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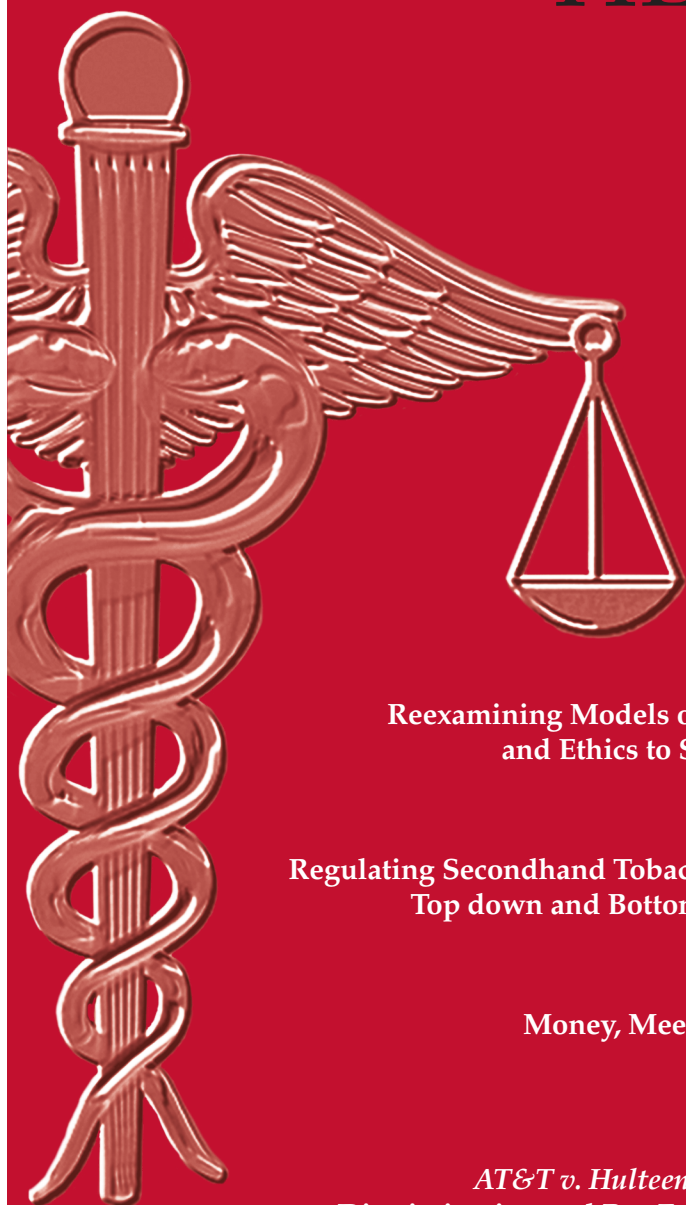
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LETTER FROM THE EDITORS

Dear *Health Law & Policy* Reader:

On behalf of the editorial board and staff, we proudly present Volume 4, Issue 1 of *Health Law and Policy*. The publication of our seventh issue comes just as history was made with the passage of the Patient Protection and Affordable Care Act. With health care reform finally a reality, it is an incredibly exciting time to be in the field of health law. Although the health care reform legislation expands coverage to 32 million uninsured Americans, creates health insurance exchanges, and prevents insurers from screening patients with preexisting conditions, several items remain unsettled. Several pieces of this legislation will not be implemented until 2014 leaving the details and true impact of reform to be seen.

Our current issue covers health care reform and provides articles that delve into a wide range of issues and assert diverse perspectives. Our first article provides an excellent summary of the saga to pass health care reform. The second piece tackles an extremely divisive and timely topic; the legislative battle to legalize marijuana in Washington, D.C. Our third article provides a unique and valuable perspective on disability and the right to reproduce. This issue also includes a comparative piece on international second hand smoke legislation and an article arguing in favor of legalizing prescription drug importation. Our last article, written by a member of the editorial board, examines the controversial topic of pregnancy discrimination.

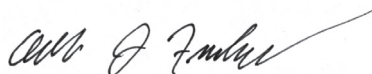
We would like to thank our staff for their hard work on this issue and our advisor, Professor Corrine Parver, Esq., for her dedication both to this publication and to her students in furthering an understanding of health law issues. This is our last issue together as co-editors in chief and we hope you enjoy reading it as much as we have enjoyed working together over this last year.

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INTERVIEW WITH PROFESSOR LINDSAY WILEY, NEW WCL HEALTH LAW PROFESSOR



Professor Corrine Parver: American University Washington College of Law's focus on Health Law and Policy, Program on Law and Government, really began five years ago. Significant growth has occurred over this time — for example, the Summer Health Law and Policy

Institute, the *Health Law and Policy* Brief, and the Health Law and Justice Initiative are just a few projects organized and run by the Program. Approximately twenty health law-related courses, including Food and Drug Law, Bioethics, Genetics, Health Care Legislative and Regulatory Process, Privacy and Health Information Technology, Medical Liability, Public Health, Current Trends in American Health Policy, and Reproductive Rights, are taught each academic year. A series of "Lunch and Learns" brings in specialists from various health law fields to discuss their areas of expertise, and several Symposia are held each semester on health care issues.

