's decision effectively invalidated the clinical trial regulations, and the MoH stopped accepting clinical trial applications in October 2010.[50]

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42. *Supra* note 2.
43. *Id.*
44. *Id.*
45. *Id.*
46. *Id.*
47. *Id.*
48. *Supra* note 2.
49. *Id.*
50. *Id.*

As a result of this decision, confusion regarding the status of ongoing clinical trials ensued.[51] Educational institutions and universities decided to proceed with the clinical trials already in progress and took steps to form the independent ethics committees banned by the original regulations.[52] The universities established Ethical Committees within the scope of their authority under Turkey's Higher Education Law.[53] This law grants universities the authority to conduct "scientific trials," including clinical trials.[54] Universities interpreted this to mean that Ethical Committees could be properly established under that authority.[55] After seeing these developments with leading Turkish universities, the MoH announced that it would begin accepting clinical trial applications once again.[56]

Finally, in May 2011, the 10th Chamber of Council delivered its final judgment.[57] Contrary to PSCAC's ruling, the 10th Chamber held that the MoH has the authority to regulate clinical trials and that the rules promulgated by the MoH had the force of regulations.[58] Consequently, a law was enacted that provided the MoH with the legal authority to issue new clinical trial regulations.[59] The MoH acted quickly, and by August 2011, new regulations provided that: clinical trials cannot be conducted in, or by, private hospitals, but only by education, research, or government hospitals and healthcare institutions; either the pharmaceutical company sponsoring the clinical trial or the Contract Research Organization (CRO) must be a resident of Turkey; all clinical trials require approval by an Ethics Committee; and in the course of obtaining consent, a member of the

51. *Id.*
52. *Id.*
53. *Id.*
54. *Id.*
55. *Supra* note 2.
56. *Id.*
57. *Id.*
58. *Id.*
59. *Id.*

research team can inform participating volunteers.[60]

In the EU, clinical trials procedures have slight variations from country to country.[61] However, the EU Voluntary Harmonization Procedure (VHP), for which state participation is entirely voluntary, was created to streamline the application process. [62] To date, all EU countries with the exception of Poland have recognized VHP as a "valid approach to gaining clinical trial approval. . ."[63] Under this procedure an application is submitted to the Clinical Trials Facilitation Group (CTFG) for review.[64] The CTFG is comprised of authorities from each member state where the clinical trial will be performed.[65]

Like in Turkey, Ethical Committees (ECs) in the EU play an important role in that they review clinical trial materials for thing like discrepancies in protocol and informed consent documents.[66] The Clinical Trials Directive outlines their role and the clinical trials process in greater detail. It provides that a pharmaceutical company must submit an application to the EC documenting aspects of the trial including protocol, subject information, and consent.[67] Detailed requirements for each country are set forth in documents issued by the European Commission.[68] ECs then have sixty

60. *Id.*

61. Franz Buchholzer, *Implementing the EU Harmonization Procedure for Accelerated Clinical trial Approval*, PHARMANET: INVENTIVE HEALTH,http://blog.pharmanet.com/post/Implementing-the-EU-Voluntary-Harmonization-Procedure-for-Accelerated-Clinical-Trial-Approval.aspx (last visited Mar. 20, 2012).

62. *Id.*

63. *Id.*

64. Susan Bhatti, *EU Incentives for Simplifying Clinical Trial Approval Concerns and Initiative: An Overview*, *available at* http://www.premier-research.com/files/EU_Initiatives_for_Simplifying_Clinical_Trial_Approval.pdf.

65. *Id.*

66. *Id.*

67. National Health Service, *The Ethical Review Process for Clinical Trials in the European Union*, *available at* http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2010/06/WC500093372.pdf.

68. maRS, *Clinical Trial Authorization Process: EU (UK)*, *available at* http://www.marsdd.com/dmsassets/entrepreneurtoolkit/Regulatory-PDFs/Clinical_Trial_Authorization_EU.PDF.

days to issue an opinion upon receipt of a valid application.[69] In reviewing an application, the EC looks to the relevance and design of the clinical trial, the risks, benefits, and protocol, quality of the facilities, consent procedures, and subject information.[70] During this time the EC also has the option to request more information from the sponsor, which stops the sixty day clock.[71] If the application is denied, a pharmaceutical company can appeal or submit an amended request for further consideration.[72] All approved clinical trials are then registered in an online database called EudraCT, which makes certain clinical trial information available to the public.[73]

As it stands now, it is apparent that significant differences remain between Turkish and EU clinical trial processes. While Turkey has instituted several reforms to address regulatory issues in its clinical trials process, Turkey should consider restructuring its clinical trial process to parallel those of the EU in light of ongoing negotiations for EU membership. Because each EU state has requirements that vary slightly in nature, Turkey would not have to completely reform its existing structure, but merely harmonize its application procedures and tweak the roles of its Ethical Committees to comply. Thus, the regulatory changes Turkey instituted, particularly with respect to consent, could likely remain intact. Adopting EU clinical trial processes would improve Turkey's potential for EU ascension, as well as streamline clinical trial procedures with other Western and European nations. Doing so may increase Turkey's potential for foreign investments and opportunity for development within the industry.

69. National Health Service, *supra* note 67.
70. *Id.*
71. *Id.*
72. maRS, *supra* note 68.
73. *Id.*

V. CONCLUSION

The Turkish pharmaceutical industry is at a pivotal point. Despite its prominent status in the global pharmaceutical market, a plethora of political and regulatory issues remain. These issues have the potential to transform Turkey's pharmaceutical industry and make it an even bigger international player, but also threaten the industry's growth and operation, as well as its functionality and international relations.

While Turkey's intellectual patent laws have made huge strides to comply with international agreements such as TRIPS, it remains to be seen whether these developments will continue to be enforced and progress as to satisfy the European Union standards. Patent reforms had a great impact on Turkey's pharmaceutical industry, but should continue to evolve, as they will likely continue to shape the industry in the near future.

Similarly, with respect to pharmaceutical research and development, clinical trials in Turkey underwent substantial changes in the past twenty years, which greatly affected the functionality of Turkish pharmaceutical operations.[74] Regulations were promulgated and re-promulgated as Turkey struggled to find the right balance between pharmaceutical companies conducting the trials and patient rights. These changes have transformed the Turkish pharmaceutical industry and will continue to do so for the foreseeable future.

74. *Supra* note 2.

ANNALS OF HEALTH LAW
Advance Directive

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The National Essential Medicines List in China and What theUnited States Can Learn

*Patrick Gleeson**

I. DEVELOPMENT OF AN INTERNATIONAL STANDARD FOR ESSENTIAL MEDICINES LISTS

The World Health Organization (WHO) first developed the model essential medicines list in 1977 to assist developing and developed countries in allocating limited healthcare resources.[1] The WHO defines essential medicines as being "those that satisfy the priority health care needs of the population."[2] The model essential medicines list was born out of a request from the World Health Assembly to help member states achieve the mutually exclusive goal of greater access to care and cost containment.[3]

The initial list contained 205 medications[4] that were considered absolutely vital to meeting the basic healthcare needs of the population.[5] Although the list has evolved over time, the model has remained largely unchanged in selecting the types of drugs to be included on the list.[6] The

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1. Richard Laing et al., *25 Years of the WHO Essential Medicines Lists: Progress and Challenges*, 361 LANCET 1723, 1723 (2003); *see also*, Hans V. Hogerzeil, *The Concept of Essential Medicines: Lessons for Rich Countries*, 329 BMJ 1169, 1169 (2004) (the first *Model List of Essential Medicines* was published by the World Health Organization in 1977, and the list is revised every two years).

2. *Essential Medicines*, WORLD HEALTH ORGANIZATION, http://www.who.int/medicines/services/essmedicines_def/en/index.html (last visited February 12, 2012).

3. Laing, *supra* note 1, at 1723.

4. *Id.* at 1724.

5. Michael R. Reich, *Essential Drugs: Economics and Politics in International Health*, 8 HEALTH POL'Y 39, 40 (1987).

6. Laing, *supra* note 1, at 1724.

list has grown in number to include over 300 medications.[7] Currently, over 150 countries have adopted national essential drug lists.[8]

The ultimate goal of the essential drug list was to address the growing gap between the medical needs of the population and what essential drugs those countries were willing and able to provide.[9] Specifically, the national essential medicine lists were designed to balance the competing needs of efficacy, safety, and cost.[10] The list also encourages other reforms, such as reducing trade impediments, improving efficient distribution of the necessary medications, and encouraging more public funding of the essential drugs on the list.[11]

China[12] and the United States[13] have both implemented different forms of an essential medicines list. China developed a more substantial national list[14] while the U.S. has delegated the development of the lists to the individual states to be used in Medicaid pharmaceutical procurement.[15] China's system, while imperfect, provides a reasonable template for the

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7. *See* WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES 17th List (March 2011), *available at* http://www.who.int/medicines/publications/essentialmedicines/en/index.html; *see also* WORLD HEALTH ORGANIZATION, WHO MODEL LIST OF ESSENTIAL MEDICINES FOR CHILDREN 3RD LIST (March 2011), *available at* http://www.who.int/medicines/publications/essentialmedicines/en/index.html (the World Health Organization also developed an essential drug list that deals exclusively with children and their unique medical requirements. This published list is in its third edition and includes medications that are considered to be essential for the health and wellbeing of children).

8. Pieter Stolk, Marjolein JC Willemen, & Hubert GM Leufkens, *"Rare Essentials": Drugs for Rare Diseases as Essential Medicines*, 84 BULL. OF THE WORLD HEALTH ORG. 745, 745 (2006); *see also* Laing, *supra* note 1, at 1723 (the number of countries has varied but consistently remained above 150).

9. Reich, *supra* note 5, at 40.

10. Hogerzeil, *supra* note 1, at 1169.

11. Stephen P. Marks, *Access to Essential Medicines as a Component of the Right to Health*, HEALTH: A HUMAN RIGHTS PERSPECTIVE 85, *available at* http://www.swisshumanrightsbook.com/SHRB/shrb_03_files/04_453_Marks.pdf.

12. Xiaodong Guan, et al, *An Analysis of China's National Essential Medicines Policy*, 32 JOURNAL OF PUBLIC HEALTH POLICY 305, 306 (2011).

13. Timothy Millar, et al, *Applying the Essential Medicines Concept to US Preferred Drug Lists*, 101 AMERICAN JOURNAL OF PUBLIC HEALTH 1444, 1444 (2011).

14. Guan, *supra* note 12, at 306.

15. Millar, *supra* note 13, at 1444.

U.S. to develop and integrate an essential medicines list for the purposes of cost containment and greater access to necessary medicine.

The paper will first discuss China's essential medicines list, its implementation, and benefits and concerns. Next, it will provide an overview of the U.S. system, its use at the state level in Medicaid, and its inefficiencies. Finally, this paper will discuss the challenges and opposition to the implementation of a national essential medicines list in the U.S.

II. THE ESSENTIAL DRUG LIST IN CHINA AND ITS INTEGRATION INTO NATIONAL HEALTHCARE POLICY

China first developed a national essential medicine list (NEML) in 1982, which included 278 Western medicines.[16] The current list contains 307 different chemical varieties and provincial lists contain up to 200 additional medicines.[17] The NEML is governed by several Chinese ministries, including the Ministry of Health (MOH), which has been tasked with developing and maintaining the list; the National Development and Reform Commission (NDRC) (formerly the State Commission of Development and Planning[18]), which is engaged in managing costs through price controls[19]; and the State Food and Drug Administration (SFDA), which engages in inspections of production facilities to guarantee safety.[20]

16. Guan, *supra* note 12, at 306 (China began work on developing a NEML in 1979 and published the first NEML three years later).

17. *Id.* at 307 (the number of medicines on the list has fluctuated greatly, dropping from 2033 in 2004 to 307 in 2009); *see also* Wang Wenjie, *Perfecting the Essential Drug System Takes Time*, BEIJING REV. (March 12, 2010), http://www.bjreview.com/Cover_Story_Series_2010/2010-03/12/content_257598.htm.

18. Yingyao Chen & Stuart O. Schweitzer, *Issues in Drug Pricing, Reimbursement, and Access in China with References to Other Asian Pacific Regions*, 11 VALUE IN HEALTH S124, S125 (2008).

19. Qiang Sun et al, *Pharmaceutical Policy in China*, 27 HEALTH AFF. 1042, 1044 (2008) (the state mandates the mark-up at 15%; however, there is no significant oversight and realistic markups are most likely over 40%).

20. *Id.* at 1044 (the NDRC is engaged in issuing policies and setting maximum prices by allowing a standard mark-up on the average cost of production. Overall, approximately 60% of pharmaceutical products sold in China are governed by NDRC price controls).

State support for China's hospitals has fallen from approximately 60% in the 1980s to 8.3% in 2003.[21] As state support for the healthcare system was reduced, hospitals were encouraged to develop new revenue stream.[22] As a result, hospitals now subsidize clinical services with income derived from prescriptions, which motivates physicians to prescribe more expensive medications.[23] Physicians are also inclined to overprescribe, often prescribing multiple medications per clinic visit.[24]

Hospitals also profit from the prescribing of higher priced medications and from the encouragement of physicians to prescribe these costly medications. Patients in China are more likely to fill their prescriptions in hospitals than patients in the U.S.[25] This is due to the patients' concern regarding the quality of medication available at retail pharmacies, the recommendation of the treating physician, convenience, and availability of prescription drugs at hospitals versus retail pharmacies.[26] In 2006, 41.5% of the hospital revenue was derived from pharmaceutical sales.[27]

Another systemic issue in China is the distribution of pharmaceuticals. In 2009, the NDRC has implemented retail price controls on 2,349 different medical products.[28] Retail price controls are statutory maximum prices, which have effectively reduced retail prices by, on average, twelve

21. *Id.* at 1046.
22. *Id.*
23. Guan, *supra* note 12, at 308.
24. Lifang Dong et al, *Drug Prescribing Indicators in Village Health Clinics Across 10 Provinces of Western China*, 28 FAMILY PRACTICE 63, 65 (2011) (the rate at which physicians prescribe antibiotics is much higher than in other countries, suggesting that there is a general tendency to overprescribe); *see also* Guan, *supra* note 12, at 309 ("[s]eventy per cent of prescriptions contained antibiotics, making China one of the heaviest users of antibiotics").
25. Sun, *supra* note 19, at 1046 (approximately four-fifths of all prescriptions filled in China are filled in retail pharmacies within the hospitals themselves).
26. *Id.* at 1047.
27. *Id.* at 1046.
28. Guan, *supra* note 12, at 311.

percent.[29] However, corruption within the system has allowed some drugs covered by the price controls to be rebranded as new medicines, which enables them to escape these controls.[30]

The pharmaceutical industry's response to the price controls and the NEML has been problematic in the efforts to increase access to these drugs. First, because of price controls, pharmaceutical companies lack sufficient incentive to produce these drugs.[31] As a result, there are chronic shortages of necessary medications in various markets across China.[32] Second, pharmaceutical companies respond to price controls by rebranding these drugs so that they are not subjected to these price controls.[33] Again, this serves to limit the access patients have to affordable medicines.

China has enacted considerable health care reforms to address these issues.[34] They seek to find a solution for the high cost of medicine, as well as to extend medical insurance to over ninety percent of the population.[35] Currently, China maintains two separate systems for rural and urban healthcare, with urban participants receiving more benefits and coverage than those in rural areas.[36] In total, China is devoting 850 billion RMB (approximately $124 billion USD) to revamping the healthcare system to increase access to necessary medical care and pharmaceuticals.[37]

To address the issues of shortages of essential drugs on the market, in 2007 the SFDA designated ten pharmaceutical companies to manufacture

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29. *Id.*
30. Sun, *supra* note 19, at 1044-1045.
31. *Id.* at 1045-1046.
32. *Id.* at 1046.
33. *Id.* at 1044-45.
34. Wenjie, *supra* note 17; *see also* Guan, *supra* note 12, at 306 (the three year plan will conclude in 2012; however, it will take some time to fully realize the impact the program had on expanding full healthcare coverage to the population).
35. Guan, *supra* note 12, at 306.
36. *Id.* at 313 (however, the rural cooperative scheme for reimbursement has not been implemented).
37. *Id.* at 306.

eighteen essential medicines to prevent future disruptions in production.[38] The SFDA has also invested energy and formulated policy to reduce the number of steps in the distribution chain to limit the markup that the end-using patient eventually pays.[39]

III. USE OF ESSENTIAL DRUG LISTS IN THE UNITED STATES AND RELATED PROBLEMS

The U.S. developed the Medicaid system in 1965 to address providing health care for low-income citizens.[40] All fifty states manage their own Medicaid system.[41] Each state's Medicaid system has developed a preferred drug list (PDL) to provide practitioners with guidance regarding effective prescribing.[42]

Despite the use of a PDL within Medicaid, there are several problems associated with the lack of a national essential drug list in the U.S. First, the use of prescription medicine is likely to rise significantly as the population ages.[43] The elder age group is likely to consume more pharmaceutical products than other age groups due to health concerns commonly associated with aging.[44] This has led to an increase in pharmaceutical expenditures,[45] which is problematic because costs will most likely continue to rise as a result of the aging population and their pharmaceutical requirements. In addition, pharmaceutical costs remain

38. *Id.* at 308.
39. Sun, *supra* note 19, at 1044.
40. Millar, *supra* note 13, at 1444.
41. HEALTHCARE.GOV, http://www.healthcare.gov/using-insurance/low-cost-care/medicaid/index.html (last visited March 25, 2012).
42. Millar, *supra* note 13, at 1444.
43. Hogerzeil, *supra* note 1, at 1170; *see also* Andrew Ellner, *Rethinking Prescribing in the United States*, 327 BMJ 1397, 1397 (2003) ("the group aged over 65 is one of the fastest growing parts of the population").
44. Ellner, *supra* note 43, at 1397.
45. Hogerzeil, *supra* note 1, at 1170 (pharmaceutical spending in the US increased 18% in 1999, 16% in 2000, and 17% in 2001).

high because of inefficient prescription methodologies, higher costs of new drugs, and increased quantities of drugs being prescribed.[46]

Second, pharmacy benefits managers (PBMs) are largely responsible for creating the PDLs.[47] Undisclosed arrangements between the PDLs and the manufacturers may compromise the appropriateness of list formularies and may result in higher costs.[48] In addition, this process may remove practitioners from the development of these formularies.[49]

Third, lists produced at the state level may not be as inclusive as a list that is created at a national level.[50] This is likely due to the differences in the formularies employed by each state's program.[51] However, a national list would likely decrease costs and allow for bulk purchasing and aggregate discounts.[52]

IV. CHALLENGES TO IMPLEMENTING A NATIONAL ESSENTIAL MEDICINES LIST IN THE UNITED STATES

There is considerable opposition to a national list from several key stakeholders. First, physicians are generally opposed to a national list

46. *Id.* (newer, more expensive drugs will consume more of the limited healthcare budget at the state level than generic drugs. This suggests there may be a requirement for better systematic selection of medication).

47. Ellner, *supra* note 43, at 1398 (the conflict occurs when pharmaceutical companies control PBMs and the development of PDLs by including more expensive medications on the PDLs).

48. *Id.*; *see also* Andrew Ellner et al, *Essential Medicines in the United States*, BMJ PUBLISHING GROUP, 12 (April 25, 2003) (the private management has been largely ineffective at controlling costs where the US spends almost twice as much per capita as other OECD nations and 40% of the elderly population lacks prescription drug coverage).

49. Ellner, *supra* note 43, at 1398.

50. Jonathan D. Ketcham & Jeffrey K. Ngai, *How Similar Are States' Medicaid Preferred Drug Lists?* 14 AMER. J. OF MANAGED CARE, SP46, SP48 (2008) (there is a degree of variation among the states regarding overlap of PDLs. Only 20 drugs out of a 110-drug survey were found to overlap over ten states in the survey).

51. *Id.* at SP50 (some of the variations in prices and cost effectiveness may be due to the different prices paid by each program, with different arrangements between the states and the pharmaceutical manufacturers).