Given the success of the Health Law and Policy program and the importance of the health care industry to our nation's economy, the Dean concluded that it was time to engage a tenure track faculty member who would focus solely on health law and policy issues. We are extremely fortunate to have hired Professor Lindsay Wiley, who will begin teaching at WCL in the fall 2010 academic year.

Interviewer: Professor Wiley, can you tell us about your background and some of the activities that you will be involved in at WCL this fall?



Professor Lindsay Wiley: I have my Bachelor and Juris Doctor (J.D.) degrees from Harvard. After law school, I practiced at a law firm in Baltimore called Gordan, Feinblatt, Rothman LLC where I did primarily defense-side litigation on public nuisance suits and some product liability

claims. I also worked for the American Society of Law, Medicine and Ethics, where I focused on issues surrounding pain management and the law. I looked at a range of legal issues that influence physicians' decisions regarding palliative care, ranging from reimbursements to civil and criminal liability. It was very interesting to switch gears from doing defense-side litigation to working on policy issues with a non-profit organization.

After three years of private practice, I went to John Hopkins University to get my Masters in Public Health on a part-time basis, and I worked at a policy and research institute based at Hopkins called the Center for Law and the Public's Health. While at the Center, I worked on a range of U.S. health care policy issues such as access to care, health information privacy and expedited partner therapy as well as public health law issues like bio-security and public health preparedness. A theme that has united my work going back to that time is an effort to take into account the full social context of patient care. Expedited partner therapy, for example, is an approach that seeks to loosen regulations on prescription of medications to allow a doctor to provide not just enough antibiotics for the patient herself, but also enough for her to take to her sexual partner. The old way to handle this situation

was to provide the antibiotics to the patient and ask her to notify her partner and explain that he should come in for care. Research suggested that that was unlikely to occur. This is very dangerous for women that have sexually transmitted infections such as gonorrhea and chlamydia, because they are likely to get re-infected if their partner is not treated and frequent reinfection is associated with some pretty serious complications for women like pelvic inflammatory disease and infertility. The background in public health sciences like epidemiology and environmental health that I gained during my time at Hopkins has also strongly influenced my approach to a whole range of legal issues and prompted me to see health law not just as the law of health care, but as the understanding of law more broadly as a determinant of health.

I am currently the Global Health Law Program Director at the O'Neill Institute for Global and National Health Law, based at the Georgetown University Law Center. I have worked with the faculty to develop a comprehensive health law curriculum and I have also really enjoyed the opportunity to advise LL.M. and J.D. students about course selection and career options. In addition to working on academic programs, I have been involved in several research and policy projects at O'Neill.

Next fall I will be teaching Torts and in spring I will teach Health Law and a seminar on public health law. I am also looking forward to bringing some of my policy projects from my previous work to WCL where there may be opportunities for students to get involved.

Interviewer: Thank you, Professor Wiley. Is there anything else that you would like to say to the WCL Community?

Professor Wiley: I could not be more thrilled to be joining the faculty here. Dean Grossman has fostered a vibrant academic environment overflowing with opportunities for students and faculty alike. And for health law students, Practitioner-in-Residence Corrine Parver has created so many fantastic opportunities for students to hone their advocacy skills and gain invaluable insight into cutting edge developments in health law both domestically and internationally. I am looking forward to supporting the development of the health law program here over the course of my career on the faculty and I hope to add to the resources available for students interested in health law and related fields. WCL students are known far and wide for being a particularly engaged group and the faculty here is wonderfully collegial. I am really looking forward to making American University my new intellectual home.

HEALTH CARE REFORM: THE UNENDING SOAP OPERA OF 2009–2010

Corrine Parver* and Biswajit Chatterjee†

Brief Overview/Introduction

Health care reform had never come so close to success as it has in the past year. Just prior to publication, a health care reform package finally passed the House of Representatives when House members voted to accept the Senate's health care reform bill. The President signed the bill into law on March 23, 2010. This article first provides a chronology of the health care reform process, especially during 2009 (Section I), then presents and compares the most recent versions of the full health care reform bills passed by the House and Senate (Section II) and, finally, assesses the most recent developments and the future of health care reform (Section III).

I. Chronology of the Health Care Reform Process

A. Presidential Campaign 2008

The story of American health care reform efforts is long, dating back at least to President Truman's administration in the 1950's. Despite intense interest and repeated attempts by many Presidents, Senators, and Members of Congress, comprehensive health care reform had remained unfulfilled.¹ The failure to achieve health care reform was glaring, particularly against the backdrop of the over fifty million Americans estimated to be without health insurance, impeding access to health care services.²

President Bill Clinton's efforts at health care reform in 1993–1994, shortly after coming into office, were particularly noteworthy. “Then-first lady Hillary Clinton, who headed the administration's task force on reforming the system, delivered a 1,000-page plan that was dubbed “Hillary Care,”” which included an

individual mandate for citizens and permanent residents to obtain coverage by a health plan.³ Congressional Republicans “decried the plan as overcomplicated and used it to tag the administration as big government-loving, tax-and-spend liberals.”⁴ Ultimately, President Clinton's reform efforts proved unsuccessful and, in the wake of the resulting health care debacle, the Republican Party gained Congressional majorities in both the House of Representatives and the Senate in November 1994.⁵

The impetus for national health care reform receded after the unsuccessful efforts of the Clinton Administration and did not fully resurrect until the 2008 Presidential election season. The Democratic primaries offered a new opportunity for Hillary Clinton, then a Presidential candidate, to propose a health care plan in her own right and making. She continued her efforts for universal health care, making it a centerpiece of her campaign. Then Illinois Senator Barack Obama offered opposition in that primary campaign and health care policy differences became acute. For sure, their plans had areas of agreement, such as prohibiting pre-existing condition exclusions and expanding accessibility, but the main distinction among these major candidates concerned the issue of the individual mandate.⁶ Senator Obama refused to adopt an individual mandate for health insurance coverage, in contrast to Mrs. Clinton. Instead, Senator Obama asserted that Americans would buy insurance on their own volition once reforms brought insurance to affordable levels.⁷ Later, when campaigning in the general election, he promised to make health care more affordable and accessible by lowering health insurance costs \$2,500 on average⁸ and implementing tax credits for health insurance premiums.⁹ Importantly, Senator Obama stated he would “[e]stablish a National Health Insurance Exchange with a range of private insurance options as well as a new public plan based on benefits available to members of Congress that will allow individuals and small businesses to buy affordable health coverage.”¹⁰

B. Efforts at Health Care Reform in 2009

Once Barack Obama assumed the Presidency on January 20, 2009, his nascent Administration began the task of establishing health care reform principles. This was not surprising, given the prominence of

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health care as an election issue. At the start, the Obama Administration secured tentative “deals” for the cooperation of the health care industry in health care reform with leaders of the insurance industry, physicians, hospitals, pharmaceutical companies, and labor unions. These industry leaders initially pledged to produce cost savings of two trillion dollars over ten years.¹¹ In his FY 2010 budget overview, President Obama instructed Congress to follow eight key principles in instituting comprehensive health care reform:

“[R]educe long-term growth of health care costs for businesses and government; protect families from bankruptcy or debt because of health care costs; guarantee choice of doctors and health plans; invest in prevention and wellness; improve patient safety and quality care; assure affordable, quality health coverage for all Americans; maintain coverage when you change or lose your job; end barriers to coverage for people with pre-existing medical conditions.”¹²

During the late spring and summer of 2009, Congress began to deliberate possible health care reform provisions. The House issued a multi-Committee, consensus proposal, H.R. 3200, “America’s Affordable Health Care Choices Act,” on June 19, 2009.¹³ The most important provisions of HR 3200 would have established an individual mandate for health insurance coverage, created a national health insurance exchange, and provided tax credits to enable individuals and families earning up to 400% of the federal poverty level (FPL) to afford health insurance.¹⁴ As part of the framework, a new public health insurance option plan would have been created, in addition to an employer mandate to either provide employees coverage or pay an annual fee up to eight percent of payroll expenses to support the new health exchange.¹⁵ Additionally, there would have been an expansion of Medicaid to 133% of the FPL, as well as increased regulation of insurance companies to protect consumers.¹⁶

Significantly, under the leadership of the late Senator Ted Kennedy (D-MA), a long-standing leader of health care reform, the Senate Health, Education, Labor and Pensions (HELP) Committee produced an alternative bill on July 15, 2009, S. 1679, the “Affordable Health Choices Act”.¹⁷ S. 1679 would have established state-based health exchanges (termed “gateways” in this bill) and community health insurance option plans, in contrast to the national approach of HR 3200.¹⁸ The bill would have expanded Medicaid greatly, to 150% of the FPL.¹⁹ Other major provisions were similar to HR

3200, such as the creation of an individual mandate, an employer mandate or annual fee, and affordability tax credits up to 400% of the FPL.²⁰

The White House and individual Representatives and Senators were exposed to many public opinions through the course of the summer 2009 “Town Hall” meetings. Organized conservative activists, particularly those belonging to a new group, the “Tea Party,” attempted to protest any further attempts at health care reform, particularly the public plan option.²¹

By the end of summer 2009, progress on health care legislation appeared at an impasse. President Obama attempted to seize the moment with an unprecedented televised address to a joint session of Congress on the topic of health care reform.²² The President stressed his commitment to universal health care, enumerating several reform goals: security and stability for those persons currently insured, insuring the currently uninsured, and lowering Americans’ health care costs.²³ He reiterated his plans to prohibit health insurance discrimination based on pre-existing conditions²⁴ and to establish a national insurance exchange that would allow consumers to compare competing health insurance alternatives.²⁵ In contrast to his position during the Democratic Primary season, the President now espoused a federal requirement for insurance coverage for all Americans (i.e., the individual mandate).²⁶ Also while promoting universal coverage, President Obama stated his open-ended preference for the so-called “public option” or, a federally funded health insurance plan. Recognizing the controversial nature of the plan, and dubious support even within his own party, the President also indicated that the public option could be replaced by functional alternatives like co-ops.²⁷

Senator Max Baucus, chairman of the powerful Senate Finance Committee, unilaterally delivered his signature plan almost immediately following the President’s speech, despite the fact that, earlier in the summer he had failed to garner a bipartisan compromise plan. The Senate Finance Committee passed its final version of a health care reform bill, after considerable amendments, on October 13, 2009. The bill delivered a decidedly more moderate package, especially when compared with the House’s multi-committee bill and the Senate HELP Committee’s more liberal version.²⁸ The Senate Finance Committee bill built on some areas of consensus reflected in the President’s plan and the existing Congressional bills. Similarly, it contained an individual mandate,²⁹ affordability tax credits up to

“The President stressed his commitment to universal health care, enumerating several reform goals: security and stability for those persons currently insured, insuring the currently uninsured, and lowering Americans’ health care costs.”