52. Ellner, *supra* note 43, at1399 (a national program would have more leverage in price negotiation than the current fragmented negotiation at the state level).

because the existence and widespread use of such a list may impact their "clinical freedom."[53] Specifically, physicians may be concerned that their patients would have limited access to newer medications not included on the national list.[54] In addition, physicians may be concerned that they will not be adequately represented in the discussion and formulation of the national list.[55]

Second, pharmaceutical companies are also opposed to a national list. The primary concern is that a national list would limit the types of drugs that may be prescribed within certain programs.[56] Industry opposition is most likely rooted in the fear that newer, more expensive drugs will not be included because of their cost, which could impact innovation and further research.[57]

Third, patient groups are generally opposed to implementing a national essential medicines list.[58] Criticism from patient groups is based on concern that the list will be too limited and exclude beneficiaries of the program from the newest and most efficient prescription drugs.[59] In addition, organizations devoted to a specific disease expressed concern that medicines specific to that disease would be excluded without adequate substitutes.[60]

Despite the opposition from physicians, the pharmaceutical industry, and patient advocacy groups, what is apparent is that the U.S. spends more on prescription drugs than most other Organisation for Economic Co-

53. *Id.*
54. Ellner et al, *supra* note 48, at 27.
55. *Id.*
56. *Id.* at 26 (the pharmaceutical industry is not opposed to coverage of all products but opposes coverage of a specific list because it would most likely exclude higher margin drugs. The pharmaceutical industry has also argued that such a list would curtail innovation by limiting profit and, theoretically, funds available for research and development).
57. Ellner, *supra* note 43, at 1399.
58. Ellner et al, *supra* note 48, at 27-28.
59. *Id.* at 28.
60. *Id.*

Operation and Development (OECD) nations.[61] Therefore, the essential medicines list should be a collaboration of all interested parties.

V. CONCLUSION: SOLUTIONS FOR THE UNITED STATES AND CHINESE SYSTEMS

China's national essential medicines list provides a template for the U.S. to develop and integrate an essential medicines list for the purposes of cost containment and greater access to necessary medicine. The current U.S. system should be improved because it is expensive and costs continue to rise, is under-inclusive, and there are potential conflicts when private interests develop a list absent active involvement from physicians and patient groups.

The benefits are considerable. First, patients' access to essential prescription medication would increase. Concern that medicines not included on the list would be unavailable is unfounded because those medications would still be accessible.[62] Second, due to a better allocation of resources and purchases taking place at the national level, prescription drug spending would decrease.

Developing a national list in the U.S. would first need to overcome considerable opposition from physicians, the pharmaceutical industry, and patient groups. However, including and considering these interests in the development of an essential medicines list could overcome these obstacles. Therefore, developing a national essential medicines list in the U.S. would not only provide considerable healthcare savings and increase access to care, it is completely feasible.

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61. *Id.* at 12.

62. The national list would not prohibit the use of other drugs. Rather, it would seek to better allocate limited resources by providing more coverage and reimbursement for drugs on the list.

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Italy's Health Care System: Reducing Regional Disparities for At-Risk Populations

Alexandra Hall ∗

I. INTRODUCTION

Nations across the world have implemented innovative health systems. As a global leader, the United States would benefit from modeling parts of its system based on successful policies in other countries. The main objectives of health care reform in the U.S. reside in the areas of cost containment and the expansion of insurance coverage.[1] Whether U.S. citizens should possess a right to health care, similar to many European countries, has also been a social and political debate for the past decade.[2] The U.S. will inevitably face significant political and social barriers in any attempt to adopt different health care structures and policies. However, Italy has achieved success in the areas of cost containment and patient coverage, and the U.S. would benefit from adopting specific elements of its structure and policies.[3]

This article will examine the structure and policies of Italy's health system, and explain how the U.S. should adopt specific strategies that have proven successful in the reduction of regional disparities and cost

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1. EXECUTIVE OFFICE OF THE PRESIDENT COUNCIL OF ECONOMIC ADVISERS, THE ECONOMIC CASE FOR HEALTH CARE REFORM, June 2, 2011, *available at* http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf

2. Sandhu, K Puneet, *A Legal Right to Health Care: What Can the United States Learn From Foreign Models of Health Rights Jurisprudence?*, 95 CAL. L. REV 1151, 1154, (2007).

3. Alessandra Lo Scalzo et al., *Italy: Health System Review*, 11 HEALTH SYSTEMS IN TRANSITION 6, 45 (2009), *available at* http://www.euro.who.int/__data/assets/pdf_file/0006/87225/E93666.pdf.

containment. First, this article will begin by discussing the organization and financial structure of Italy's health care system. Second, it will address the regional disparities and cost-containment issues that Italy's health care system faces and the strategies that the country has adopted to reduce inequalities and spending. Finally, this article will identify how the U.S. has addressed inequalities in health care in recent legislative reform and analyze whether the U.S. could effectively replicate certain strategies that have been successful in Italy.

II. ORGANIZATION, FUNDING, AND PATIENT CARE

Italy's health care system, *Servizio Sanitario Nazionale* (SSN), is a regionally based national health service that covers all citizens and legal foreign residents.[4] The Italian system is universal, where residents can go to a public hospital without worrying about insurance coverage.[5] The government pays the majority of the cost and patients are typically only charged a small co-pay without involvement of any insurance companies.[6] As a result, private insurance involvement is minimal.[7] However, this has caused inefficiencies in care.[8] One reason for this is that public hospitals are provided guaranteed reimbursements, which reduce the hospitals' incentive to improve services or keep costs down.[9]

The Italian government attempted to reduce these inefficiencies in 1997

4. COMMONWEALTH FUND, INTERNATIONAL PROFILES OF HEALTH CARE SYSTEMS 32 (2010), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2010/Jun/1417_Squires_Intl_Profiles_622.pdf.

5. Margherita Stancati, *Competitive Care: When Italy's Lombardy Region Pitted Private Hospitals Against Public Ones, the Quality of Care Rose Dramatically*, WALL ST. J., Apr. 13 2010, *available at* http://online.wsj.com/article/SB10001424052748704131404575118030576580248.html

6. *Id*. at 1.

7. *Id*.

8. *Id*.

9. *Id*.

through reforms, which resulted in the current structure.[10] This structure gives twenty individual regions control over public money, which is then distributed to hospitals within its own borders.[11] Individual regions have the power to adopt their own quality standards, set their own reimbursement rates, determine the funds allocated to hospitals, and withhold reimbursements if hospitals fail to meet the required standard.[12] Much of the country uses standards of care and reimbursement rates that are recommended by Rome.[13]

The central government determines the minimum national benefits package, which include the "essential levels of care" or *livelli essenziali di assistenza* (LEAs).[14] Every year, the SSN produces a positive and negative list of LEA services based on effectiveness, necessity, and efficiency of delivery.[15] The positive list includes services such as ambulatory and inpatient care, as well as some prescription drugs.[16] Individual regions may choose to offer non-LEA services such as eye care and dental care, but they must be regionally funded.[17] Although Italy's health care system may seem appealing, long waits and disorganization result in some level of patient dissatisfaction.[18] Italy's health system may seem enticing on the surface due to little or no copayments and wide coverage, but long waiting periods and crowded hospitals force some individuals to travel long distances to receive high quality care.[19]

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10. *Id.*
11. *Id.*; Lo Scalzo et al., *supra* note 3, at 1.
12. Sancati, *supra* note 5.
13. *Id.*
14. COMMONWEALTH FUND, *supra* note 4, at 32.
15. *Id.*
16. *Id.*
17. *Id.*
18. *Healthcare Systems: Focus on Italy*, 5 PERSPECTIVES 2, (Feb. 13, 2011), *available at* http://www.nextgenmd.org/archives/804
19. *Id.*

Italy's health system is publicly funded through two tax systems.[20] First, a business tax is collected into a national pool and then redistributed generally to the source region.[21] Second, with the aim of ensuring that all regions have adequate funding to provide the LEAs, the central government collects a value-added tax that is used towards grants that are distributed to each region.[22] The allocation of resources for the SSN have historically been a source of contention between the central government and individual regions, resulting in delays in the assignment of regional shares for health care.[23] Substantial difficulty arises in the allocation of funds due to the large geographical differences in levels of economic development, size and age of populations, and availability of health services.[24] To address these issues, in 1997, Italy's government implemented a weighted capitation system that took into consideration the current demand for health services, age, structure, and health condition of the population based on the mortality rate.[25] Although private health insurance plays a small role in Italy's health system, accounting for only one percent of overall health spending, roughly fifteen percent of the population has some form of private insurance to cover cost-sharing requirements.[26] Examples of health expenditures that patient's pay out-of-pocket includes prescription drugs, and in some regions, dental and eye care.[27]

III. COST-CONTAINMENT AND REGIONAL DISPARITIES

A major issue with Italy's health system is the significant regional

20. COMMONWEALTH FUND, *supra* note 4, at 33.
21. *Id.*
22. *Id.* at 32-33.
23. Lo Scalzo et al., *supra* note 3, at 58.
24. *Id.* at 10. In central and northern regions, the percentage of the population aged over 65 exceeds 20%, compared with less than 15% in some southern regions.
25. *Id.* at 179.
26. COMMONWEALTH FUND, *supra* note 4, at 33.
27. *Id.* at 32.

disparities and the effect that these inequalities have on the delivery of effective quality health care to the entire population.[28] While the central government regulates the minimum benefit package for citizens and controls the distribution of tax revenue, each region is individually responsible for the organization and delivery of services within its jurisdiction.[29] Individual regions are given significant autonomy in the allocation of funds and responsibilities, and most choose to assign duties to local health authorities.[30] In addition to the taxes controlled by the central government, regions have the power to collect their own respective taxes, leading to financial disparities.[31] The significant regional differences echo two trends in central government policy: (1) "to systematically, although not overtly, underestimate the funding needs of the SSN; and (2) to overestimate the savings to be obtained from expenditure containment strategies."[32]

Recognizing the issue of significant regional disparities, the Italian government took measures to reduce the differences and shortcomings, such as pooling funds and introducing a weighted capitation rate.[33] The autonomy given to the regions was introduced with the objective to make the regions more aware and accountable for controlling expenditures and to promote efficiency, quality, and citizen satisfaction.[34] The regions are responsible for catering to the needs of the specific population, as well as the allocating financial resources and monitoring local health care

28. Lo Scalzo et al., *supra* note 3, at xxiv.

29. Maurizio Ferrera, *The Rise and Fall of Democratic Universalism: Health Care Reform in Italy, 1979-1994*, 20 J. HEALTH POL., POL'Y & L. 275, 281 (1995).

30. COMMONWEALTH FUND, *supra* note 4, at 33.

31. *Id.*

32. Lo Scalzo et al., *supra* note 3, at 40.

33. *Id.* at 59.

34. Vittorio Maio & Lamberto Manzoli, *The Italian Healthcare System: W.H.O. Ranking Versus Public Perception*, 27 PHARMACY & THERAPEUTICS J 301, 302 (June 2002).

agencies.[35] Regions are also accountable for accrediting public and private health service providers and assuring that their guidelines are in accordance with national laws.[36]

Italy's health system has recognized the problems in the arena of cost containment in light of the growing public deficit and has taken various measures to reduce these problems.[37] Italy has one of the lowest public shares of total health care expenditures among countries in the European Union, suggesting substantial success in the area of cost containment.[38] However, the total public health care expenditure remains a central issue both nationally and regionally.[39] Public expenditure for health care steadily increased until 1991, reaching almost $65 billion – 6.6% of Italy's gross domestic product (GDP).[40] Since 1992, the Italian Government implemented two broad categories of cost containment measures.[41] The first category was aimed at increasing productivity and accountability for regions, such as spending ceilings on goods and services and closures of small hospitals.[42] The second category includes measures intended to reduce the demand for health care by patients, such as increasing copayments on drugs and outpatient specialist care.[43]

Research on public health care expenditure suggests that differences in regional health care are mainly a result of socioeconomic factors such as variations in GDP and the availability of care.[44] Reforms in the system demonstrate progress in both financing health care and reducing regional

35. *Id.*
36. *Id.*
37. Lo Scalzo at al., *supra* note 3, at 68.
38. *Id.* at 45.
39. *Id.*
40. Maio & Manzoli, *supra* note 34, at 305.
41. *Id*.
42. *Id*.
43. *Id*.
44. Lo Scalzo et al., *supra* note 3, at 45.

differences in quality and access, but the drawbacks that result from an unevenly distributed tax base and a demand for poorer regions to increase their tax rates are inevitable.[45] These issues, along with difficulties in reaching an equitable distribution of the National Solidarity Fund, have thwarted the effectiveness of the redistribution formula and demand revisions and adjustments.[46]

The central government attempted to limit the substantial deficits by requiring regions to underwrite annual "Pacts for Health" that "tie additional resources to the achievement of health care planning and expenditure goals."[47] Regional governors are also required to balance the books in health care expenditures yearly.[48] These requirements create accountability, incentives for regions to perform better, and a system in which the central government can monitor regional spending.[49]

IV. A COMPARISON WITH THE UNITED STATES

The challenges that Italy's health system faces regarding regional disparities could be considered comparable to variations among the fifty states, as well as inequalities resulting from location and income. Socioeconomic status and the location of residence inevitably have a strong influence on health.[50] In the U.S., the risk of mortality, morbidity, reduced access and poor quality of care increases as socioeconomic circumstances decrease.[51] The U.S. health care system tends to divide the population by

45. *Id.* at 53-4.
46. *Id.* at 54.
47. *Id.* at 40.
48. *Id.*
49. *Id.* at 41.
50. Gloria L. Beckles & Benedict I. Truman, *Education and Income – United States, 2005 and 2009*, 60 MORBIDITY AND MORTALITY WEEKLY REPORT 13, Jan. 14 2011, at 13, *available at* http://www.cdc.gov/mmwr/pdf/other/su6001.pdf.
51. *Id.*

"insiders" and "outsiders."[52] On one hand, the "[i]nsiders, who have good insurance, receive everything modern medicine can provide, no matter how expensive."[53] Alternatively, the "[o]utsiders, who have poor insurance or none at all, receive very little."[54] For example, a study found that among Americans diagnosed with colorectal cancer, patients without insurance were seventy percent more likely than patients with insurance to die within three years.[55] New technology and medical advancements result in increased funds spent on the wealthy, and as a result, more citizens are consigned to an "outsider" status.[56]

To address the inequalities in health care that result from socioeconomic conditions, the U.S. government put a focus on clinical interventions, counseling and education, and protective intervention in the Patient Protection and Affordable Care Act (PPACA).[57] In addition to a focus on physician-provided medical care, the PPACA is "suffused with provisions that promise to elevate the status of, and national commitment to, disease prevention, wellness promotion, and population-based interventions."[58] The PPACA authorizes Congress to sponsor grants at the state level to assist public health organizations, but is limited to targeted attempts to change behavior and lifestyle at individual and community-based levels.[59] For example, Sections 10503 and 5207 of the PPACA increase funding for community health centers and the National Health Service Corps in rural

52. Paul Krugman & Robin Wells, *The Healthcare Crisis and What to Do About It*, N. Y. REV. OF BOOKS, March 23, 2006, *available at* http://www.nybooks.com/articles/archives/2006/mar/23/the-health-care-crisis-and-what-to-do-about-it/?pagination=false.

53. *Id.*

54. *Id.*

55. *Id.*

56. *Id.*

57. Kenneth Deville & Lloyd Novick, *Swimming Upstream? Patient Protection and Affordable Care Act and the Cultural Ascendancy of Public Health*, 17 J. of Pub. Health Mgmt. 102, 107 (2001), *available at* http://journals.lww.com/jphmp/Fulltext/2011/03000/Swimming_Upstream__Patient_Protection_and.2.aspx#.

58. *Id*. at 102.

59. *Id*. at 107.

and underserved areas in order to increase access to health care services to reduce health disparities.[60] Additionally, Section 4302 aims to uncover and reduce health disparities among racial and ethnic groups through data collection techniques.[61] Through these mechanisms, the PPACA takes measures to reduce disparities by targeting specific at-risk populations and communities.

In the Italian health care system, similar inequalities exist across regional and socioeconomic lines.[62] As previously mentioned, wealthier patients are afforded quicker and more easily accessible care if they pay a fee for private insurance.[63] For example, a patient who enters the Radiology Department for a CT scan must only pay a small copayment, unless he or she is not already exempt.[64] However, it can take up to four weeks to have the exam and the patient will encounter significant chaos and disorganization in the hospitals, which are under substantial pressure to treat a large amount of patients.[65] In another case, an American citizen with private insurance who entered a hospital in Tourino, Italy after a trip and fall accident was seen immediately and avoided long lines of Italian citizens with governmental insurance waiting to be seen.[66] Therefore, those patients who can afford private care can pay a fee to avoid long waits and receive care quickly in a quiet and comfortable environment, thereby increasing the inequity between the rich and the poor on both a regional and an individual

60. Hinda Chaikind, et. al., CONGRESSIONAL RESEARCH SERVICE, PPACA: A BRIEF OVERVIEW OF THE LAW, IMPLEMENTATION, AND LEGAL CHALLENGES 3, (Mar. 2, 2011), *available at* http://www.nationalaglawcenter.org/assets/crs/R41664.pdf; C. Stephen Redhead & Erin D. Williams, CONGRESSIONAL RESEARCH SERVICE, PUBLIC HEALTH, WORKFORCE, QUALITY, AND RELATED PROVISIONS IN PPACA: SUMMARY AND TIMELINE 8-9, (Sept. 2, 2010), *available at* http://healthyamericans.org/assets/files/CRS%20Report%209-2.pdf.

61. 42 U.S.C.A. §300kk

62. Lo Scalzo et al., *supra* note 3, at xxiv.

63. *Healthcare Systems: Focus on Italy*, *supra* note 18.

64. *Id*.

65. *Id*.

66. Telephone Interview with William Young, Chief Executive Officer, Automark Inc., (Mar. 8, 2012).

level.[67] Additionally, the regional organization of Italy's health care system, coupled with the extensive interregional differences in socioeconomic indicators, has resulted in strong inequalities among regions.[68] Southern regions have a "smaller bed stock, a greater presence of private facilities and a poorer endowment of advanced medical equipment," which contributes to "heavy patient flows to central and northern regions and to other European countries."[69]

Italy addressed the regional and socioeconomic disparities in the health care system through the implementation of a regional weighted capitation system.[70] The weighted capitation formula varies annually based on negotiations among regions and aims to ensure equal access to health care for people at equal risk.[71] To serve this purpose, the formula has been constructed to address the relative needs of regional populations.[72] With the adoption of a weighted capitation scheme, individual regions also have the power to implement their own distributive justice model that "takes into account heterogeneity with respect to the resources needed to cover the diverse health care needs of the population."[73] However, the application of the weighted capitation formula has had a tendency to address health requirements within subgroups of a population rather than improving the overall outcome for that population.[74]

Additionally, the government created a National Solidarity Fund to distribute resources to individual regions with the purpose of reducing inequalities between northern regions and southern regions.[75] Northern

67. *Healthcare Systems: Focus on Italy*, *supra* note 18.
68. Lo Scalzo et al., *supra* note 3, at 185.
69. *Id*.
70. *Id*. at 178.
71. *Id*. at 179.
72. *Id*.
73. *Id*. at 184.
74. *Id*.
75. *Id*. at 178.

regions generally need less funding from the National Solidarity Fund because they hold more wealth and have higher own-source tax revenues to contribute to the core benefits package.[76] The reserves in the National Solidarity Fund are allocated based on the following four considerations: "the region's share of total [value-added tax] revenue, its fiscal capability, its health care financing needs and its non-health care financing needs."[77] However, these issues are multifaceted and complex, resulting in difficulties reaching an equitable distribution of the Fund.[78] These reforms represent progress, but have possible drawbacks related to an unevenly distributed tax base, and the greater need for poorer regions to increase tax rates coupled with negative business incentives for business location in poorer regions.[79]

The U.S. may adopt policies from Italy's health system in order to combat regional and socioeconomic disparities in health care on a large-scale level, in addition to focusing on individual communities and populations. The U.S. could create a reserve similar to the National Solidarity Fund to reduce disparities on a large-scale basis. To be effective, the fund must adopt a formula based on population size, current health need, age, and financial necessity to assist poorer states and potentially decrease funding for wealthier states. However, with the adoption of a policy too similar to Italy, the U.S. may experience the same problems that Italy faces such as the inability to nationally agree on the distribution of funds.[80] Therefore, allowing each state to collect an individual fund and the individual autonomy to allocate it would be a more effective structure. With the successful implementation of the PPACA provisions that aim to

76. *Id*.
77. *Id*. at 53.
78. *Id*. at 54.
79. *Id*.
80. *Id*.

reduce disparities in health care, current inequalities in the U.S. will predictably reduce and vary within each state.[81] Creating a fund at a state level would allow the individual states to cater to the unique needs within each state, such as elder care, similar to the way Italian regions hold the responsibility to cater to the distinct needs of the particular population.[82] To effectively decrease the regional disparities in health care that the U.S. faces, it would be most effective for each state to adopt a version of Italy's National Solidarity Fund in addition to the federal community-focused policies presented in the PPACA.

V. CONCLUSION

Italy's health system is organized regionally and offers universal health care for its citizens.[83] The central government determines the minimum level of care required for all residents.[84] A major challenge that Italy faces is inequalities in the delivery and level of care among different regions and populations.[85] The Italian government has implemented policies to reduce regional disparities and contain costs, such as the enactment of a regional weighted capitation system and the National Solidarity Fund.[86] The U.S. faces similar inequalities across regional and socioeconomic lines.[87] Although the U.S. can model some elements after Italy's system, attempts to mimic Italy's system may present the country with similar challenges that Italy currently faces. To reduce the disparities in the U.S., in addition to the policies outlined in the PPACA, individual states could adopt a variation of Italy's National Solidarity Fund to provide funding for the most

81. Deville & Novick, *supra* note 57, at 107.
82. Maio & Manzoli, *supra* note 34, at 302.
83. Stancati, *supra* note 5.
84. COMMONWEALTH FUND, *supra* note 4, at 32.
85. Lo Scalzo et al., *supra* note 3, at xxiv.
86. *Id*. at 178.
87. Beckles & Truman, *supra* note 50, at 13.

at-risk populations. As regional disparities continue to adversely affect the overall health of nations, creative solutions must be explored to provide equal care to all populations.

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Lessons from Canada's Equalization Regime: Examining America's Intergovernmental Efforts to Achieve Accessible Health Care Coverage Through Medicaid

*Michaela Brook Bantilan**

I. INTRODUCTION

The health care industry in the United States is going through a precarious transition. Medicaid,[1] the nation's largest intergovernmental program, provides public insurance to over fifty-five million enrollees,[2] and a new legislative mandate[3] is underway to expand its coverage to an additional thirty-two million individuals by 2014.[4] While Medicaid plays a crucial role in protecting vulnerable populations of Americans,[5] the program's growing cost[6] and media attention[7] have revealed intergovernmental tensions that threaten the jointly financed and

* Juris Doctor Candidate, Loyola University Chicago School of Law, Class of 2013. Ms. Bantilan is a staff member of *Annals of Health Law*.

1. U.S. DEPT. OF HEALTH & HUMAN SERVICES, MEDICAID, *available at* http://www.healthcare.gov/using-insurance/low-cost-care/medicaid/index.html.

2. John K. Inglehart, *Expanding Eligiiblity, Cutting Costs- A Medicaid Update*, THE NEW ENGLAND JOURNAL OF MEDICINE, p.105 (Jan.12, 2012) *available at* http://www.nejm.org/doi/full/10.1056/NEJMp1113561.

3. Patient Protection and Affordable Care Act, Pub. Law 111-148, 124 Stat. 119 (2010) (to be codified in scattered sections of the U.S.C.), amended by the Health Care and Education Reconciliation Act of 2010, Pub.Law. 111-152, 124 Stat. 1029 (2010).

4. Benjamin D. Sommers & Arnold M. Epstein, *Medicaid Expansion – The Soft Underbelly of Health Care Reform?* THE NEW ENGLAND JOURNAL OF MEDICINE, p.2085(Nov. 25, 2010), [hereinafter Sommers] *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1010866.

5. *See* ROBERT B. HELMS, THE MEDICAID COMMISSION REPORT: A DISSENT, HEALTH POLICY OUTLOOK, p.1(Jan. 12, 2007) *available at* http://www.aei.org/article/society-and-culture/poverty/the-medicaid-commission-report/.

6. Tami Luhby, *Rising Medicaid Costs to Blow Hole in State Budgets*, CNN, (Sept. 30, 2010), http://money.cnn.com/2010/09/30/news/economy/medicaid_state_budget/index.htm

7. Sommers, *supra* note 4, at 2086.

administered program.[8] Rather than working together to lower costs and equalize quality across states, the contentious relationship between federal and state governments[9] could be detrimental to the program's efficacy and goals.[10]

Canadian citizens enjoy universal health care.[11] In Canada, provincial and federal governments work together to drive down health care costs[12] and guarantee its residents "reasonable access" to medically necessary services.[13] The 1984 Canadian Health Act (CHA)[14] established a publicly funded health care system[15] and a set of principles that require provinces to administer accessible, universal coverage to their citizens.[16] The Canadians also employ an equalization program that is reassessed annually to equalize budgets for health care services in each of Canada's provinces and territories so that citizens get reasonably equal services regardless of their location.[17]

In Section I, this article discussed qualities of the Canadian health care system, its intergovernmental relationship, its financing structure of intergovernmental transfers, and its equalization goals, that could benefit the U.S. Medicaid program. Next, Section II will provide more information

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8. Inglehart, *supra* note 2, at 105.
9. *Id.*
10. Helms, *supra* note 5, at 2.
11. CANADIAN INSTITUTE FOR HEALTH INFORMATION, EXPLORING THE 70/30 SPLIT: HOW CANADA'S HEALTH CARE SYSTEM IS FINANCED 1, 14 (2005), [hereinafter "CIHI"] *available at* http://secure.cihi.ca/cihiweb/products/FundRep_EN.pdf.
12. *See* Matthew S. Openshaw, *Prescription Drug Prices, Government Intervention, & Importation: Importing Drugs From Canada*, 23 NURSING ECONOMICS 307, 308 (Nov.-Dec. 2005), *available at* http://findarticles.com/p/articles/mi_m0FSW/is_6_23/ai_n17211609/.
13. *See* CIHI, *supra* note 11, at 15.
14. *Id.*, *citing* Canada Health Act, R.S.C., 1985, c. C-6, [hereinafter "CHA"] *available at* http://laws-lois.justice.gc.ca/PDF/C-6.pdf.
15. CIHI, *supra* note 11, at 15.
16. CHA, *supra*, note 14, at c.6, s. 7; *see also* CIHI, *supra* note 11, at 20. The five CHA principles that guarantee universal health care coverage to Canadian citizens are: public administration, comprehensiveness, universality, portability and accessibility.
17. *Equalization Program*, DEPARTMENT OF FINANCE CANADA, [hereinafter "Canada Equalization"] *available at* http://www.fin.gc.ca/fedprov/eqp-eng.asp.

about Canada's intergovernmental relationship and how its fiscal transfers and equalization program works. Section III will chronicle the historical background of the U.S. Medicaid program and a summary of the U.S. Federal Medical Assistance Percentage (FMAP) calculation. Section IV details why the U.S. must develop a similar effective intergovernmental relationship to cost-effectively negotiate for accessible health care like Canada's provincial-federal team. Additionally, this section explains why the U.S. needs to modify its fiscal measures of states' spending capacity and adopt the principles of Canada's equalization program.

II. THE CANADIANS' PUBLIC HEALTH CARE SYSTEM

The Canadian health care system is comprised of a set of publicly financed, provincially run insurance plans.[18] This single-payer system uses public funds to reimburse private physicians for providing medically necessary services to all citizens.[19] While offering universal coverage,[20] Canada's health care spending remains at least five percent less of their gross domestic product (GDP) than that of the U.S.[21] Both levels of government work together to provide accessible coverage and to ensure that services are relatively equalized across provincial borders.[22] Health care is a public good, and the federal equalization policy is designed "to ensure that provincial governments have sufficient revenues to provide reasonably comparable levels of public services at reasonably comparable levels of

18. Raisa B. Deber, Ph.D., *Health Care Reform: Lessons From Canada*, 93 AM. J. PUB. HEALTH 20, 20 (2003).

19. CIHI, *supra* note 11, at 51-2.

20. *Id.* at 14.

21. KAISER FAMILY FOUNDATION, HEALTH CARE SPENDING IN THE UNITED STATES AND SELECTED OECD COUNTRIES, (2011), *available at* http://www.kff.org/insurance/snapshot/oecd042111.cfm.

22. *Federal Role in Health*, HEALTH CANADA, [hereinafter "Federal Role in Canada"] *available at* http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fedrole/index-eng.php#a2.

taxation," which is written directly into the Canadian Constitution.[23]

A. Shared Responsibilities and Resources Between Federal and Provincial Governments

The federal government places responsibilities at the provincial level to cost-effectively administer and deliver health care services, but both levels of government work together to contain costs.[24] All program enrollees receive the same core services as described by the CHA,[25] which allows each province to bargain on prices with providers to maximize access to care.[26] Participating providers receive a fee per patient visit and their rates are negotiated between the provincial government and the province's medical associations on an annual basis.[27] Furthermore, most of Canada's hospital care is delivered in publicly funded hospitals, which are required by law to operate within their budget.[28] This province-based system provides legal mechanisms that encourage strong oversight and cost-containment on the provincial level.

Through shared costs, budgetary committees at both provincial and federal levels can use their market power to negotiate prices and fee schedules with providers to control costs.[29] The federal government also takes measures to ensure public health policy goals are met and that affordable.[30] For example, pharmaceutical costs are set at a global median

23. *See* Kirk J. Stark, *Rich States, Poor States: Assessing the Design and Effect of a U.S. Fiscal Equalization Regime*, 63 Tax L. Rev. 957, 957(2010); *see also* Canada Equalization, *supra* note 17, at 1.

24. Federal Role in Canada, *supra* note 22, at 1.

25. CIHI, *supra* note 11, at 20. The CHA's "comprehensiveness" principle provides a list of health services that must provinces must insure.

26. *See* Openshaw, *supra* note 12, at 308.

27. CIHI, *supra* note 11, at 51-2, physicians' salaries are larged based on fee schedules that are negotiated between provincial governments and medical associations each year.

28. James Fogarty, *Free for All in Canada*,MEDICAL INDEPENDENT 2 (June 16, 2011), available at http://www.medicalindependent.ie/page.aspx?title=free_for_all_in_canada.

29. *See* Openshaw, *supra* note 12, at 308.

30. *See id.*

by government price controls and are negotiated on an annual basis between suppliers and the federal government.[31] The federal government regulates the price of patented drugs on behalf of the public since these costs are often covered by private insurers or employer-based private insurance carriers.[32] Overall, both levels of the government work together to provide accessible care.[33]

B. Intergovernmental Grants and Canadian's Equalization Formula

Canada's universal health care is equalized across provinces by a federal equalization policy.[34] These intergovernmental fiscal transfers for health services have two central features: constitutionally guaranteed equalization transfers (EQT) and Canadian Health and Social Service Transfers (collectively CHST).[35] Although government funding for health care services comes primarily from the provinces, EQT and CHST funds from the federal government are provided as a combination of tax transfers and cash contributions to ensure health care services are provided at comparable standards across borders.[36] The federal government provides provinces with CHST funding for health care expenditures as long as they each abide by the CHA accessibility guarantees.[37] CHST funds are provided in the form of block funds to support health, post-secondary education and social services, and the provinces can flexibly use those funds at their discretion.[38] EQT funds are unconditional block grants to the less prosperous provinces that enable them to provide their residents with public services at taxation

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31. *Id.*
32. *Id.*
33. *Id.*
34. Canada Equalization, *supra* note 17, at 1.
35. *Federal Transfers to Provinces and Territories*, CANADA FINANCE, [hereinafter Fiscal Transfers in Canada] *available at* http://www.fin.gc.ca/access/fedprov-eng.asp.
36. Federal Role in Canada, *supra* note 22, at 1.
37. CIHI, *supra* note 11, at 15.
38. *Id.*

levels that are reasonably comparable to the wealthier provinces.[39]

These equalization transfers are meant to address fiscal disparities among provinces and are provided unconditionally in order to give each province great flexibility.[40] The payments are determined by measuring provinces' ability to raise revenues, known as "fiscal capacity."[41] Under a representative tax system (RTS), the amount of equalization aid that a province receives is determined by (1) that province's own per capita revenue capacity, and (2) comparison to the "Ten Province Standard," which is fiscal capacity averaged across all provinces.[42] The RTS formula measures the amount of money a province could raise from thirty-three different tax bases if each taxed at national average rates.[43] This calculates each province's national revenue performance, its fiscal capacity, as compared to the national average.[44] These fiscal capacities are recalculated annually to ensure provinces receive fair benefits from their EQT grants.[45]

III. MEDICAID IN THE UNITED STATES

In contrast, the costly U.S. Medicaid system suffers from misaligned, intergovernmental incentives that foster constant tension between the federal government and the states.[46] In the public sector, Medicaid is undeniably important for providing a patient safety net, supplying funds for

39. Canada Equalization, *supra* note 17, at 1.

40. *Id.*; *See also* EXPERT PANEL ON EQUALIZATION AND TERRITORIAL FORMULA FINANCING, ACHIEVING A NATIONAL PURPOSE: PUTTING EQUALIZATION BACK ON TRACK 18 (2006) [hereinafter Expert Panel] *available at* http://www.eqtff-pfft.ca/epreports/EQ_Report_e.pdf.

41. Expert Panel, *supra* note 40, at 19 (The basic approach is to assess the financial capacity of provinces to deliver public services).

42. Stark, *supra* note 23 at 974-5.

43. Stark, *supra* note 23, at 976.

44. *Id.* at 977.

45. *Id.* at 975.

46. *See* Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 442-43 (Dec. 2011).

the states, and generally supporting U.S. healthcare.[47] However, Medicaid's dual administration and undefined roles of federal and state responsibility have led to intergovernmental inefficiencies and conflict.[48] This is particularly troubling as the Patient Protection and Affordable Care Act (PPACA) plans to vastly expand enrollment by 2014.[49]

A. Historical Background

Medicaid is a joint federal-state program that Congress passed in 1965 to protect needy populations that would otherwise be uninsured.[50] The program provides open-ended funding from the federal government to the states as long as the states accept all applicants who meet both categorically "deserving poor" and "financial" eligibility requirements.[51] Misconceptions about these terms have led to varied eligibility requirements and benefits across the states, as well as intergovernmental disputes determining who is entitled to the program's support.[52] Additionally, states continue to ask for more federal funds but continuously fight for flexibility in carrying out the goals of the program.[53] The PPACA only intensifies this adversarial relationship by exacerbating the states' administrative and budgetary weaknesses.[54]

B. Medicaid Financing: Reassessing the FMAP

Medicaid offers matched federal funds in exchange for states' agreement

47. Huberfeld, *supra* note 46, at 433.
48. *See* Inglehart, *supra* note 2, at 1.
49. Benjamin D. Sommers & Arnold M. Epstein, *Why States are so Miffed about Medicaid- Economics, Politics, and the "Woodwork Effect,"* 365 NEW ENG. J. MED. 100, 100 (2011) [hereinafter Sommers & Epstein] *available at* http://www.nejm.org/doi/pdf/10.1056/NEJMp1104948.
50. *See* Helms, *supra* note 5, at 2.
51. *See* Huberfeld, *supra* note 46, at 445-6.
52. Sommers, *supra* note 4, at 2085.
53. Huberfeld, *supra* note 46, at 472.
54. Sommers & Epstein, *supra* note 49, at 100.

to fulfill certain conditions of using those funds toward medical assistance for mandatory categories of "deserving poor."[55] These funds are determined by the Federal Medical Assistance Percentages (FMAP) calculation[56] and are largely based on the states per capita income and its expenditures on Medicaid.[57] Unfortunately, the FMAP formula does not adequately reflect the different fiscal capacities of the states and does not take into account the circumstances of states with high concentrations of entitled citizens.[58] It also creates strong incentives for states to engage in accounting schemes that enhance federal funding, and for the federal bureaucracy to spend money controlling these schemes, in turn creating a "tug of war" of funds.[59] Simultaneously, flexibility from Medicaid waivers[60] has resulted in varied quality, many tending to lower quality and the amount of services for Medicaid beneficiaries.[61] Although Medicaid's ability to deal with welfare issues has varied between states, the federal government traditionally has not intervened in such matters.[62]

However, the PPACA plans to fundamentally federalize the definition of "deserving poor" by rejecting states' restrictive categories and developing a super-FMAP that provides federal funding for the newly eligible Medicaid population.[63] This supermatch of funds will initially provide funds for 100% of the new enrollees, then phase down to a 90% federal match by

55. Huberfeld, *supra* note 46, at 447.
56. 42 U.S.C. 1396d(b)(2006).
57. CHRISTIE P. PETERS, NATIONAL HEALTH POLICY FORUM, MEDICAID FINANCING: HOW THE FMAP FORMULA WORKS AND WHY IT FALLS SHORT 4 (2008).
58. Helms, *supra* note 5, at 4.
59. *Id.*
60. *See* 42 U.S.C. §1396n (2006) (recognizing waivers and incorporating them into the Medicaid program if it is cost effective and efficient and not inconsistent with the purposes of the Act).
61. Huberfeld, *supra* note 46, at 448.
62. *Id.* at 450.
63. *See* Patient Protection and Affordable Care Act, § 2001, 42 U.S.C. §1936a (2010) (expanding Medicaid to include not only "deserving poor" but also everyone else whose income is below 133% of the poverty line).

2020, and remain at that level indefinitely.[64] Although states only have to pay a small percentage of the costs, they have decried the Medicaid expansion as coercive and unconstitutional,[65] and will have to pick up the tab for currently eligible individuals that are expected to come out of the woodwork at the start of the PPACA.[66] Therefore, despite its expansion, the PPACA extenuates Medicaid's intergovernmental tension by continuing the divided governmental responsibility for administering the program.[67]

IV. STATES AND FEDERAL GOVERNMENTS: MIRRORING THE CANADIAN INTERGOVERNMENTAL ADMINISTRATION TO IMPROVE AMERICAN HEALTH CARE

State and federal governments need to unify their efforts to offer comprehensive, basic health services to Medicaid enrollees. The program's history is filled with states' inability to manage and pay for welfare medicine.[68] State deviation based on budgetary shortfalls is not the kind of experiments or variation that is beneficial for the program and the vulnerable populations it serves.[69] Modifying the FMAP to include Canada's equalization transfers or resemble Canada's intergovernmental administration would reap benefits for the U.S. Medicaid program.

A. Improving Intergovernmental Relationships to Combat Rising Costs Together

America's strained balancing act between imposing national standards

64. *Id.*; s*ee also* Health Care and Education Reconciliation Act of 2010, H.R. 4872, 111th Cong. § 1201 (2010) (the "supermatch" only applies to the newly covered population, which is substantial in terms of raw numbers protected to be at 34 million new enrollees).
65. Huberfeld, *supra* note 46, at 451.
66. Sommers & Epstein, *supra* note 49, at 100.
67. Huberfeld, *supra* note 46, at 453.
68. *Id.* at 472.
69. *Id.* at 472.

and respecting state jurisdiction has imposed difficulties on health policy.[70] Canada's public health system is ripe with intergovernmental relationships the U.S. can and should learn from. [71] The federal and provincial governments collaborate on various health policy and programming issues by strengthening partnerships through a series of conferences and dialogue.[72] Similar to the U.S. model, the role of Canada's federal government is limited in decision-making.[73] Although it occasionally attempts to influence policy directions through funding or suggesting guidelines, the provinces enjoy a great deal of discretion and flexibility.[74] One way the federal government exerts major influence is by defining the services that are required by the CHA's "comprehensiveness" principle.[75] Furthermore, constitutionally supported policies to equalize health services unite Canada's levels of government to maintain a relatively high level of care.[76] CHST and EQT transfer calculations allow the federal government to effectively measure each province's fiscal capacity and distribute funds to those most in need.[77] What sets Canada's system apart from the U.S. is that these funding mechanisms remove centralized political judgments in the allocation of funds and allow intergovernmental efforts to focus on cost-containment and quality for the publicly insured.[78]

The U.S. struggles to balance the needs of the states and the federal

70. *See generally* Sommers & Epstein, *supra* note 49; *see also* Deber, *supra* note 18, at 23-4.

71. *Federal/ Provincial/ Territorial Collaboration*, HEALTH CANADA, [hereinafter Canada Collaboration"] *avaialble at* http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/index-eng.php.

72. *Id.*

73. Deber, *supra* note 18, at 22.

74. *Id.*

75. *Id.*

76. Stark, *supra* note 23, at 957.

77. *Id.* at 977.