400% of the FPL,³⁰ and expanded Medicaid to 133% of the FPL.³¹ It also provided for state-level insurance exchanges.³²

Perhaps the most distinctive feature of the Senate Finance bill was its adoption of non-profit, consumer operated and oriented plans (co-ops) instead of the public option plans envisioned by the preceding bills, HR 3200 and S. 1679.³³ These co-ops, however, were not mandatory for any state; rather, they were merely “encouraged” by \$6 billion of seed grant money in the bill.³⁴ The Baucus plan was also noteworthy for its complex funding structure, including hundreds of billions of dollars in cuts to Medicare and Medicaid expenditures,³⁵ “fees” (criticized as taxes by Republicans) imposed on a variety of health care industries, such as insurance and drug companies,³⁶ and excise taxes on so-called “Cadillac insurance plans” (common term for high-premium insurance plans).³⁷ Subsequently, on November 7, 2009, the House of Representatives passed its official version of health care reform, H.R. 3962, a bill that House Speaker Nancy Pelosi modified from H.R. 3200.³⁸

In an historic vote shortly before Christmas eve, the Senate passed its own version of health care reform, a synthesis of preceding Senate health bills under the leadership of Senate Majority Leader Harry Reid.³⁹ Owing to their differences, these official House (H.R. 3962) and Senate bills (H.R. 3590) required further legislative action prior to President Obama’s promised signature of health care legislation. Whereas the enactment of health care reform was considered inevitable shortly after this Senate vote, it seemed quite uncertain after a special Senate election in Massachusetts installed Republican Scott Brown in the late Senator Kennedy’s seat, which removed the Democratic Party’s previous sixty-Senator, filibuster-proof Senate majority.⁴⁰

II. Assessment of the House and Senate Bills

A. House of Representatives

The House health care bill (H.R. 3962) produced a comprehensive, albeit relatively expensive, health care reform bill. H.R. 3962 sets out total expenditures of approximately \$900 billion over the next ten years, although concurrent cost cuts from Medicare/Medicaid and additional tax revenues would produce over \$100 billion in federal deficit reductions.⁴¹ The expanded benefits are partially funded through a surtax on individual taxpayers with over half a million dollars gross income and joint-filers with over one million dollars gross income.⁴² On the other hand, the large costs of the House bill afford greater health care access by expanding health care insurance coverage to an estimated thirty-six million additional Americans.⁴³

Some of the key features of the House bill include an individual mandate for insurance coverage, expansion of Medicaid up to 150% of the poverty line, creation of a national health insurance exchange, including a public option plan, new private insurance market regulations to protect consumers, and new employer requirements.⁴⁴ With respect to the individual mandate to begin in 2013, all individuals must carry health insurance or pay a penalty of 2.5% of adjusted gross income.⁴⁵ Similarly, the bill establishes a new employer mandate, which requires employers to provide employees minimal health insurance coverage or pay a penalty of up to eight percent

of payroll, although smaller employers are exempted.⁴⁶ There would also be affordability tax credits to subsidize private health insurance premiums up to 400% of the FPL.⁴⁷ Among other provisions, HR 3269 eliminates the gap in Medicare Part D prescription coverage (the so-called “donut hole”)⁴⁸ and prohibits exclusions for pre-existing conditions for private insurance coverage.⁴⁹ The House bill also removes the long-standing exemption for health insurance companies from anti-trust laws in order to promote competition and thereby reduce premium prices.⁵⁰

Several large health care stakeholders weighed in on the House health bill. Indeed, it was historic that both the national groups representing the elderly (AARP) and physicians (the American Medical Association) supported the bill, helping ensure its passage.⁵¹ On the other hand, there was significant health insurance industry opposition, including from America’s Health Insurance Plans (AHIP) and the Blue Cross Blue Shield Association (BCBSA), which resented the detrimental effect of the public option on their businesses.⁵² The Independent Insurance Agents & Brokers of America opposed the bill on similar grounds. This group opposed the employer mandate/fee for covering employees and the surtax on wealthy individuals, claiming that these provisions would hurt small businesses.⁵³ Similarly, the U.S. Chamber of Commerce also opposed the legislation, citing the impact of what it characterized as a “pay or play” employer mandate which it believed would force employers to react by outsourcing, providing lower wages, and laying off employees.⁵⁴ Due to a perceived effect of shifting costs onto the private sector, the Chamber also strongly opposed the notion of a government-run health insurance plan and its concomitant provisions to pay below-market rates.⁵⁵

B. The Senate

The Senate bill, H.R. 3590, also provides for comprehensive health care reform and includes an individual mandate, affordability tax credits, creation of state insurance exchanges with funding to encourage co-ops, new insurance market reforms to protect consumers, and new employer requirements.⁵⁶ The Congressional Budget Office (CBO) estimates that this bill would insure thirty-one million additional Americans who are currently uninsured and require net expenditures of \$871 billion by 2019, but also reduce the federal deficit by \$132 billion.⁵⁷ The deficit reduction will come from cost cuts to the Medicare/Medicaid federal health programs and additional tax revenues.⁵⁸ For instance, there would be taxes on the “Cadillac” health care plans.⁵⁹ Unlike the House plan, there were no surtaxes on the wealthy.