78. *Id.*

government regarding health care costs.[79] The U.S. Medicaid program already has a financial structure of large federal transfers made annually to states administering health care services.[80] Indeed, the Medicaid Act also requires certain services be provided to enrollees in each state.[81] Therefore, one main change the U.S. needs is improved intergovernmental dialogue toward political compromises for program reform and administration.[82] Currently, any discussion of reforming Medicaid funding policies is seen as a possible threat to the open-ended flow of federal funds to the states.[83] This is not conducive to any serious discussion of reform and will only continue the program's political stalemate. Federal and state governments need aligned federal incentives to focus on cost-containment and improved quality of care.[84] This can be done by updating the FMAP formula that has not changed since its genesis in 1965.[85]

B. Reassessing the FMAP to Equalize Health Care Services Across State Borders

Numerous nations throughout the world, such as Canada, have in place a complex system of "equalization" grants, whereby the central government makes fiscal transfers to ensure that resources available to state or provincial governments do not vary significantly.[86] The United States does not have such a system. In fact, since existing grants using the FMAP formula actually exacerbate the states' fiscal disparities, Medicaid enrollees

79. *See generally* Sommers & Epstein, *supra* note 49.
80. *See* Peters, *supra* note 57, at 4.
81. *See* 42 C.F.R. §440 (a list of required or mandatory services for states to provide under Medicaid).
82. *See* Helms, *supra* note 5, at 4.
83. *Id.*
84. *Id.* at 5. The dissonance between state incentives to expand eligibility and federal attempts to control program expenditures will only intensify as rising costs add pressure to federal and state budgets.
85. Peters, *supra* note 57, at 6.
86. Stark, *supra* note 23, at 957.

are left with health care that wildly varies in quality across states.[87]

Rather than attempting to impose a complex and expensive equalization regime on the U.S. Medicaid program,[88] modifying the outdated FMAP calculation could align governmental efforts to provide relatively equal health services nationwide.[89] Currently, the FMAP does not accurately measure fiscal capability, requiring states with fewer economic resources to exert greater fiscal effort to provide public services on par with wealthier states.[90] By modeling the FMAP closer to a RTS system that determines the CHST and EQT funds in Canada, the remodeled FMAP formula would take better account of the states' relative fiscal capacity in the federal allocation of funds.[91] In fact, public finance experts generally regard the RTS system as an alternative methodology that provides superior measures of states' fiscal capacities because it offers a broader definition of states' available economic resources.[92] If the U.S. Medicaid program incorporated RTS system measurements to de-politicize and more accurately reflect states' fiscal capacity, state and federal governments could focus their efforts toward improved administration and equalized services across states.

V. CONCLUSION

The U.S. Medicaid program could be more efficient, beneficial, and equalized across states. To improve the program, leaders need to adopt Canada's mechanisms for collaborative intergovernmental dialogues. The program also needs to incorporate Canada's RTS system of fiscal

87. Peters, *supra* note 57, at 5-6.

88. Stark, *supra* note 23, at 959. Beyond budgetary expenses, equalization policies are notoriously complicated and difficult to administer.

89. Peters, *supra* note 57, at 7.

90. Stark, *supra* note 23, at 1005-6.

91. *Id.* at 1006.

92. *Id.*; *see also* ADVISORY COMMISSION ON INTERGOVERNMENTAL RELATIONS, MEASURING STATE FISCAL CAPCITY: ALTERNATIVE METHODS AND THEIR USES 17-21(1986), *available at* http://www.library.unt.edu/gpo/acir/Reports/information/m-150.pdf (describing alternative methods of measuring states' fiscal capacity).

measurements and bolster its equalization goals.[93] It is imperative that the U.S take proactive measures to prepare for Medicaid's upcoming expansion in order to reign in costs and provide consistent, quality care to its beneficiaries.

93. Stark, *supra* note 23, at 1005-6.

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Shortfalls of the Canada Health Act: Overstatements of Financial Benefits and Potential Pitfalls for the Critically Ill

*Jeremy Ross**

I. INTRODUCTION

As portions of the Patient Protection and Affordable Care Act (PPACA) are contested through the United States federal courts[1], there is ongoing discussion about American health reform and how it could have been more ambitious in its scope of coverage and in the level of government involvement. According to an Associated Press poll conducted by Stanford University in late 2010, twice as many Americans think that the PPACA should have done more as think that the government should stay out of healthcare.[2] In fact, according to a New York Times/CBS poll, seventy-two percent of Americans think that there should be a government administered insurance plan.[3]

Furthermore, there is still talk of an entirely socialized system in the public discourse.[4] Those who favor a socialized system sometimes look to Canada's government health insurance system as a model.[5] One of the

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1. *See, e.g.*, Florida *ex rel.* Atty. Gen. v. U.S. Dep't. of Health and Human Servs., 648 F.3d 1235, 1328 (11th Cir. 2011).

2. *Poll: U.S. Wants More Health Reform, Not Less*, WWW.CBSNEWS.COM (Oct. 14, 2010, 3:54 PM), http://www.cbsnews.com/stories/2010/09/25/politics/main6899989.shtml.

3. Kevin Sack & Marjorie Connelly, *In Poll, Wide Support for Government-Run Health*, N.Y. TIMES 1, 1 (2009), *at* http://www.nytimes.com/2009/06/21/health/policy/21poll.html?_r=1&ref=us.

4. *See, e.g.*, Atul Gawande, *Getting There From Here: How Should Obama Reform Healthcare?*, THE NEW YORKER, Jan. 26, 2009, at 26-27

5. *See Id*. at 33.

claims made by President Barack Obama is that the U.S. healthcare system, in the way that it prices many consumers out of the healthcare market, causes far too many consumer bankruptcies, and that further reform would alleviate this unfortunate result.[6] The contention that bankruptcy rates will decrease, however, does not seem to be supported by the facts.

This article will look briefly at the history of the Canadian system of public healthcare and at comparative bankruptcy rates in the U.S. and Canada. I will offer a potential explanation for a portion of insolvencies in Canada by showing the unique role that private actions for reimbursement take in the Canadian system. By looking at an example of the convoluted process of administrative claims for reimbursement, it will become apparent that the Canadian system itself is not without pitfalls and compromises. These pitfalls jeopardize the health and finances of those who are most in need of life-saving health services.

II. THE CANADIAN HEALTH ACT

Canadian universal healthcare was introduced in measures throughout the course of the second half of the twentieth century. The march toward universal coverage started in Saskatchewan with the passage of the first iteration of the Saskatchewan Hospitalization Act in 1946.[7] From there, Canada moved progressively closer to universal coverage, with prepaid medical service covering more than ninety percent of Alberta residents.[8] By 1957, the federal government in Canada had passed a program that would cover fifty percent of the cost of any provincial health plan that

6. Invitation to the *Hamilton/Fairfield Democratic Club Healthcare Kickoff Organizing Meeting*, MY.BARACKOBAMA.COM, available at https://my.barackobama.com/page/event/detail/gpcqvz (last visited Mar. 4, 2012).

7. Saskatchewan Hospitalization Act, R.S.S. 1978, c. S-23, s.31 (Can.).

8. History, *Alberta Medical Association*, WWW.ALBERTADOCTORS.ORG (last updated: July 25, 2011), http://www.albertadoctors.org/bcm/ama/ama-website.nsf/0/72D6C5EEBCA2CA9787256E1C0056E7A8?OpenDocument.

provided universal inpatient and outpatient services, without any additional payments for specific services.[9]

It was not until 1985 that uniform healthcare in Canada was effectively guaranteed to all residents with the passing of the Canada Health Act.[10] In the modern bill, the federal government of Canada provides payment to the provincial governments for their healthcare programs provided that they meet five criteria.[11] The first such criterion is public administration: that is, that it be operated publicly, not-for-profit, and with direct governmental oversight.[12] The next criterion, comprehensiveness, requires that the provinces provide coverage for all "insured health services. . ." provided by physicians, dentists, and other qualified providers.[1314] The third criterion, universality, requires that all "insured persons" in the province be covered by the province's medical plan.[15] "Insured persons" are defined as those residents of the province who have resided there for at least three months and are neither a member of the Canadian Forces, nor a member of the Royal Canadian Mounted Police, nor a person serving a term of imprisonment.[16] The fourth criterion, portability, is met in part if the plan provides for services in other provinces and outside of Canada on a substantially similar basis to the services provided in the province.[17] Portability, as it relates to coverage outside of Canada, will be a focus of the

9. J. Gilbert Turner, *The Hospital Insurance and Diagnostic Services Act: Its Impact on Hospital Administration*, 78 CAN. MED. ASS'N, J. 768, 768 (1958), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1829926/?page=1.

10. Canada Health Act, R.S.C. 1985, c. C-6 (Can.), *available at* http://laws-lois.justice.gc.ca/PDF/C-6.pdf.

11. *Id*. s. 4, 7.

12. *Id*. s. 7, 8.

13. *Id.* s. 9**.**

14. *See, e.g.*, Ont. Ministry of Health and Long-Term Care, *Schedule of Benefits for Physician Services under the Health Insurance Act*, WWW.HEALTH.GOV.ON.CA, http://www.health.gov.on.ca/english/providers/program/ohip/sob/physserv/physserv_mn.html (last visited Mar. 24, 2012) (providing a list of insured services in Ontario).

15. R.S.C. 1985, c. C-6, s. 10.

16. *Id*. s. 2.

17. *Id*. s. 11.

second half of this paper. The fifth and final criterion, accessibility, is met in part if the plan "does not impede or preclude, either directly or indirectly whether by charges made to insured persons or otherwise, reasonable access to those services by insured persons."[18]

Ostensibly, the Canadian system for federal payment of provincial healthcare coverage outlined in the preceding paragraph provides coverage to all Canadian citizens in a manner that guarantees relative uniformity. While this proposition seems to be basically true, fundamental financial implications are often overlooked in the discussion of this system's efficacy.

One need not look any further than relative rates of bankruptcy to see how the implications of Canada's healthcare system are misinterpreted. The total number of consumer bankruptcies in Canada in 2007 was 79,796 out of a government-estimated population of 32,929,700.[19] [20][21] In contrast, the number of consumer bankruptcies in the U.S. in 2006 was 617,660 out of a government-estimated population of 299,398,484.[22] [23] This puts the rate of consumer bankruptcies in Canada at 242 for every 100,000 of

18. *Id*. s. 12(a).

19. Office of the Superintendent of Bankruptcy Canada, *Annual Statistical Report for the 2007 Calendar Year – Tables 1 to 5*, OSB.IC.GC.CA (last modified: Jan. 1, 2012), http://www.ic.gc.ca/eic/site/bsf-osb.nsf/eng/br01779.html#table2.

20. Statistics Canada, *Population by Year, by Province and Territory*, WWW.STATCAN.GC.CA (last modified: Sep. 28, 2011), http://www40.statcan.gc.ca/l01/cst01/demo02a-eng.htm.

21. Note that I have chosen to compare 2007 Canadian bankruptcy statistics to 2006 U.S. bankruptcy statistics. The reason for this comparison is that in 2007, the U.S. experienced a dramatic increase in consumer bankruptcies of approximately 35%, whereas Canada experienced a relatively minor increase in bankruptcies in 2008 of approximately 12% prior to which they had been relatively constant. I chose to compare the two most recent years for which there was little presumed statistical noise due to the global economic crisis.

22. U.S. Federal Courts, *Bankruptcy Cases Commenced, Terminated, and Pending during the Twelve Month Periods Ended Dec. 31, 2006 and 2007*, WWW.USCOURTS.GOV, http://www.uscourts.gov/uscourts/Statistics/BankruptcyStatistics/BankruptcyFilings/2007/1207_f.pdf.

23. U.S. Census Bureau, *Table 1: Annual Estimates of the Population for the United States, Regions, and States and for Puerto Rico: April 1, 2000 to July 1, 2006*, CENSUS.GOV, http://www.census.gov/popest/data/historical/2000s/vintage_2006/index.html.

population, versus 206 out of every 100,000 of population in the U.S. Unfortunately, due to both a limited amount of reliable historical data regarding bankruptcy rates and the gradual nature of Canada's introduction of universal coverage, an analysis of Canadian bankruptcy rates pre- and post-their enactment of universal health coverage is not feasible. A study published in The American Journal of Medicine, however, seems to buck the conventional wisdom on the relationship between increasing healthcare coverage and a subsequent decrease in the bankruptcy rate, finding that consumer bankruptcy rates in Massachusetts were not greatly affected by the enactment of universal healthcare there in 2006.[24] The relative rates of bankruptcy in the U.S. and Canada, coupled with the analysis of bankruptcy data in Massachusetts calls into question the notion that should universal health care be enacted, we would see a different bankruptcy picture.

Of course, the conclusion outlined above appears to be perplexing. It seems a reasonable assumption that in a system with universal government-provided coverage where there are no other obvious anomalies, the rate of bankruptcy would be lower than in a more market-based system where many individuals are priced out of the insurance market entirely. However, when you look at just a small sampling of private administrative actions for health care reimbursement in Canada, a problem becomes clear. Although the general populace seems to be in relatively good health in Canada, with a 2009 average life expectancy of eighty-one years compared to seventy-eight years in the U.S.,[25] those who become exceptionally ill, requiring treatment outside of Canada, appear to be at a unique financial disadvantage. In part, these instances of financial catastrophe are the result of the limits of the

24. David U. Himmelstein et al., *Medical Bankruptcy in Massachusetts: Has Health Reform Made a Difference?*, 124 AM. J. MED. 224, 224 (2011).

25. The World Bank, *Life Expectancy at Birth, Total (Years)*, WWW.WORLDBANK.ORG, http://data.worldbank.org/indicator/SP.DYN.LE00.IN.

portability requirement of the Canada Health Act.[26] Particularly, the portability requirement for medical care sought outside of Canada is explicitly set up to respect provincial legislation requiring pre-approval for such care.[27] I will examine the problematic administration of the portability requirement through a few decisions of the Health Services Appeal and Review Board of Canada's most populous province, Ontario.

III. CASE STUDIES

The case of *S.A. v. The General Manager, Ontario Health Insurance Plan*, is a clear demonstration of the potential personal financial and health dangers of the way Ontario's portability requirement is administered for those with serious medical conditions who require treatment outside of Canada.[28] Ms. A, a colorectal cancer patient at the Juravinski Cancer Centre in Ontario (Juravinski), was advised by her Canadian oncologist (Dr. Major) in October 2005 that her cancer had metastasized and that she should start treatment with Erbitux (cetuximab).[29] Dr. Major recommended that Ms. A receive infusions of Erbitux in the U.S., because although Erbitux could have been purchased in Ontario, Juravinski would not pay for her infusions.[30] Under Ontario's healthcare regulation, outpatient visits solely for the administration of "drugs, vaccines, sera or biological products" would not be covered by the Ontario Health Insurance Plan (OHIP).[31]

Ms. A filed an application with OHIP for pre-approval of payment for

26. Canada Health Act, R.S.C. 1985, c. C-6, s. 11 (Can).

27. *Id*.

28. S.A. v. Ontario (Health Insurance Plan), 2006 CanLII 79506 (ON HSARB) (Can. Ont.), *available at* http://www.canlii.org/eliisa/highlight.do?text=denial&language=en&searchTitle=Ontario+-+Health+Services+Appeal+And+Review+Board&path=/en/on/onhsarb/doc/2006/2006canlii79506/2006canlii79506.html.

29. *Id*. at 3.

30. *Id*.

31. *See* Health Insurance Act, R.R.O. 1990, Reg. 552 /8(1)(5)(iv) (Can.), *available at* http://www.e-laws.gov.on.ca/html/regs/english/elaws_regs_900552_ev002.htm#BK5.

out of country care in the U.S at the "private infusion clinic" of Dr. Isosceles Garbes (Dr. Garbes) in West Seneca, New York.[32] Her application was denied.[33] The reasons for denial were (1) that Erbitux treatment was still considered experimental and (2) that Erbitux treatment was available in Ontario, although not as a covered service under OHIP.[34] It is important to note that Erbitux was approved to treat advanced colorectal cancer in the U.S. in early 2004, nearly two years prior to Ms. A's application for payment.[35]

Ms. A began treatment at Dr. Garbes' clinic at a cost of U.S. $14,000 out-of-pocket per month, at the same time commencing her appeal of the OHIP decision to deny coverage.[36] After a little over a month, she was allowed to receive Erbitux at Juravinski under a Canadian federal Special Access Programme at a cost to her of U.S. $8,000 a month.[37] After three months of care at Juravinski under the Special Access Programme, she filed another application with OHIIP for pre-approval of out of country care, this time for treatment at the Roswell Park Cancer Center in Buffalo, New York.[38] Her application was approved, and she received Erbitux treatment at the Roswell Park Cancer Center completely covered by OHIP.[39] At this point, she had incurred around U.S. $30,000 in out-of-pocket costs for the administration of life-saving Erbitux treatment.[40]

The appellate panel affirmed OHIP's denial of coverage for Ms. A's

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32. *S.A.*, CanLII 79506 (ON HSARB) at 3.
33. *Id.*
34. *Id.*
35. F.D.A. News Release, FDA Approves Erbitux for Colorectal Cancer (Feb. 12, 2004), *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2004/ucm108244.htm.
36. *S.A.*, CanLII 79506 (ON HSARB) at 3.
37. *Id*.
38. *Id*.
39. *Id*.
40. *See id.*.

Erbitux treatment at Dr. Garbes' private clinic.[41] The regulation governing medical services outside Canada require that the services be performed at a hospital or health facility as defined by statute and that the services be generally accepted in Ontario and either be not available in Ontario or requiring travel out of Canada to avoid a delay that would result in death or medically significant irreversible tissue damage.[42] Interestingly, however, the appellate panel's denial of coverage for Ms. A's treatment was on the grounds that Dr. Garbes' office did not satisfy the statutory definition of "health facility."[43] The definition required that the facility be licensed, and, although Dr. Garbes was a fully licensed physician, his private clinic was not separately licensed.[44] The fact that Dr. Garbes' office's licensure was at issue in the case was not disclosed to Ms. A until after she had accumulated over $14,000 in medical bills there.[45] The appellate panel, however, did not view OHIP's failure to disclose the true reason for denial of payment as relevant and consequently, affirmed OHIP's decision to deny coverage of Ms. A's treatment at Dr. Garbes' offices.[46]

Additionally, with little fanfare, the appellate board denied coverage for the more than $20,000 in Erbitux treatment provided to Ms. A at Juravinski under the Special Access Programme.[47] The grounds for this denial were that Section 8(1)(5)(iv) of Regulation 552 of Ontario prohibits payment for medical visits that are solely for the administration of "drugs, vaccines, sera or biological products."[48] It is not at all clear in the record, how, given this regulation, Canada's healthcare system might cover such care outside of the

41. *Id*. at 8.
42. *Id*. at 4.
43. *Id*. at 7
44. *Id.*
45. *See id.* at 6.
46. *Id*. at 7.
47. *Id*. at 8.
48. *Id*.

inpatient hospital context.

The purpose of the aforementioned appellate tribunal decision is not to provide a reader with anything approaching a comprehensive view of Ontario's problems with the portability requirement. Rather, the account above is intended to illuminate something that distinguishes the Canadian from the U.S. system. Specifically, it is the dangerous effect of coverage decisions being administrative decisions that are in many ways akin to those that the Internal Revenue Service in the United States makes on a daily basis.[49] In this decision, the Ontario Health Services Appeal and Review Board denied coverage for care that Ms. A received in Canada under a Special Access Programme, all while Ms. A was receiving identical care covered by OHIP outside of Canada at a Buffalo, NY cancer center all at a higher cost to OHIP.[50] Any attempts to reconcile the Board's decision to deny reimbursement for past care with the fact of Ms. A's continued coverage for the same medical services out of country defies logic.

Even in cases where the appellate panel eventually ordered OHIP to reimburse patients for out-of-country medical care, the process is not without its own particular hardships, both financial and otherwise. One example of this is the case of *D.L. v. The General Manager, The Ontario Health Insurance Plan*.[51] In this appeal, Mr. L was contesting a denial of coverage to seek orthopedic surgery at a facility in Lake Worth, Florida for

49. The mechanism for opposing out of country coverage in Ontario works similarly to the Internal Revenue Code's anti-injunction provisions. That is, the party seeking coverage for out of country care must formally be denied coverage. Then, after being denied coverage and paying out of pocket for service, the patient must then initiate litigation to recover money already expended. This is analogous to the U.S. taxpayer first having to pay a tax and then suing to seek reimbursement only after the government makes a determination as to the applicability of the tax. *See* 26 U.S.C. § 7421(a) (2006).

50. *S.A.*, CanLII 79506 (ON HSARB) at 3.

51. D.L. v. Ontario (Health Insurance Plan) 2006 CanLII 79436 (ON HSARB) (Can. Ont.), *available at* http://www.canlii.org/eliisa/highlight.do?text=denial&language=en&searchTitle=Ontario+-+Health+Services+Appeal+And+Review+Board&path=/en/on/onhsarb/doc/2006/2006canlii79436/2006canlii79436.html.

a severe injury to his left shoulder.[52] After visiting his primary care physician, Mr. L waited three months to see a specialist, who was ultimately unable to perform the necessary surgery.[53] Mr. L waited an additional three months to see another specialist, who then advised him that it would be approximately one and a half to two years before he could perform the surgery.[54] Because of extreme pain that was preventing him from performing his job, Mr. L sought and received surgery almost immediately in the U.S.[55] Payment for this surgery was initially denied by OHIP on the grounds that the treatment was available in Ontario, although approximately two years later the Appeal and Review Board reversed and ordered OHIP to reimburse Mr. L.[56] It is easy to see how a system that often necessitates long drawn out procedures for reimbursement of medical care can lead to substantial financial burden, even when it is functioning properly.

Despite constitutional challenges to the PPACA pending,[57] it is still salient to examine how we might adapt our healthcare system in a way that optimally responds to complex health conditions and does not put personal healthcare and financial needs at odds with one another. It seems clear that a Canadian style single payer system as it exists is a less than ideal solution. Specifically, Americans have reason to fret over a system such as Canada's that allows provinces to be making highly technocratic decisions about what healthcare does and does not get paid for. The cases highlighted elucidate why we probably should not strive to a future where the payment of substantial healthcare bills depend on strict definitions of phrases such as

52. *Id*. at 2.
53. *Id*.
54. *Id*.
55. *Id*.
56. *Id*. at 5.
57. *See supra* p. 1 and note 1.

"health facility."[58]

IV. CONCLUSION

Although the piecemeal system of American healthcare is far from perfect, with respect to the most critically ill, Canada's system presents a bleak alternative. Claims during the U.S. healthcare debate that a socialized system will lead to death panels are of course ill founded and overstated.[59] Nevertheless, Canada's system presents a legitimate fear that when the government finances healthcare, it is often ill equipped to make coverage decisions and pay for the treatment of serious and life-threatening maladies when more immediate care is needed than the system can normally provide. Where a patient is unable to finance their own treatment, this reality may leave patients with few good options. In a system that in some cases requires its sickest to finance their own care, it is not hard to see how bankruptcy and the foregoing of available, but costly, out-of-pocket remedies might pose a significant threat.

58. *See S.A.*, CanLII 79506 (ON HSARB) *supra* note 28 at 7.

59. Jim Rutenberg & Jackie Calmes, *False 'Death Panel' Rumor Has Some Familiar Roots*, N.Y. TIMES, Aug. 14, 2009, *available at* http://www.nytimes.com/2009/08/14/health/policy/14panel.html?pagewanted=print.

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The Future of Dementia Care: What the U.S. Can Learn From Norway

Chris McAdam ∗

I. INTRODUCTION

Dementia care is a primary concern for the retiring "baby boom" generation both in the United States and abroad. As this spike in population begins moving into older age, there is a host of medical issues confronting governments. An expensive issue amongst seniors is the prevalence of dementia, which costs society approximately $172 billion a year.[1] Dementia is not a new disease; rather, as the population is living longer, it is becoming more prevalent, as it typically occurs later in life.[2] In the U.S., there are approximately 5.2 million people over the age of sixty-five suffering from Alzheimer's, and by 2030, that number is expected to increase by fifty percent to 7.7 million.[3] Currently, Alzheimer's disease is the sixth-leading cause of death in the U.S., and for those over sixty-five years of age, it is the fifth-leading cause of death.[4] The challenges presented by those suffering from dementia include expensive personalized care for both the government and individuals,[5] along with a lack of housing

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1. ALZHEIMER'S ASSOCIATION, FACT SHEET: NATIONAL ALZHEIMER'S PROJECT ACT (2010) *available at* http://www.kintera.org/atf/cf/%7BB96E2E84-AF7D-4656-9C86285306F00E19%7D/NAPA%20Fact%20Sheet%209-16.pdf.

2. *See* ALZHEIMER'S ASS'N, 2011 ALZHEIMER'S DISEASE FACTS AND FIGURES 17 (2011), *available at* http://*www.alz.org/downloads/Facts_-_2011.pdf.*

3. *Id.*

4. *Id.* at 20.

5. *See id.* at 35.

equipped to host dementia patients.[6] There is no cure for dementia, but research continues, making many prescriptions experimental.[7] Often referred to as "the long good-bye,"[8] patients suffering from dementia can live up to twenty years with the disease before dying, resulting in a heavy burden on their caregivers and government subsidized health programs.[9] Government action can help provide quality care and reduce the costly impact of this disease.

This article will first examine dementia and its impact on the population. Next, it will look at the health care system in Norway and provide a brief history of its development. This article will then describe how Norway's health care system has responded to the epidemic of dementia. Finally, this article will assess the action of the United States and apply lessons that can be learned from Norway's Dementia Plan 2015.

II. WHAT IS DEMENTIA?

The term dementia is an umbrella, under which several types of the disease fall.[10] Approximately 60-70% of those suffering from dementia have Alzheimer's disease, while 15-20% suffer from vascular dementia, which is typically the result of a stroke.[11] The remaining cases are from less frequently occurring brain diseases.[12]

The brain of an Alzheimer's patient begins to fail due to a breakdown of

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6. *See* Claudia Kalb, Aging: Small is Beautiful, The Daily Beast, http://www.thedailybeast.com/newsweek/2005/07/31/aging-small-is-beautiful.html (last visited February 19, 2012).

7. ALZHEIMER'S ASS'N, *supra* note 2, at 9.

8. Chris Matthews, *Your Mom's Not What She Was*, THE SHRIVER REPORT (Mar. 24, 2012, 3:56 PM), http://www.alz.org/shriverreport/matthews.html.

9. ALZHEIMER'S ASS'N, *supra* note 2, at 23.

10. *Id.* at 5.

11. NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., DEMENTIA PLAN 2015 11 (2008), *available at http://www.regjeringen.no/upload/HOD/Dokumenter%20KTA/Dementia Plan2015.pdf.*

12. *Id.*

communication between synapses located in the brain.[13] The brain's synapses decline in number, leading to the death of the neurons that host the synapses.[14] Patients with dementia suffer from impaired memory, thinking skills, communication, and orientation.[15] They have trouble performing daily tasks and "coping with everyday problems."[16] Personality changes are common, resulting in aggression, poor judgment, "anxiety, depression, suspiciousness, delusions and compulsive behaviors."[17] Dementia is a degenerative disease,[18] and those suffering from it will become progressively more dependent on assistance from unpaid caregivers, primarily family, or friends.[19]

III. NORWAY'S HEALTH SYSTEM

Norway has a reputation for one of the best health systems in the world; in 2000 it was ranked by the World Health Organization as having the eleventh best health care system.[20] The cornerstone of Norway's health system is the policy that "all inhabitants should have the same opportunities to access health services, regardless of social or economic status and geographic location."[21] Since shortly after its independence in the nineteenth century, Norway bases its health system on the response of the states and the municipalities to public health needs.[22] A step towards universal coverage came in 1967 with the passage of the National Insurance

13. ALZHEIMER'S ASS'N, *supra* note 2, at 8.
14. *Id.*
15. NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., *supra* note 11, at 11.
16. *Id.*
17. *Id.*
18. *Id.*
19. ALZHEIMER'S ASS'N, *supra* note 1, at 25.
20. WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2000 154 (2000), *available at* http://www.who.int/whr/2000/en/whr00_en.pdf.
21. JAN ROTH JOHNSEN, HEALTH SYSTEMS IN TRANSITION: NORWAY 1 (Vaida Bankauskaite ed., European Observatory on Health Systems and Policies, 2006), *available at* http://*www.euro.who.int/document/e88821.pdf.*
22. *Id.* at 13.

Scheme, which provides a public universal insurance and a minimum of social security for everybody regardless of income.[23] Also, in 1969, The Hospital Act introduced a unified system for all medical institutions, placing counties in-charge of "planning, building, and managing hospitals . . . "[24] The national government sets policies and doles out block grants to the five health regions for specialty care and the 431 municipalities for primary care.[25]

IV. NORWAY'S DEMENTIA PLAN 2015

In 2008, the Norwegian government recognized the growing epidemic of dementia and it implemented the Dementia Plan 2015.[26] The number of dementia patients is expected to double in the next thirty-five years, with the largest growth in the next ten to fifteen years.[27] Norway recognized that eighty percent of residents in nursing homes were suffering from some sort of dementia, and yet hardly any of these facilities were equipped to care for dementia patients.[28] The cost for caring for dementia patients in 1995 was fourteen billion NOK (Norwegian Krone) with gross expenditure for the entire health system on the municipal level around forty-five billion NOK.[29] The plan emphasizes three main areas of focus: day programs; living facilities better adapted to patient needs; and increased knowledge and skills.[30] The plan sets out to provide "a good quality of life . . . and . . . a meaningful day-to-day existence . . ." for dementia patients.[31]

Current care for dementia patients lacks services in the areas of social

23. *Id.* at 14.
24. *Id.*
25. *Id.* at 1, 51.
26. *See*, NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., *supra* note 11, at 7.
27. *Id.*
28. *Id.*
29. *Id.* at 13.
30. *Id.* at 7-8.
31. *Id.* at 9.

and cultural care.[32] Amongst dementia patients, approximately fifty percent live inside the home, yet only four percent of those patients have day programs adapted to their needs.[33] Day programs take place at an adult day center away from the primary residence where dementia patients have the opportunity to interact with others in a structured environment.[34] Daily activities at a center may include music or recreation, while having the convenience of a nurse or social worker on staff.[35] Day programs can provide a needed respite to family caregivers who often become overwhelmed by caring for their loved one.[36] There is a strong economic incentive for day programs as well. These programs allow dementia patients to remain living with primary caregivers, postponing institutionalization of the patient, which is paid for by the government.[37] The goal is to boost the capacity and quality of these programs " . . . with a greater emphasis on social education, occupational therapy, physiotherapy and social work."[38]

A substantial shortfall has been identified in the amount of residences equipped to provide quality care for dementia patients.[39] In Norway, it is estimated that approximately half of dementia patients are living in an institution; seventy-five percent of institutionalized patients have some sort of dementia disorder; and only a fraction of those institutions have adapted to care for these patients.[40] The Norwegian government estimates that approximately 37,000 housing units need to be constructed or renovated by

32. *Id.* at 11.
33. *Id.*
34. ALZHEIMER'S ASSOCIATION, CARE FINDER: FINDING THE CARE THAT'S RIGHT FOR YOU 7 (2010) *available at* http://www.alz.org/national/documents/brochure_carefinderguide.pdf.
35. *Id.*
36. NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., *supra* note 11, at 11.
37. *Id.*
38. *Id.* at 20.
39. *Id.* at 7.
40. *Id.* at 12.

2030 to properly care for these patients.[41] The ideal institutional dwelling for a dementia patient consists of small living groups that accommodate four to eight patients.[42] The "small is beautiful"[43] concept includes stable staffing, shared social activities, direct access to adapted outdoor space, and easily navigable floor plans.[44] The Norwegian State Housing Bank has designed and will administer a new grant scheme to encourage investment in these small-scale facilities.[45]

There is certainly greater expertise needed by health care providers, but also by caregivers and society at-large.[46] A stigma exists for those with dementia and their families, causing the disease to be hidden instead of seeking proper care.[47] When families are given guidance in dealing with dementia and caring for their loved ones, they themselves have a higher quality of life.[48]

The greatest challenge could be recruiting health and social services personnel into geriatrics.[49] The first key strategy is to retain current staff and invest in their development via professional training and schooling.[50] The government decided to add to the municipal care services an additional 10,000 new man-years (amount of time one person works in a year) equipped with professional training in dementia care.[51] In order to achieve this goal, the government aims to improve the professional status of working with the elderly, and producing better equipped health-care professionals by having all social service and health care educational

41. *Id.*
42. *Id.*
43. *Id.* at 9.
44. *Id.* at 12.
45. *Id.* at 17.
46. *Id.* at 8.
47. *Id.*
48. *Id.* at 12.
49. *Id.* at 13.
50. *Id.*
51. *Id.* at 17.

programs adapt their curriculum to include caring for dementia patients.[52] For those who have already obtained college-level degrees, the government will provide continuing professional education to those practicing in the areas of elder care and mental health, with the goal to reach 6,000 persons.[53]

V. CURRENT STATUS IN THE UNITED STATES

The United States lags behind other modern countries in developing a national plan that addresses preparing to care for the population growth of those suffering from dementia.[54] In 2011, dementia care in the U.S. constituted $183 billion worth of aggregate payments for health, long-term, and hospice care, with that number expected to grow to $1.1 trillion by 2050.[55] Seventy percent of dementia patients in the U.S. live at home, usually with family or friends, which is a greater percentage than the dementia patients in Norway.[56] Day programs for dementia patients averages $69 per day, assisted living averages $38,596 per year, and nursing home care ranges from $74,239 to $82,113 per year.[57] In 2009, the average cost of nonmedical home care was $160 per day.[58] Medicaid is the only federal program that covers the costs of a long-term nursing home stay, however, Medicaid requires beneficiaries to meet certain financial requirements demonstrating need before they can obtain coverage.[59]

In response to the growing epidemic of dementia, Congress unanimously passed, and the President signed into law, the National Alzheimer's Project

52. *Id.*
53. *Id.* at 18.
54. ALZHEIMER'S ASS'N, *supra* note 1.
55. ALZHEIMER'S ASS'N, *supra* note 2, at 35.
56. *Id.* at 39. NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., *supra* note 11, at 12.
57. ALZHEIMER'S ASS'N, *supra* note 1, at 39.
58. *Id.* at 40.
59. *Id.* at 39.

Act (NAPA) on January 4, 2011.[60] NAPA was passed with the purpose of guiding federal agencies as they make policy decisions, improving early diagnosis of Alzheimer's and related dementia, and improving the coordination of care and treatment of patients.[61] However, in creating a strategic plan for the U.S. to tackle dementia, perhaps we should look to the strategies that other countries are employing to battle this disease—namely Norway.

The challenges that the U.S. health care system faces are not identical, but the goals can be aligned. As opposed to Norway, ninety-five percent of adult day centers in the U.S. provide care for people with dementia.[62] However, at an average of $69 per day, the cost could be a barrier for use.[63] As discussed above, day centers can provide needed respite for caregivers and allow them to continue to function in the economy and society, while postponing the need for the patient to enter into an out-of-home facility.[64] The U.S. should adopt a policy that would extend access to these day programs because they greatly benefit people with dementia and can reduce the overall cost to public and private payers.[65]

Pertaining to assisted living facilities and nursing homes, some believe that an entire culture shift is necessary to affect positive change for dementia patients.[66] Of the thousands of care facilities, the vast majority of them follow a traditional hospital type model of long corridors, impersonal

60. ALZHEIMER'S ASS'N, FACT SHEET: NATIONAL ALZHEIMER'S PROJECT ACT (March 2011), *http://www.kintera.org/atf/cf/%7BB96E2E84-AF7D-4656-9C86-285306F00E19%7D/2011%20NAPA%20Factsheet.pdf.*

61. National Alzheimer's Project Act, 42 U.S.C. § 11225 (2011).

62. ALZHEIMER'S ASS'N, *supra* note 2, at 43.

63. *Id.*

64. NORWEGIAN MINISTRY OF HEALTH & CARE SERVS., *supra* note 11, at 11.

65. THE NAT'L ALZHEIMER'S STUDY GROUP, A NATIONAL ALZHEIMER'S STRATEGIC PLAN 34 (2008) *http://www.pioneernetwork.net/Data/Documents/NewPressRelease/National_Alzheimers_Strategic_Plan.pdf*

66. Kalb, *supra* note 6.

surroundings, and decades old buildings.[67] The Norwegian model of small facilities has a strong following in the U.S. as well, advocating that residences should accommodate no more than ten patients.[68] Patients respond positively to smaller environments with personal touches and opportunities for personal interactions and relationships.[69] However, this smaller, more personalized environment comes at a higher price tag, ranging from $4,300 to $5,500 per month.[70] In addition to a higher cost, these facilities are often considered assisted living facilities, not nursing homes, and are thus ineligible for government reimbursement.[71]

The NAPA advisory panel needs to take these matters into consideration when deciding how to ensure adequate housing for dementia patients. Reimbursement eligibility for these facilities needs to be expanded under Medicare and Medicaid. Also, to begin steering patients away from the traditional hospital model for living facilities, NAPA needs to include incentives for developers to adopt these smaller scale facilities. Norway has made it a priority to provide residences that put the dementia patient's care first, and the U.S. should follow this example.

Maintaining quality personnel to assist with daily activities and provide quality medical care is an enormous challenge. In the U.S., care providers are typically underpaid and receive little or no training, which leads to high turnover rates.[72] These working conditions will make it a national challenge to recruit the additional 3.5 million health care providers needed by 2030 to care for these patients.[73] NAPA should include funding that will provide investments in human capital; thereby establishing a labor

67. *Id.*
68. *Id.*
69. *Id.*
70. *Id.*
71. *Id.*
72. ALZHEIMER'S ASS'N, *supra* note 2, at 31.
73. *Id.*

foundation for the future of the health care industry. For those care positions where there is no high degree of medical training necessary, there should be affordable avenues for training, including programs at high schools and junior colleges. However, this shortfall exists on the professional side of the spectrum as well - only four percent of social workers, and one percent of registered nurses, physician assistants, and pharmacists identify themselves as specializing in geriatrics.[74] A condition of on-going certification for these professionals should be continued education that includes training in geriatrics and dementia. The elderly will represent the majority of health care consumers, and it is a national priority to ensure that those providing care are adequately equipped. Norway recognized this as a priority when it demanded continuing education and training for dementia, and the U.S. should consider doing the same.

VI. CONCLUSION

The passage of NAPA is a great first step towards committing the United States to providing the level of care and attention to dementia patients that is consistent with the respect and dignity that they deserve. Although the challenges of the U.S. are somewhat unique to our country, we can learn a great deal from the other countries that have already committed themselves to action in dealing with dementia. The U.S. should not avoid systemic changes that require investments today to bring about long-term savings and an elevated level of care. The one thing that the U.S. certainly cannot afford to do is nothing; inaction is dementia's greatest ally.

74. *Id.*

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Sex-Selective Abortion Law in China and Corresponding Conception in the United States

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I. INTRODUCTION

The debate over the regulation of birth is still in its infancy. Nowhere is this more apparent than in China and India, where the use of modern medical technology to determine gender for purposes of sex-selective abortion has ignited a debate over how to regulate and remedy the largest known gender imbalance in human history.[1]

The Chinese government has been directly and indirectly regulating its skewed sex ratio for decades, to little effect. Recent evidence that this practice is also prevalent in the U.S. among communities of Asian and Indian descent sparked substantial interest among state and congressional legislators. It is believed that the prevalence of son preference in such communities in the U.S. stems from the same cultural norms underlying such preferences in China, India, and South Korea,[2] though little is known about Chinese legal redress for pre-natal sex discrimination. This paper explores the Chinese legal and cultural conception of sex-selection in birth and discusses its impact on current and impending U.S. efforts to regulate

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1. Mara Hvistendahl, *Unnatural Selection: Choosing Boys Over Girls and the Consequences in a World of Men*, 6 PUBLIC AFF. (2011). China and India alone account for about 1/3 of the global population. However, the skewed birth totals of the two countries are so severe that they have ratcheted up the world gender ratio from 105 men for every 100 women (the natural ratio) to 107 men for every 100 women. *Id.*

2. Generations Ahead, Nat'l Asian Pacific American Women's Forum & Asian Communities for Reproductive Justice, Taking a Stand: Tools for Action on Sex Selection 3 (2009), *available at* http://napawf.org/wp-content/uploads/2010/01/Toolkit-final.pdf.

this area.

II. REGULATING BIRTH

After several decades of regulations aimed at balancing the birth ratios, China's male to female sex ratio is still rising.[3] In the 1960s and 1970s, the national birth ratio was 106 male births for every 100 female births.[4] In 2009, the Chinese Academy of Social Sciences (CASS) stated that the national birth sex ratio had erupted to 121.[5] Regional disparities are also striking. Some rural and urban provinces have seen such breathtaking disparities as 190 (Anhui) and 192 (Jiangsu) for second births and 227 for third (Anhui).[6] Building upon the work of Nobel-laureate economist Amartya Sen nearly two decades ago,[7] Mara Hvistendahl, author of *Unnatural Selection*, estimates the number of missing girls to be approximately 160 million and counting.[8] In 2005, the United Nations Population Fund (UNFPA) placed the total number of missing girls at 163 million in Asia alone.[9]

The perverted parity in birth ratios from the first-born to later births represents an equally disturbing component of this distortion in China and is perhaps the most significant indication of the widespread utilization of

3. Lesley Wexler, *Allowing Girls to Hold Up Half the Sky: Combining Norm Promotion and Economic Incentives to Combat Daughter Discrimination in China*, 7 CHI. J. INT'L L.79, 79 (2006).