This bill delays the effect of many reforms. Most notably, it delays the individual mandate an additional year until 2014.⁶⁰ There is a financial penalty for not obtaining insurance coverage, either \$750 per person or two percent of gross income, whichever is greater.⁶¹ There is ostensibly no mandate for employers to provide their employees with health insurance, but the effect may be the same.⁶² In that regard, “large employers” (over fifty employees) not providing their own minimal health benefits must pay a financial penalty of \$750 per uninsured full-time employee receiving an affordability tax credit or cost-sharing reduction.⁶³

The Senate bill establishes state-based exchanges (American Health Benefits Exchanges) for consumers and small businesses to purchase

health insurance within one year of enactment.⁶⁴ Significantly, this provision is unlike the national exchange envisioned by the House. Also, the Senate bill would expand Medicaid up to 133% of FPL, which is somewhat lower than the House bill (150% of the FPL).⁶⁵ Like the House, affordability tax credits would be offered to subsidize insurance premiums for individuals and families up to 400% of the FPL.⁶⁶

Further, the Senate bans exclusions for pre-existing conditions and directs the Secretary of the Department of Health and Human Services (HHS) to establish a temporary high-risk pool for such individuals until 2014.⁶⁷ Similarly to the House bill:

New insurance market regulations will prevent health insurers from denying coverage to people for any reason, including their health status, and from charging people more based on their health status and gender. These new rules will also require that all new health plans provide comprehensive coverage that includes at least a minimum set of services, caps annual out of pocket spending, does not impose cost sharing for preventive services, and does not impose annual or lifetime limits on coverage (existing individual and employer sponsored plans do not have to meet the new benefit standards).⁶⁸

Although there was consideration of a public option by the Senate,⁶⁹ ultimately the final version of the bill does not contain any mandatory provisions for state-based exchanges to contain government-run insurance plans.⁷⁰ As partial replacement, the final Senate bill tasks the Office of Personnel Management to ensure that each state-based exchange has at least two insurance plans, including a non-profit plan, through a private contracting process.⁷¹

The Senate bill contains no revocation of the exemption for private insurers from antitrust laws or any modification to the antitrust laws to spur further competition within the health insurance industry.⁷² There also appears to be an attempt to reduce, albeit not eliminate, the donut hole in Medicare prescription drug coverage by having the Secretary of HHS negotiate discounted prices with manufacturers to reduce the gap.⁷³

Concerning abortion, both the House and Senate bills contain stringent prohibitions on any coverage of abortion services. The last minute Stupak amendment to the House bill served to codify the Hyde amendment

in the health care bill. Essentially, this would prohibit abortion services under the public option plan to the extent subsidized by affordability tax credits.⁷⁴ In the same vein, the Senate bill also raises a high wall between public funds and abortion services. A provision in the Senate bill prohibits private insurance plans from using public funds from affordability tax credits and cost-sharing reductions to subsidize any abortion services.⁷⁵

In plans that do cover abortion, beneficiaries would have to pay for it separately, and those funds would have to be kept in a separate account from taxpayer money. Moreover, individual states would be able to prohibit abortion coverage in plans offered through the exchange, after passing specific legislation to that effect. Exceptions would be made for cases of rape, incest and danger to the life of the mother.⁷⁶

The House bill is the harsher of the two, prohibiting private insurers from covering abortion services if the new credits subsidize any portion of the insurance plan.⁷⁷ On the other hand, the Senate appeared to resolve the matter by proper accounting of public funds.

One noteworthy proposed amendment contained bipartisan language offered by Senators Ron Wyden (D-Ore.) and Susan Collins (R-Maine).⁷⁸ These Senators joined together to propose a “Free Choice” amendment that “would permit employees already covered by their employers’ health care policies to purchase insurance in the proposed exchange,” by means of a voucher equal to the employer’s annual health insurance cost for the employee.⁷⁹ The amendment would also allow consumers to purchase catastrophic coverage regardless of age.⁸⁰ Finally, the amendment would adjust the health care bill’s tax on insurers to annual premium changes, so that the tax would rise or fall with premiums.⁸¹ It does not appear that there was any subsequent action or vote upon this amendment.

In general, the Senate health bill was widely criticized for containing too much political backroom dealing, especially to win the holdout vote of Senator Ben Nelson of Nebraska. The general public and Republican opponents seized upon a provision that excuses Nebraska from the costs of expanding Medicaid programs, amounting to nearly \$100 million over the next ten years.⁸²

“Although there was consideration of a public option by the Senate, ultimately the final version of the bill does not contain any mandatory provisions for state-based exchanges to contain government-run insurance plans.”