4. Y Zeng, *Sex Ratio of China's Population Deserves Attention*, 9 CHINA POPUL. TODAY 1, 3-5 (1992).

5. VALERIE M HUDSON & ANDREA M. DEN BOER, *Bare Branches: Security Implications of Asia's Surplus Male Population*, 68 (MIT Press 2004).

6. Wei X. Zhu, *China's Excess Males, Sex Selective Abortion, and One Child Policy: Analysis of Data from 2005 National Intercensus Survey*, 338 BRITISH MED. J. 1211, T3 (2009).

7. *See generally*, Amartya Sen, *More Than 100 Million Women Are Missing*, *in* 37 N.Y. REV. BOOKS, Dec. 20, 1990, *available at* http://ucatlas.ucsc.edu/gender/Sen100M.html.

8. Hvistendahl, *supra* note 1, at 6. Not all missing girls are aborted or murdered following birth, of course, but sex-selective abortion has been attributed to the vast majority of this unnatural disparity. *Id*.

9. Christophe Guilmoto, *Sex-Ratio Imbalance in Asia: Trends, Consequences, and Policy Responses*, UNITED NATIONS POPULATION FUND (UNFPA), 1 (2005).

sex-selective abortion. In 1989, the sex ratio at birth was 105 for firstborns, but reached 121, 125, and 132 for second, third, and fourth parity births, respectively.[10] In 2005, the sex ratio had increased only to 108 for first parity births, but exploded to 143 and 157 for second and third parity births.[11] The extremely high incidence of boys among second births where first parity births are near normal ratios indicates that gender manipulation through sex-selective abortion is aggressively utilized in later pregnancies to ensure that later children are male.[12]

The scale of this misogynistic practice adduce drastic societal effects, particularly in China. Sex-selection has been tied to "bride trafficking"[13] from neighboring countries, increased suicide rates among Chinese women,[14] and increased crime (particularly rape), murder, and delinquency.[15] A 2009 review (published in the British Medical Journal (BMJ)) of the Chinese Academy of Social Sciences (CASS) study on population disruption noted that in 2005, there were just under 33 million Chinese men under the age of 20 in excess of natural birth ratios and that 1.1 million excess males were born just that year.[16] However, other

10. Zeng, *supra* note 4, at 3-5.

11. Zhu, *supra* note 6, at T3.

12. Research suggests that sex-selective abortion of potential female children is significantly more common when the first child born is female. *See, e.g.*, Jason Abrevaya, *Are There Missing Girls in the United States? Evidence from Birth Data*, 1 AMER. ECON. J. 1, 23-27 (2009) (noting that for families with two female children, the likelihood of trying for a third child is substantially higher than the second, as is the incidence that a boy will be born. . .).

13. *Add Sugar and Spice*, THE ECONOMIST, Apr. 7, 2011; *see also* Hvistendahl, *supra* note 1, at 159-166. Among Chinese bachelors, Vietnamese women serve as an important source for "mail-order" brides due to their cultural "sameness" and subservience.

14. *The Worldwide War on Baby Girls*, The Economist, Mar. 4, 2010. Chinese female suicide rates are already among the highest in the world, according to the World Health Organization. *Id.* Suicide is the most common form of death among Chinese rural women aged. *Id.* Frequently, young mothers drink agricultural fertilizers, which are easy to come by. *Id.* Journalist Xinran Xue attributes most of these suicides to the fact that young mothers cannot live with the knowledge that they have aborted or killed their baby daughters. *Id.*

15. Hvistendahl, *supra* note 1, at 197-201.

16. Zhu, *supra* note 6, at 1213.

estimates suggest that the Chinese government grossly underestimates the magnitude of the problem, placing current bachelor estimates at 90 million.[17] Gita Aravamudan argues in her 2007 book, *Disappearing Daughters: The Tragedy of Female Feticide*, "female infanticide is akin to serial killing. But female feticide is more like a holocaust. A whole gender is getting exterminated."[18]

Sex-selective abortion is not exclusive to China. It occurs in Korea, Taiwan, Vietnam, Singapore, India,[19] Pakistan, and the Caucasus (Armenia, Georgia, Azerbaijian).[20] Moreover, sex-selection abortion occurs in the United States as well. A 2008 study of the 2000 U.S. Census by the Proceedings of the National Academy of Sciences (PNAS) in the U.S. found substantial evidence of manipulation, particularly among children of higher parity births.[21] In 2009, an analysis of California's population exhibited a strong son bias among Chinese, Indian, and Korean families and surprisingly noted that empirical results suggested that gender selection was not being used to achieve a gender mix within a given family,[22] but rather, to have as few girls as possible. A 2011 study on Indian immigrants in the U.S. found that forty percent of the women interviewed had terminated

17. HUDSON, *supra* note 5, at 179-81.

18. Gita Aravamudan, *Disappearing Daughters: The Tragedy of Female Feticide*, xv-xvi (Penguin Books 2007).

19. Arindam Nandi & Anil Deolalikar, *Does a Legal Ban on Sex-Selective Abortions Improve Child Sex Ratios? Evidence from a Policy Change in India*, CENTERS FOR DISEASE DYNAMICS, ECON. AND POLICY, 2, (April 2011), *available at* http://www.cddep.org/publications/does_legal_ban_sex_selective_abortions_improve_child_sex_ratios_evidence_policy_change.

20. Carl Haub, *Surprising Son Preference in the Caucasus*, Popul. Reference Bureau (May 4, 2011), http://prbblog.org/index.php/2011/05/04/surprising-son-preference-in-caucasus/. Reference Bureau, May 4, 2011, *available at* http://prbblog.org/index.php/2011/05/04/surprising-son-preference-in-caucasus/. In the Caucasus, too, there was a large disparity in later parity birth sex ratios. In 2000-2004, the parity for third births in Armenia was about 140; in Azerbaijan, about 150; and in Georgia, about 145. *Id.*

21. Douglas Almond & Lena Edlund, *Son-Biased Sex Ratios in the 2000 United States Census*, 105 PROC. OF THE NAT'L ACAD. OF SCI. (PNAS) 5681, 5681-82 (April 15, 2008). *See also*, Jeff Jacoby, *Choosing to Eliminate Unwanted Daughters*, BOSTON GLOBE, Apr. 6, 2008.

22. Abrevaya, *supra* note 12, at 28.

prior pregnancies with female fetuses and that eighty-nine percent of women carrying female fetuses in their pregnancy at the time of interview later proceeded to abort.[23]

Many U.S. clinics have capitalized on this practice and directly advertise in Chinese-American and Indian-American newspapers and magazines offering various sex-selection techniques, termed "family balancing".[24] But this practice of fetal gender discrimination occurs among the broader American public as well. Sociological data indicates that while American parental sex preferences tend towards an equal number of male and female children, Americans have also exhibited strong son preference for first-born and only children.[25]

The debate over the role of government in regulating natural diversity in human birth has evolved remarkably little over time, despite thousands of years of cultural, medical, and legal progress. Consider two substantially contradictory views: in Pope Paul VI's *Humanae Vitae*, he argues that respect must be granted the natural course of reproduction which no man or government may overcome.[26] Paul VI's conception of the role of

23. Sunita Puri et al., *"There is Such a Thing as Too Many Daughters, But Not Too Many Sons": A Qualitative Study of Son Preference and Fetal Sex Selection Among Indian Immigrants in the United States*, 72 SOC. SCI. & MED. 1169, 1169-76 (2011). Another important finding in the study was that the women studied remained highly vulnerable to family violence and coercion even in the U.S., where cultural and societal influences for son preference are far less pervasive.

24. Sam Roberts, *U.S. Births Hint at Bias for Boys in Some Asians*, N.Y. TIMES, June 14, 2009.

25. April L. Cherry, *A Feminist Understanding of Sex-Selective Abortion: Solely a Matter of Choice?* 10 WIS. WOMEN'S L. J. 161, 171 (1995).

26. ". . .if the mission of generating life is not to be exposed to the arbitrary will of men, one must necessarily recognize insurmountable limits to the possibility of man's domination over his own body and its functions; limits which no man, whether a private individual or one invested with authority, may licitly surpass. And such limits cannot be determined otherwise than by the respect due to the integrity of the human organism and its functions. . ." Paul VI, Encyc. Letter, *Humanae Vitae: On the Regulation of Birth* (1968) *available at* http://www.papalencyclicals.net/Paul06/p6humana.htm. Charles Darwin also wrote on the natural course of reproduction, "individual differences between the members of the same species are admitted by every one to occur under a state of nature. . .I had always perceived, that rare and strongly−marked deviations of structure, deserving to be called

government is limited to only such role that permits the preservation of natural diversity of birth. Plato, in one of the earliest known precursors to modern eugenic theory,[27] posited instead that it is instead the obligation of a government of men to ensure that they produce only the most desirable offspring with the most desirable features[28] and advocated limiting diversity in birth through infanticide.[29] When viewed in a historical sense, sex-selective abortion differs remarkably little in effect from its predecessor, sex-selective infanticide.[30] So, too, our current understanding of government's role in regulating undesirable offspring has evolved remarkably little from that which accorded Plato's conception of "purity" in reproduction several thousand years ago.

The two most obvious candidates for the regulation of sex-selection in birth are to either interfere with access to information concerning the sex of the child or to begin regulating (or even criminalizing)[31] the personal nature

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monstrosities, could seldom be preserved through natural selection. . ." CHARLES DARWIN, DESCENT OF MAN AND SELECTION RELATED TO SEX 221 (Penguin Classics, 2nd ed. 1874), (Republished, 2004).

27. Eugenic theory, the selective breeding for certain desirable traits, is now often associated with the "racial hygiene" campaigns of Nazi Germany, selecting Jews, homosexuals, and the "hereditarily sick" for mass extermination. Christine A. Khalili-Borna, *Technological Advancement and International Human Rights: Is Science Improving Human Life or Perpetuating Human Rights Violations?* 29 MICH. J. INT'L L. 95, 101 (2007).

28. "'The offspring of the good, I suppose, they will take to the pen or créche, to certain nurses who live apart in a quarter of the city, but the offspring of the inferior, and any of those of the other sort who are born defective, they will properly dispose of in secret, so that no one will know what has become of them.' 'That is the condition,' he said, 'of preserving the purity of the guardians' breed.'" PLATO, *Republic*, Book 5, 460(c), vers. *Plato in Twelve Volumes*, Vols. 5 & 6 (Harv. Univ. Press 1987).

29. DIANE B. PAUL, CONTROLLING HUMAN HEREDITY: 1865 TO THE PRESENT 5 (Humanities Press 1995) (where Plato analogized animal and human breeding, elaborating that just as shepherds and breeders must purge their herds, so must the legislator purify the state). Eugenics was defined broadly enough by early medical geneticists so as to include prenatal diagnosis and other technologies. *Id.* at 3. Thus, post-natal infanticide is not the only mechanism thought to exist within the purview of modern eugenics. *Id.* Many argue that our enhanced ability to make reproductive choices has already ushered in an era of "new eugenics" that goes beyond mere bioethics debates in medicine. *Id*.

30. David M. Smolin, *The Missing Girls of China: Population, Policy, Culture, Gender, Abortion, Abandonment, and Adoption in East-Asian Perspective*, 41 CUMB. L. REV. 1, 13-14 (2011).

31. H.R. 3541, 112th Cong. (Dec. 1, 2011).

of the choice made. However, if the U.S. federal and state governments are to regulate in this area, they will have to tread very carefully to avoid running afoul of established law. How, then, to regulate the choice to manipulate the natural diversity in birth without interfering with the right to choose? These are questions that U.S. legislators are just beginning to explore.

It may concededly be overly simplistic to translate the legal solutions of one society to another. But a brief exploration of Chinese regulatory efforts, if not determinative, is certainly instructive.[32] First, China has been directly and indirectly regulating this problem for decades by attempting to adjust demographic behavior on state and provincial levels.[33] Second, Indian and South Korean birth sex ratios have regressed as a result of economic, land, and women's liberalization policies[34] that have, for the most part, already been implemented in China (and currently exist in the U.S.) to no avail. Despite this development in legislation, China's birth sex ratio is still rising. Finally, the Chinese understanding of sex-selective abortion in societal and legal relations contrasts significantly with our own. If no attempt is made to understand the historical regulatory regime and cultural motivations behind the decision to abort, future U.S. attempts at regulation cannot expect to have any impact.

III. SEX-SELECTION IN CHINESE LAW

Though references to birth control appear in Chinese medical books as early as 2000 B.C., the earliest laws regulating access to abortion in Chinese culture appeared towards the end of the Qing dynasty (1644-1911

32. "Laws are organic and they benefit from cross-pollination. We should keep our eyes open for innovations in foreign jurisdictions that, with some grafting and pruning, might be transplanted to our own legal system." Sandra Day O'Connor, *Secundum Legem*, INT'L JUD. OBSERVER, No. 4 (1997), *available at* http://bulk.resource.org/courts.gov/fjc/intobs04.pdf.

33. Wexler, *supra* note 3, at 84.

34. *See, e.g.*, Aravamudan, *supra* note 18.

A.D.).[35] Regulations dating back to the early Tang Dynasty (618-906 A.D.) created special legal codes protecting pregnant women from assault, certain methods of execution, and *duotai* (procured abortion) where the pregnancy was noticeable.[36]

The legal conception of fetal "personhood" in Chinese society, however, never developed in a manner similar to the Christian life beginning at conception or the Western legal life beginning at birth.[37] In Chinese society, human life evolves through stages of worthiness based not only on age and ability, but also on gender and class.[38] In a historically patrilocal society, where inheritance passed through the son and couples reside at the husband's parent's home,[39] daughters were not expected to support their parents when the parents reached advanced age.[40] Males inherited property and controlled land and effectively worked to support health, retirement, and pension costs of their parents.[41] A family was not "complete" without a son. The "worth" of a daughter was thus limited enough to justify infanticide on a significant scale.[42] As such, infanticide, while illegal, was

35. Bernard Luk, *Abortion in Chinese Law*, 25 AM. J. COMP. L. 372, 374 (1977). A list of toxic herbs crushed for pregnant women due to their purported abortifacient properties include: croton fruit, morning glory seed, Peking spurge, blister beetle, India pokeberry, musk, burred rhizome, zedoary tumeric rhizome, peach kernel, safflower, rhubarb root, immature bitter orange, and the bark of the Chinese cassia tree. *Id*. *See also*, C.K. Yun et al., *Potential Anti-Fertility Plants from Chinese Medicine*, 4 AM. J. CHIN. MED. 105, 107 (1976).

36. Susan M. Rigdon, *Abortion Law and Practice in China: An Overview with Comparisons to the United States*, 42 SOC. SCI. MED. 543, 544 (1996).

37. *Id.* at 546. However, the purported incompatibility does not bespeak a lack of value of the worth of the fetus in Chinese society. For example, a common expression upon the death of a pregnant woman was "one corpse, two lives". *Id.*

38. *Id.* at 547. Consistent with this view, the Chinese government has also imposed draconian eugenic controls mandating sterilization for those stricken by mental retardation, disease, and deficiency. Nicholas Kristof, *Chinese Region Uses New Law to Sterilize Mentally Retarded*, N.Y. TIMES, Nov. 21, 1989.

39. Wexler, *supra* note 3, at 100.

40. Rigdon, *supra* note 36, at 550.

41. Smolin, *supra* note 30, at 40-41.

42. Reports attributed largely to infanticide of a ratio of males to females as high as 135 to 100 in Jiangsu Province in the 1930s indicates that daughter discrimination is hardly a new phenomenon in China. X.T. FEI, PEASANT LIFE IN CHINA 34 (Oxford Univ. Press 1946).

not considered immoral. It was a "product of rational decision-making embedded in a peculiar cultural attitude toward life."[43]

Abortion has replaced infanticide (described by some as "post-natal abortion")[44] as the primary means of daughter discrimination. China's 1979 abortion law legalized abortions at up to twenty-eight weeks of gestation;[45] a significant change from the 1953 cap of ten weeks. But it was the introduction of ultrasound and amniocentesis in China in the mid-1980s which made gender-selective abortion procedures possible. Ultrasound and amniocentesis are both able to identify gender with nearly 100% accuracy in the first half of the pregnancy,[46] which allowed Chinese women to determine the sex of the child and subsequently abort based on the determined gender. A consequence of economic progress, there were more than 100,000 ultrasound machines in China in 1994.[47]

Since the mid-1980s, legal promulgations governing the regulation of birth have taken a wide variety of forms, often accompanying significant and sweeping changes to Chinese domestic polity. Between 1979 and 1985 alone, China passed and subsequently implemented over 400 new statutes and regulations, the majority of which dealt with economic reforms.[48] A new Chinese constitution was executed in 1982, offering broad pledges of gender equality.[49]

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43. JAMES Z LEE & WANG FENG, ONE QUARTER OF HUMANITY: MALTHUSIAN MYTHOLOGY AND CHINESE REALITIES, 1700-2000 60-61 (Harv. Univ. Press 1999).

44. *Id.* at 61.

45. Rigdon, *supra* note 36.

46. Abrevaya, *supra* note 12, at 5. Amniocentesis, generally performed between the fourteenth and eighteenth weeks of pregnancy, and ultrasound, generally performed between the sixteenth and twentieth weeks of pregnancy are both technologies introduced in the 1970s. *Id.* But evidence shows that neither medical technology was particularly prevalent in China until much later.

47. Khalili-Borna, *supra* note 27, at 118.

48. YuFan S. Wang, *The Triumph of Confucianism: How a Subjugated Legal System is Failing a Generation of Chinese Women and Girls*, 15 CARDOZO J. L. & GENDER 691, 706 (2009).

49. *Id.*

The 1980 Marriage Law proscribed female infanticide, stating, in relevant part, "infant drowning, deserting and any other acts causing serious harm to infants and infanticide shall be prohibited."[50] The 1992 Women's Protection Law established a progressive regime of women's interests, introducing a wide variety of legal rights pertaining to women's ability to inherit property, obtain fair labor wages, equal status in family matters, and achieve equality in education.[51] Its provisions also expressly prohibited discrimination and cruel treatment against women who gave birth to female babies.[52] This discrimination ban reflects some of the earliest focused efforts by the Chinese government to specifically combat the cultural misogyny underpinning the practice of sex selection. In addition, the "cruel treatment" language may properly be construed to reiterate restrictions going back to the Tang Dynasty forbidding assault of pregnant women and the subsequent causing of abortion by means of violence.

The 1994 Maternal and Infant Health Care Law shifted its focus to regulating the information received by the aborting mother by prohibiting the use of medical technologies such as ultrasound and amniocentesis to identify the gender of the fetus.[53] The regulation provided a necessary exception for medical grounds reviewed and certified by a physician.[54] This was later supplemented by the Regulation On Prohibiting Fetal Sex Identification and Selective Termination of Pregnancy for Non-Medical

50. Law of the People's Republic of China on Marriage, Art. 21, Sept. 10, 1980, amended with Decision Regarding the Amendment of Marriage Law of the People's Republic of China, Apr. 28, 2001.

51. *See generally*, Christine M. Bulger, *Fighting Gender Discrimination in the Chinese Workplace*, 20 B.C. THIRD WORLD L.J. 345, 364-65 (2000).

52. Law of the People's Republic of China on the Protection of Rights and Interests of Women, Art. 35, amended with the Decision Regarding the Amendment of the Law of the People's Republic of China on the Protection of Rights and Interests of Women, Aug. 28, 2005.

53. Law of the People's Republic of China on Maternal and Infant Health Care, Art. 32, Oct. 27, 1994.

54. *Id.*

Reasons in 1998[55] and the Population and Family Planning Law in 2002.[56] Both banned determination of fetal sex for non-medical services. Article 35 of the Population and Family Planning Law also expressly banned sex-selective pregnancy termination for non-medical reasons.[57] The impact of the technological ban has largely gone unmeasured, due to poor enforcement and easy means of avoiding prosecution. Where enforced, however, a possible effect of the technology ban would likely be a lower fertility rate where couples may be less inclined to have children for fear of having a girl.