To balance it out a bit and retain the support of liberals, the leadership added a few sweeteners in the final version including more funding for Community Health Center and the Children's Health Insurance Program (CHIP). The final bill also bulked up some of the consumer protections in the bill. For example, patients would be guaranteed the ability to appeal coverage denials and requiring insurance companies to spend at least 80 percent of premiums on actual health care.⁸³

There was opposition to the Senate health bill from a few key health care stakeholders. For instance, health insurance underwriters criticized the bill for its requirements that private insurers maintain high minimum loss ratios of at least eighty percent of premiums, as well as its ineffective and unworkable individual mandate that could cause premiums to "skyrocket."⁸⁴ Also, a leading small business association protested the bill on grounds that it would provide insignificant reductions in insurance costs for small businesses and, instead, would likely impose burdensome new duties on employers.⁸⁵ The U.S. Chamber of Commerce also opposed the bill, offering several suggestions for inclusion in health care reform, including the following principles: 1) control health care costs with medical liability reform, Food and Drug Administration pathway for biosimilars, health information technology, comparative effectiveness research, wellness and prevention coordination of care and medical homes, pay-for-performance reform, combating fraud and abuse, living wills and end-of-life issues, reinsurance, consumer-driven health options, small business pooling, administrative simplification, long-term care reform, and achieving tax parity by allowing individuals/small business to deduct the full cost of insurance expenses; 2) reform the health insurance system by eliminating the use of pre-existing conditions or health status, guaranteeing that any individual or entity will be issued a policy, guaranteeing that policies will not be revoked, placing reasonable limits on rating differences, subsidizing those who cannot afford coverage, and providing an individual obligation to obtain coverage; and finally; 3) create a vibrant marketplace by creating a national all-inclusive connector/exchange that removes fragmentation, allowing individuals and businesses from anywhere in the country to enroll, and facilitating improved pooling mechanisms, choice, and competition.⁸⁶

Despite the criticisms, other health care stakeholders supported the Senate health bill. The powerful pharmaceutical industry was surprisingly in favor of the bill, noting the expansion of insurance coverage and market reforms as helping the overall health care system.⁸⁷ Physicians, represented by the AMA, also supported the bill, citing benefits from expanded access to health insurance coverage, reforms to private insurance market practices, and wellness promotion and preventative measures.⁸⁸ The AARP praised the bill for instituting private insurance market reforms and beginning to close the doughnut hole in Medicare Part D coverage.⁸⁹ The American Hospital Association also supported the passage of HR 3590.⁹⁰

C. Republican Alternatives

There is no updated or unified Republican health care bill to contrast with either the official House or Senate health bills, or the President's proposal. The Senate Republicans did not produce their own alternative to what was crafted by Senate Majority Leader Reid. On the other hand, the House Republicans attempted, albeit unsuccessfully, to pass their own proposal as an amendment to HR 3962.⁹¹ The amendment focuses heavily on reducing costs within the health care system, as opposed to the Democrats' focus on

expanding access, but it is dramatically more modest in the scope of both the text and the plan itself.⁹² CBO expects the House Republican plan would reduce the number of uninsured by only three million people. Notably, the plan would be less expensive with a net cost of only eight billion dollars, while reducing the deficit sixty-eight billion dollars by 2019.⁹³

The House Republican bill proposes to lower health care premiums; establish universal access programs to guarantee access to affordable health care for those with pre-existing conditions and expand and reform high-risk pools and reinsurance programs to improve access to affordable care and lower costs; end costly "junk lawsuits" and reduce the practice of defensive medicine through medical liability reforms, modeled after successful state laws in California and Texas; prevent insurers from revoking insurance policies; encourage small business health plans; give small businesses the power to pool together and offer health care at lower prices; encourage innovative state programs; reward innovation by providing incentive payments to states that reduce premiums and the number of uninsured; allow Americans to buy insurance across state lines; promote healthier lifestyles; enhance Health Savings Accounts (HSAs); and allow dependents to remain on their parents' policies through the age of twenty-five.⁹⁴

III. Developments in 2010

A. Negotiations Begin to Resolve House-Senate and Democratic-Republican Differences

After the passage of both the House and Senate health reform bills, significant differences between the bills needed to be resolved. Usually a Conference Committee process provides the mechanism for resolving such differences. Rather than deal with the procedural demands of a Conference Committee, the Democrat leadership initially decided to use an informal "ping-pong" strategy where multiple issues are slowly but informally resolved.⁹⁵ After the special election for the Massachusetts Senate seat in January 2010, the Democrats needed at least one Republican vote to gain the sixty votes to break a filibuster and pass a final version of health care reform, under the normal rules of the Senate. This introduced considerable uncertainty and challenge into the process of enacting health care reform. Nonetheless, President Obama responded by affirming his commitment to passing health care reform during his 2010 State of the Union speech and asserted his willingness to entertain Republican alternatives.⁹⁶

B. President's Proposal

The White House submitted its own proposal in advance of a high-profile health care summit, held in February 2010, with both Democratic and Republican leaders. The President's proposal attempted to bridge the differences between the official House and Senate health reform bills. The most distinctive features of his plan included an increased penalty of 2.5% to enforce the individual mandate, the notable absence of a public option, higher premium tax credit levels, state-based exchanges, a new rate-setting commission to oversee insurance company premium hikes, closure of the Medicare prescription drug "donut hole" coverage gap, raising the threshold for "Cadillac plan" excise taxes, and several programs to fight fraud, waste, and abuse in Medicaid and Medicare.⁹⁷ Significantly, the President's proposal also prohibited pre-existing condition exclusions.⁹⁸ With respect to employer obligations, the White House was "consistent

with the Senate bill in that it does not impose a mandate on employers to offer or provide health insurance, but does require them to help defray the cost if taxpayers are footing the bill for their workers.”⁹⁹ The White House claimed these proposals would reduce budget deficits by \$100 billion over the next ten years, although there is no CBO score of the plan to confirm these figures.¹⁰⁰