IV. RECONCILING POLICY SUCCESSES & FAILURES

Chinese attempts to directly regulate this problem have proven largely ineffective.[58] Direct legal regulation was stunted by easily identifiable, macro-scale oversights: decades of lax enforcement; widespread availability of ultrasound and amniocentesis technology; no legal barrier to abortion; and potential abortion subsidization by the Chinese government.[59] A 2011 study done in India suggested that upon India's 1994 enactment of the Pre-Natal Diagnostics Techniques (PNDT) prohibiting diagnostic methods to identify the sex of the unborn child, the sex imbalance rose less rapidly than it otherwise would have had the law never been enacted, despite concessions that the PNDT was "unevenly and weakly enforced."[60] A

55. *See* Law of the People's Republic of China on the Regulation On Prohibiting Fetal Sex Identification and Selective Termination of Pregnancy for Non-Medical Reasons.

56. *See* Law of the People's Republic of China on Population and Family Planning, Art. 35, Dec. 29, 2001. Art. 35 states, in relevant part:

"Use of ultrasonography or other techniques to identify fetal sex for non-medical purposes is strictly prohibited. Sex-selective pregnancy termination for non-medical purposes is strictly prohibited."

57. *Id.*

58. *See generally*, AVRAHAM Y. EBENSTEIN & ETHAN J. SHARYGIN, *The Consequences of the "Missing Girls" of China*, 23 WORLD BANK ECON. REV. 399, 418-21 (2009).

59. Valerie M. Hudson, *The Missing Girls of China and India: What is Being Done?*, 41 CUMB. L. REV. 67, 69-70 (2011).

60. Nandi, *supra* note 19, at 20. This all despite the fact that the policy was largely

similar study has yet to be done on the equivalent Chinese prohibition, though the study clearly suggests an increase in enforcement would be quite beneficial. In 2006, Chinese authorities closed down 201 medical clinics and fined hundreds of others in the northern Hebei province when it was determined they were helping detect and abort female fetuses.[61] Frequent prosecution and publicizing of major crackdowns such as this would go much further in returning regional disparities to normal ratios.

Another failure of direct regulation is cultural. Family planning guidelines in China are generally considered "policy," not "law," and compliance is thus voluntary.[62] As noted above, abortion is envisaged in the context of economic and family well-being,[63] not individual "right" and is typically not regarded as improper.[64] The failure to criminalize an otherwise strictly cultural practice is a considerable policy flaw in the promulgation of the prohibition on sex selection. In addition to campaigns pressuring medical professionals not to release information regarding the sex of the child, a principal reason for South Korea's successful reduction of sex selection has been its criminalization of the practice.[65] China has not capitalized on the success of its neighbor and taken the necessary steps to

considered a failure. The authors further expressed optimism that India's expansion of provisions of PNDT in 2003 and strengthening of enforcement would positively shift the imbalance back in favor of female births. *Id.*

61. Joseph Kahn, *China: Crackdown on Abortion of Girls*, N.Y. TIMES, June 1, 2006, *available at* http://www.nytimes.com/2006/06/01/world/asia/01briefs-brief-003.ready.html?_r=5.

62. Rigdon, *supra* note 36, at 545.

63. A first born son is estimated, on average, 1.85 years of his parent's income whereas a first born daughter is worth 0.43 years of income, with regressive values attributable to second and third children. Avraham Ebenstein, *Estimating a Dynamic Model of Sex Selection in China*, Population Association of America, 4 (2011), *available at* http://www-leland.stanford.edu/group/SITE/SITE_2009/segment_9/segment_9_papers/ebenstein.pdf.

64. Pro-choice activists in the U.S. tend to think of access to abortion as a matter of individual freedom and female empowerment. In Chinese thinking, however, the birth is considered within the social context of family and state and much less credence is given to the individual nature of the choice. Sulamith Potter, *China's Peasants: The Anthropology of a Revolution* 231 (Cambridge Univ. Press 1990).

65. Guilmoto, *supra* note 9, at 10-11.

protect the next generation of young girls.

Authors on this subject have frequently posited that sex-selective abortion is an unintended consequence of China's one-child policy, but the connection remains tenuous at best. A primary reason cited in support of this theory is that population control policies push families to take the step of eliminating daughters because the policy "cuts off" the possibility of having an additional child.[66] In theory, a low fertility rate may be thought to provide an impetus for resort to sex-selective abortion in areas where son preference is strong.[67] However, if the one-child policy was the driving force behind the substantial growth in sex-selective abortions, the birth sex ratio parity would be significantly higher among first-born children. It would also be true that the sex ratio imbalance would have begun to increase almost immediately after the policy was implemented instead of nearly a decade later.[68] Finally, it would have been true that the Chinese government's efforts to limit population control enforcement and supplement a "two child" policy in provinces with highly skewed birth ratios would have changed sex-selection rates instead of exacerbated them.[69] As we have seen in the U.S. and other countries without such population controls, the absence of the one-child policy is not likely to significantly impact gender discrimination in affected communities.

Other indirect policies have also met with limited success. China has yet to provide a comprehensive economic and health insurance security

66. Smolin, *supra* note 30, at 6.

67. Haub, *supra* note 20, at 1.

68. Monica Das Gupta et al., *Why is Son Preference So Persistent in East and South Asia? A Cross-Country Study of China, India, and the Republic of Korea*, WORLD BANK POLICY RESEARCH WORKING PAPER, 3 (2003). These researchers noted that the sex-ratio didn't began to rise sharply until after 1985, 6+ years following the implementation of the Chinese "one-child" policy in 1979. *Id.* While it has been argued that China's family planning program may have exacerbated son preference, South Korea's similar sex ratios at birth absent such strict limitations lend to the argument that this problem is culturally-based rather than the unfortunate bi-product of an oppressive policy. *Id.*

69. Ebenstein, *supra* note 63, at T3.

program for its elderly population.[70] Fiscal security is one of the principal economic justifications for son preference,[71] though implementation of such a program for nearly two billion people is admittedly no easy task. Alternatively, the Chinese government has focused much of its national policy on reducing high poverty levels and low education, a correlation that is often cited in the U.S. to correspond to higher incidence of abortion (though not particularly sex-selective abortion).[72] However, the Economist noted a seemingly counterintuitive trend – that disparate sex ratios actually tend to rise with income and education.[73] In China, the "higher a province's literacy rate, the more skewed its sex ratio. The ratio also rises with income per head."[74]

A frequent solution offered by feminist observers of this problem – liberalization of women's rights – has also had practically no measurable effect on the Chinese sex ratio imbalance. In the early 1990s, South Korean birth sex ratios saw a remarkable recovery, largely due to laws concerning who may be head of household, inheritance rights, provision of credit, and other initiatives to promote the economic status of women.[75] All of these initiatives have been credited with South Korea's near-normalization of birth sex ratios.[76] China, too, has substantially improved the role of women in Chinese society in the last few decades and has been credited with "some of the world's most progressive gender-equality and women's protection

70. EBENSTEIN, *supra* note 58, at 419.
71. *Id.* at 416.
72. Lawrence B. Finer & Stanley K. Henshaw, *Disparities in Rates of Unintended Pregnancy in the United States*, 1994 and 2001, 38 PERSPECTIVES ON SEXUAL AND REPRODUCTIVE HEALTH, 90–96 (2006). China has seen some success in this area. It has made some strides in the last two decades in its efforts to provide compulsory education and drive economic growth for targeted rural areas. Zhang Tiedao et al., *Universalizing Nine-Year Compulsory Education for Poverty Reduction in Rural China*, WORLD BANK, 1 (2004).
73. The Economist, *supra* note 14.
74. *Id.*
75. Hudson, *supra* note 59, at 77.
76. *Id.*

laws on its booksFalse"[77] However, China has yet to see the results experienced by South Korea. The principal difficulty in furthering liberalization policies in China is that the current policies are weakly enforced and the potential effects of increased enforcement immeasurable.[78]

Targeted campaigns in regions with the highest disparities in birth sex ratio have proven most successful in reducing the disproportion. The Chinese government implemented a "Care for Girls" campaign in 2005 that offered cash and other incentives to families with daughters, scholarships for girls, and better housing or loans for targeted families.[79] The campaign also included several awareness-raising campaigns, as well as repressive measures against illegal abortions and infanticide.[80] The program experienced initial success, as the sex ratio imbalance has decreased in 24 counties from an average of 133.8 in 2000 to 119.6 in 2005.[81] Another venture entitled the Chaohu Experimental Zone Improving Girl-Child Survival Environment, jointly funded by the Ford Foundation and the United Nations Children's Fund (UNICEF), succeeded in lowering the sex ratio at birth from 125 in 1999 to 114 a mere three years later.[82]

The lessons from Chinese regulation are relatively straightforward: (1) criminalization of sex selection must serve as the cornerstone of any successful policy; (2) strict and thorough enforcement of the law must be a priority while retaining a commitment to promote influencing factors such as women's rights; (3) legislators must target through sagacious legislation the cultural and economic motivations for the prevalence of son preference; (4) legislators must simultaneously employ directed campaigns in areas with high incidences of sex-selective abortions which offer funding and

77. Wang, *supra* note 48, at 694.
78. *Id*.
79. Guilmoto, *supra* note 9, at 12.
80. *Id.*
81. Smolin, *supra* note 30, at 42.
82. Ebenstein, *supra* note 63, at 418-19.

other incentives to raise awareness of the issue in a given community or family unit and promote the equality, importance, and worth of girls in affected communities.

V. REGULATING "CHOICE" IN THE U.S.

Nearly forty years after *Roe v. Wade*, the difficulty of regulating "choice"[83] under a legal regime of individual, reproductive "privacy rights"[84] in the U.S. "prevents action on a problem of great importance".[85] One of the principal obstructions in employing a law that regulates "choice" on the U.S. federal or state level is that there is no requirement for women to disclose either privately or on the record their reasoning in coming to their choice. The application of heightened scrutiny under *Roe* and its progeny have torn to tatters nearly any look into the nature of "choice" as a facially invalid attack on such right.[86] Any legislation intended to regulate choice within a given cultural or communal context may be found to disparately impact immutable characteristics of alienage, national origin, or race. Any further attempt to implement policy initiatives to ban such abortions have been consistently obfuscated by powerful reproductive rights organizations such as the National Abortion Rights Action League (NARAL), National Abortion Federation (NAF), and Planned Parenthood.[87]

Yet, when gender becomes the basis upon which a gender right is effectuated, sex discrimination is necessarily implicated.[88] Many state and

83. Roe v. Wade, 93 S.Ct. 705, 727 (1973).

84. *Id.*

85. Hvistendahl, *supra* note 1, at 43.

86. *See generally*, Text of Senate testimony of Edward Whalen on *Roe v. Wade*, President of Ethics and Public Policy Center, June 22, 2005, *available at* http://www.eppc.org/programs/constitution/publications/pubID.2377,programID.39/pub_detail.asp.

87. *See, e.g.,* Pam Belluck, *If You Really, Really Wanted a Girl. . .*, NY TIMES, August 20, 2011.

88. Khalili-Borna also contends that developments in genetics technology may give rise to human rights violations pertaining to "discrimination based on genetic characteristics", which is banned by the United Nations Educational, Scientific, and Cultural Organization's

federal lawmakers have voiced their support for this construction during the most recent decade and have indicated increasing sensitivity to the need to implement regulations that limit this practice accordingly.[89] Illinois (1975)[90] and Pennsylvania (1982)[91] were the first to ban an abortion sought solely on the basis of the sex of the unborn. The 2008 introduction (and subsequent failure) of the first Pre-Natal Non-Discrimination Act (PreNDA) in the U.S. House of Representatives (House)[92] revitalized interest in the issue, as Michigan, Minnesota, and Oklahoma introduced bills banning sex-selective abortions in 2009.[93] Oklahoma and Arizona signed similar bills into law effective 2010 and 2011, respectively.[94] In 2010, Idaho, New Jersey, Georgia, Mississippi, and West Virginia all proposed eliminating sex-selection as well.[95] Finally, a second version of PreNDA was put forth in December 2011, citing a remarkable amount of national support for a blanket ban (86%),[96] passed through U.S. House Committee on the Judiciary on February 16, 2012 by a 20-13 vote and, at the time of this publication, awaits approval by the House.[97]

(UNESCO) Universal Declaration on the Human Genome and Human Rights. Khalili-Borna, *supra* note 27, at 102-105.

89. It is noteworthy to point out that the U.S. is not the only developed country to consider a ban. Much of Europe already bans sex-selection in abortion, particularly the United Kingdom (which hails from the same common law tradition). PARLIAMENTARY OFFICE OF SCIENCE AND TECHNOLOGY, *Sex Selection Postnote*, No. 198 (July 2003) *available at* http://www.parliament.uk/post/pn198.pdf.

90. 720 Ill. Ann. Stat. 510/6(8) (1975).

91. 18 P.A. C.S.A. § 3204 (1982).

92. H.R. 1822, Susan B. Anthony and Frederick Douglass Prenatal Nondiscrimination Act of 2009. H.R. 1822 was referred to the Subcommittee on the Constitution, Civil Rights, and Civil Liberties on April 27, 2009 and effectively died therein.

93. S.B. 799/H.B. 5125 (Mich. 2009); S.F. 1073/H.F. 1196 (Minn. 2009); H.B. 1595 (Okla. 2009).

94. AZ Rev. Stat. Ann. § 13-3603.02; 63 Okl. St. Ann. § 1-731.2.

95. H.B. 693 (Id. 2010); A. 162 (N.J. 2010); S.B. 529/H.B. 1155 (Ga. 2010); S.B. 2166 (Miss. 2010); H.B. 2302/S.B. 62 (W. Va. 2010).

96. HR 3451, Susan B. Anthony and Frederick Douglass Prenatal Nondiscrimination Act of 2011. Recent polls evidence eighty-six percent (86%) of Americans object to the knowing and deliberate choice to abort based on the sex of the child, including a substantial proportion of those who consider themselves pro-choice. *Id.* at 5-6.

97. Bill Summary and Status, 112th Congress (2011-2012), HR 3541, *available at*

The Arizona statute, upon which PreNDA II appears to be modeled, is particularly notable for its depth and attempt to address some of the gaps left by Chinese legislators. Arizona criminalizes only the "knowing" seeking of an abortion "based on the [sex] of the child. . .",[98] a standard that does not contemplate liability for negligent or even "reckless perform[ance]" of the act.[99] Arizona's choice to target close family members gets to the core of the coercive nature and motivations behind some discrimination that are often no fault of the woman seeking abortion. Husbands may threaten divorce, abandonment or violence.[100] One mother-in-law threatened to take poison if her daughter-in-law failed to produce a son.[101] Under Arizona law, a person who "uses force or threat of force to intentionally injure or intimidate any person for the purpose of coercing [sex-selection]" may be criminally liable.[102] Arizona also holds liable providers who "knowingly [do] not report known violators"[103] and prohibits acceptance of "monies to finance a sex-selection abortion."[104] While this would not prevent all sex-selective abortions from taking place in Arizona, this method has proven quite successful in China, where several well-publicized arrests served as sufficient warning to discourage others from operating clinics that offer selection-based services.[105] Finally, Arizona, like all states, jointly funds and operates with the federal government Medicare and Medicaid programs that provide social safety nets for families

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http://thomas.loc.gov/cgi-bin/bdquery/z?d112:HR03541:@@@L&summ2=m&.

98. AZ Rev. Stat. Ann. § 13-3603.02(A)(1).

99. 63 Okl. St. Ann. § 1-731.2(B).

100. Richard Miniter, *America's Male Only Child Policy?*, FORBES, Dec. 5, 2011.

101. *Id. S*ocietal discrimination is sometimes threatened as well, where female feelings of worthlessness may lead to suicide or difficulties living in a state of extreme familial conflict. Wexler, *supra* note 3, at 82.

102. AZ Rev. Stat. Ann. § 13-3603.02(A)(2).

103. AZ Rev. Stat. Ann. § 13-3603.02(D).

104. AZ Rev. Stat. Ann. § 13-3603.02(A)(3).

105. In Shenzen, China, a reward money policy was used with great success to report to local police ultrasound "clinics" that were specifically used for sex-determination. Hudson, *supra* note 59, at 71. Over 2,200 clinics were put out of business by Chinese officials. *Id*.

in need of fiscal security.

However, such efforts should not be limited to legal proscription. The federal government, pursuant to civil prosecution of offending health practitioners under PreNDA, might also be able to limit access to Medicaid dollars for those practitioners that have been found to engage in "selectionist" practices that offend equal protection of the laws.[106] In addition, an advisory opinion was issued by the American College of Obstetricians and Gynecologists (ACOG) determining that it was unethical for physicians to participate in sex selective abortions where the parents request an abortion based on family balancing, cultural grounds, or personal preferences.[107] Likewise, the American Society for Reproductive Medicine has opined that "serious ethical concerns" are implicated where such practice is pursued.[108] These ethical guidelines, though not typically binding on practitioners, should be binding on the profession and enforceable through licensing and associational mechanisms.

Other initiatives may include targeted state education programs and information campaigns in areas heavily populated with residents of Chinese, Indian, and Korean descent. These programs can promote the importance of women in U.S. society and discourage family in-laws and grandparents from pressuring pregnant women to produce sons. Adoption programs and orphanages that specifically cater to girls born of such

106. The Office of Inspector General (OIG) in the Department of Health and Human Services (HHS) is already equipped to enforce such laws, as they possess the authority to exclude as a remedy for misconduct any person or entity from federal health program benefits. OIG Special Advisory Bulletin, *The Effect of Exclusion from Participation in Federal Health Programs* (Sept. 1999), *available at* http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm. Were the statutory scope of "misconduct" expanded to include such detestable ethical practices suggested above, such authority could serve as a powerful disincentive to engage in such conduct.

107. American College of Obstetricians and Gynecologists (ACOG) Committee Opinion, *Sex Selection*, 4, No. 360 (Feb. 2007), *available at* http://www.acog.org/~/media/Committee%20Opinions/Committee%20on%20Ethics/co360.pdf?dmc=1&ts=20120212T1600368190.

108. Ethics Committee of the American Society of Reproductive Medicine, *Preconception Gender Selection for Nonmedical Reasons*, 861 (Jan. 18, 2001).

circumstances, coupled with eased restrictions on adoption procedures, cost, and counsel, may encourage the proliferation of young girls while simultaneously demonstrating a state's commitment to birth.[109]

VI. CONCLUSION

The opportunity to implement in the U.S. any lessons gleaned from Chinese regulation of this issue is limited by our legal conception of a choice to abort as an individual right, which differs greatly from the Chinese conception.[110] This should not, however, consequently limit alternative government efforts to combat gender-based discrimination in the womb to unenforceable or indirect legislation. A cursory review of Chinese regulation nominally implies that government must be permitted to directly censure the practice of sex-selective abortion where the intent to dispose based on gender can be clearly established. Further, state and local governments must be granted sufficient latitude in fashioning additional remedies to combat the use of sex-selection within their respective jurisdictions. As the debate over the regulation of birth continues into the coming decades, our laws must strive to preserve the natural diversity in birth by opposing the seed of misogyny that endeavors to dilute it.

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109. "The Constitution does not forbid a State or city, pursuant to democratic processes, from expressing a preference for normal childbirth." Webster v. Reproductive Health Services, 109 S.Ct. 3040, 3053 (1989).

110. While the Supreme Court's jurisprudence appears to protect a right to abortion, even for reasons of sex-selection, it is likely that a narrowly-framed statute may avoid the court's undue burden examination. In *Casey*, "the fact that a law which serves a valid purpose, one not designed to strike at the right itself, has the incidental effect of making it more [difficult] to procure an abortion cannot be enough to invalidate it." Planned Parenthood v. Casey, 505 U.S. 833, 874 (1992).

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Lessons From New Zealand: The "No-Fault" Alternative to Medical Malpractice

Jason A. Robin ∗

I. INTRODUCTION

The medical malpractice system in the United States has many flaws.[1] Patients face an uphill legal battle to obtain damages for their doctors' negligence.[2] Derided as a "forensic lottery," the tort model lacks fairness and consistency as victims with similar injuries often receive wildly disparate compensation.[3] Consequently, many injured patients forgo the process entirely, deterred by the lengthy and uncertain adjudication process.[4]

Few would blame them. The rancor that flows from lawsuits can be toxic.[5] The adversarial nature of litigation tears at the doctor-patient relationship, inducing silence and bitterness.[6] Where mistakes are accompanied by protracted struggles to apportion blame, doctors are less

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1. Michelle M. Mello, et al., *Administrative Compensation for Medical Injuries: Lessons from Three Foreign Systems*, THE COMMONWEALTH FUND 1, 1 (July 2011), *available at* http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2011/Jul/1517_Mello_admin_compensation_med_injuries.pdf.