Importantly, the President’s proposal recognized differences in the House and Senate approaches to making health care more affordable through tax credits for premiums and cost sharing assistance. In fact, the President’s proposal would have increased tax credits to lower the effective price of health insurance premiums, compared to both the House (families earning \$55,000–\$88,000) and the Senate (\$44,000–\$66,000).¹⁰¹ The proposal would also provide insurers with additional funding to improve cost sharing assistance for lower-income families earning less than \$55,000.¹⁰²

With the goal of incentivizing insurers to lower premiums, Obama’s proposal contained an excise tax on Cadillac plans. It differed in two respects: first it raised the threshold from \$8,500 to \$10,200 for individuals and from \$23,000 to \$27,500 for families;¹⁰³ second it extended the effective date for the tax from 2013 until 2018.¹⁰⁴

The President declined to adopt the House bill’s 5.4% surcharge on wealthy Americans (individuals with over \$500,000 AGI). President Obama did call for a 2.9% “Medicare unearned income tax” that would have assessed income from interest, dividends, etc. from high-income taxpayers (\$200,000 AGI for individuals and \$250,000 AGI for married couples filing jointly) to obtain additional revenues to sustain the Medicare trust fund, which were not already subject to the Medicare payroll tax on earned income.¹⁰⁵

Recognizing the political backlash against the Senate bill’s heavy criticized political concession to Senator Nelson, the President’s proposal explicitly purported to be fairer by providing uniform 100% federal support for all states in their Medicaid expansion for newly eligible individuals through 2017.¹⁰⁶ The plan only expanded Medicaid to 133% of the FPL, which is the same as the Senate plan but less than the House plan (150%).¹⁰⁷

The President’s proposal also proudly displayed an entire section showing adoption of Republican ideas, including personal responsibility incentives in assigning premiums, implementation of medical liability reforms at the state level by providing grants, extended dependent coverage to age twenty-six, and automatic enrollment by employers in health insurers with the opportunity for employee opt-out.¹⁰⁸

C. February 2010 Health Care Summit with Obama, Democrats, and Republicans

In an attempt at garnering bipartisan support for health care reform, the President invited several Republican and Democratic Congressional leaders to a health care summit on February 25, 2010. The ensuing discussion was a day-long, nationally televised event that ultimately failed to bridge fundamental partisan and substantive differences between President Obama and Republican opponents.¹⁰⁹ Republican Congressional leaders emphasized their view that the Democratic plans were simply too large in scope and that the proper structural mechanism for reforming health care was to start over using an incremental approach. Republicans, however, did offer several ideas for reform, including medical malpractice tort reform,

enabling small business insurance compacts, and expanding high-risk pools to insure those with pre-existing conditions. The President offered to incorporate provisions to foster medical liability reforms at the state level.”¹¹⁰

One outstanding area of contention was cost-containment and deficit reduction. Representative Paul Ryan (R-WI) criticized the plan for failing to control runaway health inflation and excessive health care costs, especially from Medicare and Medicaid growth.¹¹¹ Congressman Ryan remarked that the Senate health care bill “treats Medicare like a piggy bank” and “raids a half a trillion dollars out of Medicare, not to shore up Medicare solvency, but to spend on this new government program.”¹¹² The President indicated Congressman Ryan’s assertion was specious, noting that significant reductions in Medicare costs would come from eliminating subsidies to Medicare Advantage private insurers.¹¹³ In that regard, the Senate plan would reduce Medicare Advantage payments by \$118 billion.¹¹⁴

In analyzing any eventual health care reform, whether proposed by Republicans or Democrats, it is crucial to understand that access, quality, and costs are countervailing factors. In health policy circles, the “iron triangle of health care” refers to an equilibrium of the three pillars of access to health care, quality of services provided, and the underlying cost of providing any health care services.¹¹⁵ For instance, expanding access to health care, as proposed by the Democrats, would require a concomitant expansion of financing. Conversely, reigning in costs of the health care system, as demanded by the Republicans, would in turn produce tremendous pressure to reduce access. The Republican House proposal expands access to only a tenth of those covered by the Democratic plans. In this regard costs remain an eternal concern for the American public. The annual inflation rate of health care service costs averaged nearly nine percent over the last decade.¹¹⁶ Unless reforms are instituted to reduce these costs, annual premium costs for families could balloon to over \$30,000 by 2019.¹¹⁷

In a post-summit address on health care reform, President Obama suggested that his plan was a middle path that rejected the liberal notion of government-run health care on the one hand and the conservative notion of easing insurance regulations to reduce costs on the other.¹¹⁸ The President rejected Republican suggestions to take a “piecemeal approach” and to “start over,” because the health care system must be reformed comprehensively to make any effective improvements and because health insurance premium increases and coverage abuse are too acute a problem.¹¹⁹

The President asserted that his proposal would affect three major changes to the health care system. First, the proposal would curb abusive practices by insurance companies by denying coverage for pre-existing conditions, rescinding coverage based on health status, allowing unlimited out-of-pocket payments, and imposing arbitrary and excessive premium increases.¹²⁰ Second, he stated that his “proposal would give uninsured individuals and small business owners the same kind of choice of private health insurance that members of Congress get for themselves...”¹²¹ Third, his proposal promised to reduce health care costs across the board, by eliminating “waste and abuse” in the health care system.¹²²

D. 2010 Congressional Actions

President Obama and the Democratic leadership in the House and Senate ultimately agreed to a framework for final passage of health care reform.