2. *See id.*

3. Mello, *supra* note 1, at 1; Marie Bismark & Ron Paterson, *No-Fault Compensation in New Zealand: Harmonizing Injury Compensation, Provider Accountability, and Patient Safety*, 25 HEALTH AFF. 278, 282 (2006).

4. Mello, *supra* note 1, at 1.

5. Marie Bismark, No-Fault Compensation for Treatment Injury in New Zealand 5 (Mar. 12, 2008) (unpublished manuscript), *available at* http://www.tau.ac.il/law/cegla3/Bismark.doc.

6. David Studdert & Troy Brennan, *No-Fault Compensation for Medical Injuries: The Prospect for Error Prevention*, 286 JAMA 217, 218 (2001); Mello, *supra* note 1, at 1.

apt to report errors.[7] Researchers lose opportunities to reform procedures and improve training when physicians withhold data about mistakes.[8] Some physicians feel compelled to practice defensive medicine, ordering a battery of unnecessary tests to limit their liability,[9] which drives up the cost of healthcare.[10]

Ironically, there is no conclusive proof that fault actually deters negligence.[11] For these reasons, alternatives to the tort model deserve consideration, and New Zealand offers one such alternative. In New Zealand, victims of medical errors receive compensation without having to prove that their doctor was at fault.[12] This article will explore the pros and cons of New Zealand's "no-fault" model to ascertain its viability in the United States.

II. BACKGROUND

New Zealand abandoned personal injury torts in the 1970s as part of a movement to broaden the scope of disability insurance.[13] Widespread dissatisfaction with the variability of coverage under the tort regime prompted calls for reform.[14] Created in 1967, a special committee called the Woodhouse Commission concluded that the government should bear the cost of injuries, regardless of fault, when victims of accidents lose their self-sufficiency.[15] Under the proposed scheme, injured New Zealanders

7. Studdert & Brennan, *supra* note 6, at 218; Mello, *supra* note 1, at 1.
8. Bismark, *supra* note 5, at 1; Mello, *supra* note 1, at 1.
9. Mello, *supra* note 1, at 1-2.
10. *Id.*
11. Bismark & Paterson, *supra* note 3, at 279.
12. *See* Studdert & Brennan, *supra* note 6, at 219.
13. Allen B. Kachalia, et al., *Beyond Negligence: Avoidability and Medical Injury Compensation*, 66 SOC. SCI. & MED. 387, 391 (2008).
14. Bismark, *supra* note 5, at 2.
15. Bismark & Paterson, *supra* note 3, at 279; Mello, *supra* note 1, at 2.

would waive their right to sue in exchange for compensation.[16] So long as the injury qualified for coverage, New Zealanders could apply for state-funded entitlements.[17]

In 1974, the Accident Compensation Corporation (ACC) was created to adjudicate a wide swath of personal injury claims ranging from workplace injuries to "domestic cooking accidents and injuries sustained in sporting activities."[18] However, owing to its emphasis on workers' compensation, the initial legislation left medical injuries inadequately defined.[19] It simply provided for reimbursement in the event of "medical, surgical, dental or first aid misadventure" without elaboration.[20] The ACC and the courts struggled to flesh out the parameters of coverage under the medical misadventure standard until 1992, when the legislature introduced the concepts of *medical error* and *medical mishap*.[21]

A *medical error* was defined as an injury attributable to negligence requiring proof of individual error.[22] Under the medical error standard, the specter of liability remained, bothering doctors who complained that it "hindered open communication and delayed compensation."[23] In contrast, a *medical mishap* was defined as a rare and severe consequence of proper treatment.[24] Rare meant occurring in less than one percent of cases.[25] An injury was classified as severe if it resulted in more than fourteen days in the hospital, "significant disability lasting more than 28 days, or death."[26]

16. Bismark & Paterson, *supra* note 3, at 279.
17. *See id.*
18. Kachalia, *supra* note 13, at 391.
19. *Id.*
20. Bismark & Paterson, *supra* note 3, at 279.
21. *Id.*; Kachalia, *supra* note 13, at 391.
22. Bismark & Paterson, *supra* note 3, at 279.
23. *Id.*
24. Mello, *supra* note 1, at 4.
25. Bismark & Paterson, *supra* note 3, at 279-80.
26. Kachalia, *supra* note 13, at 399.

In practice, these criteria were difficult to apply.[27] In addition, only injuries sustained from "active treatment" qualified.[28] Consequently, injuries resulting from omissions, such as the failure to diagnose, were not entitled to compensation.[29]

III. TREATMENT INJURY

On July 1, 2005, the ACC eliminated the vestiges of fault by adopting the "treatment injury" standard.[30] This most recent legislation aimed to expand coverage[31] and remove a source of tension between physicians and patients.[32] Physicians welcomed the shift because many considered the previous medical error standard "punitive and stigmatizing."[33] Broadly defined, "treatment injury" encompasses all personal injuries that a patient may suffer at the hands of a health professional, so long as the injury is not a "necessary and ordinary" consequence of treatment.[34] Patients still must establish causation, but without the added burden of proving fault, rarity, or severity.[35] However, some barriers to compensation have endured.[36] Isolating the causal factor, for instance, will remain a challenge in complicated cases.[37] Moreover, it is not clear what constitutes a "necessary and ordinary" consequence of treatment.[38]

Aside from these ambiguities in the eligibility criteria, the ACC has

27. *Id.*
28. *Id.*
29. *Id.*
30. Kachalia, *supra* note 13, at 399; Bismark & Paterson, *supra* note 3, at 278.
31. Kachalia, *supra* note 13, at 399.
32. *See* Mello, supra note 1, at 4.
33. Kachalia, *supra* note 13, at 392.
34. Bismark, *supra* note 5, at 3.
35. *Id.*
36. Kachalia, *supra* note 13, at 400-1.
37. *Id.*
38. *Id.* at 399.

made the claims process straightforward and easy to navigate.[39] Patients file a claim through a physician of their choice.[40] Any doctor may initiate the claim – not necessarily the one involved in the injury.[41] After reviewing the medical records, a panel of neutral experts determines whether the injury satisfies the eligibility criteria.[42] Claim handlers rely on precedent and institutional memory for guidance,[43] but outside experts might be consulted in complicated cases.[44] If displeased with the outcome, the claimant has the right to appeal in court.[45] Ultimately, the ACC accepts about sixty percent of the claims that are submitted.[46]

A qualified claimant may obtain coverage for treatment costs, rehabilitation, weekly compensation for loss of earnings up to eighty percent of previous wages, and lump sum compensation for noneconomic losses due to permanent impairment up to $85,000.[47] While the average compensation per claim is low ($4,450) compared to the United States ($324,000),[48] this figure is somewhat misleading because New Zealand's universal healthcare system shares the compensation burden with the ACC.[49] Pursuant to its "collateral-source offset" rules, the ACC avoids paying for expenses such as hospital care, prescription drugs, and other expenses, which get charged to the national insurance system.[50]

While the law mandates that claims be processed within nine months of

39. *See* Bismark & Paterson, *supra* note 3, at 280.
40. Mello, *supra* note 1, at 5.
41. It is typical for the patient's general practitioner to serve as the filing physician. Kachalia, *supra* note 13, at 391.
42. *Id.* at 400.
43. *Id.*
44. Mello, *supra* note 1, at 6.
45. However, few claims reach this level of review. Kachalia, *supra* note 13, at 392.
46. *Id.* at 390.
47. Bismark, *supra* note 5, at 3-4; Bismark & Paterson, *supra* note 3, at 280-81; Mello, *supra* note 1, at 7.
48. Mello, *supra* note 1, at 7.
49. *See* Bismark & Paterson, *supra* note 3, at 281.
50. *See* Bismark & Paterson, *supra* note 3, at 281; *see also* Mello, *supra* note 1, at 6-7.

filing,[51] generally, straightforward claims can be resolved within sixteen days.[52] This quick turnaround is a distinguishing feature of the New Zealand scheme. In the United States, it often takes four to five years to resolve a negligence dispute.[53] Administrative efficiency contributes to low overhead costs, which account for ten percent of the total cost of the system.[54] Hence, patients receive the lion's share of every dollar that goes into the ACC budget.[55] In contrast, legal and administrative expenditures account for fifty-five to sixty percent of total costs in the United States.[56]

Critics of no-fault contend that it promotes a lack of accountability.[57] Where substandard care goes unpunished, doctors have less incentive to improve their performance.[58] However, New Zealand does have a mechanism for physician discipline.[59] In the event a doctor poses a "risk of harm to the public," the Medical Council of New Zealand may request a competence review.[60] Educational rather than disciplinary, the review is meant to identify and correct deficiencies in the doctor's practice.[61] Thus, New Zealand proves that a no-fault regime can be structured to promote accountability.[62]

In theory, error reporting should increase under the no-fault model

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51. Farzad Soleimani, *Learning from Mistakes in New Zealand Hospitals: What Else Do We Need Besides "No-Fault"?* 119 J. N.Z. MED. ASSOC. 1, 2 (2006), *available at* http://journal.nzma.org.nz/journal/119-1239/2099/.

52. Mello, *supra* note 1, at 5.

53. Kachalia, *supra* note 13, at 400.

54. Bismark & Paterson, *supra* note 3, at 281.

55. *See Patient Compensation for Medical Injuries: International Approaches* (July 7, 2011), http://www.commonwealthfund.org/~/media/Files/Podcast/New%20Directions%20in%20Health%20Care/Compensation_transcript_final.pdf.

56. Mello, *supra* note 1, at 7.

57. *See* JOCELYN BOGDAN, MEDICAL MALPRACTICE IN SWEDEN AND NEW ZEALAND: SHOULD THEIR SYSTEMS BE REPLICATED HERE? 5 (Center for Justice & Democracy 2011).

58. *See Id.*

59. Mello, *supra* note 1, at 7.

60. Bismark, *supra* note 5, at 7.

61. *Id.*

62. *See* Studdert & Brennan, *supra* note 6, at 220.

because the punitive consequences of disclosure are reduced.[63] As reporting contributes to a database for study, quality of care is supposed to improve as well.[64] Proponents base this proposition on an analogy to other industries, such as aviation and nuclear power, where error reporting has led to gains in safety.[65] However, error reporting in New Zealand is not as robust as expected, and recent studies indicate that New Zealand's healthcare system is not demonstrably safer than that of the United States.[66] The risk is one percent that a patient will suffer a preventable adverse event, which approximates the risk of the same occurring in a tort jurisdiction.[67] One study concluded that no-fault has yet to fulfill its promise in terms of "facility of quality improvement."[68]

According to a 2006 survey, doctors in New Zealand attribute their reluctance to report errors to the fear of losing patient trust and the threat of public outcry, among other factors.[69] Sensitive to negative portrayals in the media, physicians complain about "doctor bashing" that follows from disclosure of mistakes.[70] The study suggests extending confidentiality to reporting of errors to insulate doctors from unwarranted media scrutiny.[71]

IV. REPLICATING NO-FAULT IN THE UNITED STATES

Implementing no-fault in the United States will not be without its challenges. Controlling costs will require careful drafting of the eligibility criteria. The treatment injury standard in New Zealand may be too broad

63. BOGDAN, *supra* note 57, at 5.
64. Soleimani, *supra* note 51, at 1.
65. *Id.* at 2.
66. *See id.*; Peter Davis et al., *Preventable In-hospital Medical Injury Under the "No Fault" System in New Zealand*, 12 QUALITY & SAFETY IN HEALTH CARE 251, 254-55 (2003).
67. Soleimani, *supra* note 51, at 2.
68. *Id.* at 1.
69. *Id*. at 5.
70. *Id.* at 8.
71. *Id.* at 9.

for the United States,[72] where it may cause an unmanageable influx of minor claims.[73] The survival of the ACC is attributable in part to New Zealand's universal healthcare system, which absorbs many expenses associated with treating iatrogenic injuries.[74] Furthermore, the culture is not so litigious and patients who sustain injuries due to negligence are unlikely to submit a claim.[75] One study placed the ratio of potentially compensable adverse events to successful claims in New Zealand at thirty-to-one.[76] To ensure sustainability, U.S. policymakers should consider enacting disability thresholds — similar to New Zealand's rare and severe criteria under its previous no-fault regime — to exclude claims for minor injuries.[77]

Policymakers should expect resistance from the plaintiffs' bar, and it is a foregone conclusion that the legality of no-fault will face scrutiny in court.[78] Because the success of no-fault hinges on the waiver of the right to sue, planners must anticipate the legal arguments that a patient can raise to void the waiver.[79] For instance, the patient may argue that she did not give informed consent because of some defect in the notification procedure.[80] On this point, policymakers can learn from Florida's Birth-Related Neurological Injury Compensation Plan (NICA), which provides coverage on a no-fault basis for newborns who sustain severe neurological injuries during delivery at the hands of their obstetrician.[81]

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72. Kachalia, *supra* note 13, at 399.
73. David M. Studdert & Troy A. Brennan, *Toward a Workable Model of "No-Fault" Compensation for Medical Injury in the United States*, 27 AM. J.L. & MED. 225, 232 (2001) [hereinafter *Toward a Workable Model*].
74. *See* Bismark & Paterson, *supra* note 3, at 281.
75. *Id.*; Mello, *supra* note 1, at 8.
76. Bismark & Paterson, *supra* note 3, at 281.
77. *See Toward a Workable Model*, *supra* note 73, at 232.
78. *Id.* at 235.
79. *Id.* at 239.
80. *Id.* at 235.
81. *Id.* at 234, 240.

In *Galen v. Braniff*, the obstetrician and hospital failed to give pre-delivery notice of their involvement in NICA.[82] Consequently, the Florida Supreme Court refused to enforce the exclusivity clause that would have made NICA the plaintiff's sole remedy.[83] The court found that without adequate notice, the patient could not "make an informed choice between using a health care provider participating in the NICA plan or using a provider who is not a participant and thereby preserving her civil remedies."[84] To ensure compliance with the enabling statute, the court insisted that obstetrical patients receive an informational brochure explaining their rights under the no-fault alternative.[85] In light of *Galen*, physicians in any no-fault program would be wise to put patients on notice at their first meeting to counteract the argument that the plaintiff could not give informed consent because the doctor did not timely disclose her participation.[86]

However, full information alone will not suffice. Patients must volunteer their consent freely.[87] This could be problematic because courts might find that there is coercion if the patients live in a region that offers limited healthcare options or they feel compelled to agree in order to remain in the good graces of their doctor.[88] Plaintiffs may also assert a related contractual claim that the tort waiver was adhesive by arguing that an imbalance of bargaining power denied the patient a meaningful choice, thereby rendering the agreement unenforceable.[89] To address this inequality, one scholar suggests placing "an agent between the patient and

82. Galen of Florida, Inc. v. Braniff, 696 So. 2d 308, 309 (Fla. 1997).
83. *Id.*
84. *Id.* at 310.
85. *Id.*
86. *Toward a Workable Model*, *supra* note 72, at 234.
87. *Id.*
88. *Id.*
89. *Id.* at 236.

participating institution/provider that is capable of negotiating participation with the patient's best interests in mind."[90] The patient's employer, for instance, can serve as the third party agent if the patient obtains coverage under the employer's health plan.[91]

It is critical that courts reject attempts to circumvent the jurisdiction of no-fault.[92] If courts vitiate tort waivers, it will promote duplicative claiming in no-fault and tort venues, enabling patients to game the system in order to maximize financial payouts.[93] Florida encountered this problem with NICA, which failed to eliminate "bad baby" cases from the tort system because the eligibility criteria were too narrow, inviting "jurisdictional disputes between common law and no-fault remedies."[94] If policymakers opt for a limited no-fault program to address a particular class of injury, they should learn from NICA's flaws by covering the full spectrum of injuries belonging to that particular class.[95] In the alternative, legislators could define the scope of no-fault coverage "according to whether the injury in question was suffered at the hands of participating provider or within the walls of a participating institution."[96]

Jurisdictional wrangling aside, no-fault will also be challenged on constitutional grounds.[97] *State Farm Mutual Automobile Insurance v. Broadnax* is illustrative.[98] There, State Farm asked the Colorado Supreme Court to repudiate a state statute that remanded all disputes arising out of

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90. *Id.* at 235.
91. *Id.* The patient's health insurer could also fill the role of third party agent.
92. *Id*. at 239.
93. *See id.* at 240.
94. *Id.* at 240-41.
95. David M. Studdert et al., *The Jury Is Still In: Florida's Birth-Related Neurological Injury Compensation Plan after a Decade*, 23 J. HEALTH POL. POL'Y & L. 499, 524 (2000).
96. *Id.*
97. *Toward a Workable Model*, *supra* note 73, at 235.
98. *See generally* State Farm Mut. Auto. Ins. v. Broadnax, 827 P.2d 531 (Colo. 1992) (illustrating constitutional arguments against Colorado statute requiring binding arbitration for controversies arising under no-fault auto insurance policies).

no-fault automobile insurance contracts to binding arbitration.[99] State Farm claimed that binding arbitration violates the right of access to the courts, "rights to a jury trial, and equal protection and due process."[100] However, the court upheld the statute as constitutional.[101] Since binding arbitration affords parties the opportunity to be heard, the court found that the right to judicial process was satisfied.[102] On the due process issue, the court applied a rational basis test and ruled that the statute was "rationally related to legitimate interests in expediting dispute resolution, reducing parties' costs, and securing prompt payment of benefits."[103]

However, there is no consensus on the constitutionality of no-fault.[104] In *University of Miami v. Echarte*, the Florida Supreme Court upheld a monetary cap on non-economic damages pursuant to a medical malpractice arbitration statute, but the dissent provided the counterargument, which other jurisdictions have embraced.[105] By dividing victims of medical malpractice into two classes — "those with serious injuries whose recovery is limited by caps and those with minor injuries who receive full compensation" — the dissent concluded that the statute violated equal protection guarantees and the right of access to the courts.[106]

V. CONCLUSION

On the whole, the ACC has achieved the objectives of its architects.[107] It provides extensive coverage to a large proportion of claimants, without

99. *Id.* at 532; *Toward a Workable Model*, *supra* note 73, at 242.
100. *Toward a Workable Model*, *supra* note 73, at 242.
101. *Id.*
102. *State Farm*, 827 P.2d at 536-37.
103. *Id.* at 540; *Toward a Workable Model*, *supra* note 73, at 242.
104. *See Toward a Workable Model*, *supra* note 73, at 243.
105. *Id; See* Univ. of Miami v. Echarte, 618 So. 2d 189, 198-202 (Fla. 1993) (Barkett, C.J., dissenting).
106. *Miami*, 618 So. 2d at 198; *Toward a Workable Model*, *supra* note 73, at 243.
107. Mello, *supra* note 1, at 8.

bankrupting New Zealand's healthcare system or compromising quality. Moreover, it enjoys the support of the public.[108] Spared the burden of establishing fault, patients find it easier to recover damages.[109] Doctors cooperate in the claims process because liability does not attach to admissions of error.[110] While safety remains a concern, errors occur at the same frequency in no-fault as in tort systems, rebutting the notion that liability deters mistakes.[111]

Replicating no-fault in the United States is no simple proposition.[112] New Zealand's treatment injury standard may not work in the United States because its broadness will open the floodgates to minor claims.[113] Viability will depend on effective cost controls,[114] but caps on damages may not gain traction. Furthermore, courts must enforce patients' agreements to forgo tort remedies.[115] This means quashing challenges predicated on contractual and constitutional grounds.[116] However, the survival of several states' pilot programs augurs well for the future of no-fault in the United States.[117]

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108. *See* Kachalia, *supra* note 13, at 400.

109. David Dobbs, *Do the Swedes Have a Faultless Fix*, SLATE, Feb. 22, 2005, http://www.slate.com/articles/news_and_politics/how_they_do_it/2005/02/malpractice_mess.html.

110. Mello, *supra* note 1, at 5.

111. *See* Soleimani, *supra* note 51, at 2.

112. *See* David M. Studdert et al., *Can the United States Afford a "No-Fault" System of Compensation for Medical Injury?*, 60 LAW & CONTEMP. PROBS. 1, 33-34 (1997) [hereinafter *Can the United States Afford?*].

113. Kachalia, *supra* note 13, at 399-400.

114. *Toward a Workable Model*, *supra* note 73, at 231; *Can the United States Afford?*, *supra* note 112, at 29.

115. *Toward a Workable Model*, *supra* note 73, at 239.

116. *Id.* at 252.

117. Kachalia, *supra* note 13, at 401.