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The House would initially pass the Senate's version of a health care reform bill (H.R. 3590), which the President would sign into law. That would be followed by a planned enactment of a "Reconciliation" bill to bridge differences between the House, Senate and President's plans.¹²³ The reconciliation process was chosen since it only required the Senate to make a simple fifty-one vote majority, allowing the Democratic majority to evade the filibuster process and Republican opposition.¹²⁴ In a momentous vote on Sunday, March 21, 2010, the House passed H.R. 3590 by a 219-212 vote.¹²⁵ This was followed shortly thereafter by passage with a 220-211 vote of the companion Reconciliation bill making changes to the Senate bill.¹²⁶ The original Senate bill (H.R. 3590) has now been enacted. On March 23, 2010, President Obama at last signed federal health care legislation into law,¹²⁷ making the "Patient Protection and Affordable Care Act" Public Law 111-148.¹²⁸ On March 25, 2010 Senate Republicans forced two minor provisions unrelated to health care reform to be removed from the Reconciliation bill because they violated the rules of reconciliation.¹²⁹ Despite this, the House and Senate passed the Reconciliation bill later that day.¹³⁰ President Obama signed the reconciliation bill into law on March 30, 2010.¹³¹

The House-passed Reconciliation bill, H.R. 4872, the "Reconciliation Act of 2010,"¹³² was scored by CBO prior to its passage. CBO estimates that, with the Reconciliation bill's modifications to H.R. 3590, the health plan would produce gross costs of \$940 billion and \$138 billion in deficit reductions from 2010 to 2019.¹³³ The modified version of H.R. 3590 would result in coverage of thirty-two million more Americans.¹³⁴

The Reconciliation bill includes many of the major provisions outlined by the President's plan, including the individual mandate for coverage,¹³⁵ greater levels of affordability tax credits,¹³⁶ and an employer fee for uninsured workers who obtain health care premium tax credits.¹³⁷ There will be expanded federal funding assistance available to all states, not just Nebraska as in the Senate bill, for expanding the Medicaid coverage.¹³⁸ In 2010, Medicare beneficiaries would receive a \$250 coverage gap rebate to begin filling in the Medicare Part D "donut hole."¹³⁹ The reconciliation bill would gradually reduce the out-of-pocket costs for Medicare Part D beneficiaries through 2020 to only twenty-five percent of the costs of drugs in the donut hole.¹⁴⁰

By design, the enacted health plan has some of the most broadly supported provisions taking effect

within six months of enactment. These include: 1) extension of dependent coverage to age twenty-six;¹⁴¹ 2) prohibition on lifetime benefit caps or unreasonable annual benefit caps;¹⁴² 3) prohibition on insurance policy rescissions for those who become sick, absent fraud;¹⁴³ 4) prohibition on pre-existing condition exclusions for children;¹⁴⁴ 5) placing pre-existing conditions for all others into an interim high-risk pool to allow coverage (within ninety days of enactment).¹⁴⁵

In stark contrast, less popular provisions will not take effect for several years, allowing the public and insurance market sufficient time to adjust. For example, the individual mandate and associated monetary penalty for noncompliance are phased in gradually, starting in 2014.¹⁴⁶ By 2013, the enacted plan imposes an excise tax on Cadillac plans, defined as premiums over \$8,500 for individuals and over \$23,000 for families.¹⁴⁷ In contrast, the Reconciliation bill waits nearly a decade from now to begin imposing an excise tax on insurers of employer-sponsored health plans with high-cost premiums, defined as premiums over \$10,200 for individuals and over \$27,500 for families.¹⁴⁸ Effective in 2013, the plan raises the Medicare Part A (hospital benefits) earned income tax rate by 0.9% (up to 2.35% total) on individuals and married couples, earning over \$200,000 and \$250,000 AGI, respectively.¹⁴⁹ In 2013 the Reconciliation bill also assesses a 3.8% tax on unearned income (i.e., interest, dividends, rents, royalties, annuities, etc.) to add further revenues to the Medicare fund.¹⁵⁰

It is worth noting that the House's passage of the health care reform bill remained uncertain, requiring extensive campaigning and compromises by the President. At the eleventh hour, a deal on abortion ensured passage. Pro-life Democrats led by Representative Stupak agreed to support the Reconciliation and Senate bills in exchange for President Obama's promise of an Executive Order to prohibit any federal health care funding to cover abortions.¹⁵¹ An Executive Order was issued on March 24, 2010, the day after President Obama signed the Senate bill into law.¹⁵² This compromise implements the Hyde amendment into health care reform.¹⁵³ Specifically, the Executive Order states, "[t]he Act maintains current Hyde Amendment restrictions governing abortion policy and extends those restrictions to the newly created health insurance exchanges."¹⁵⁴ In a move that has alienated some pro-choice groups, women must personally pay for elective abortion coverage under a separate policy and insurance companies must maintain these personal funds separately from federal tax funding.¹⁵⁵

Criticisms of the health care package remain. The prime criticism is that the program will be underfunded like Social Security and Medicare.¹⁵⁶ CBO answered Republican Congressman Paul Ryan's skepticism on the bill's accounting by revealing that the health plan would result in a fifty-nine billion dollar deficit if Congress rescinds scheduled cuts of twenty-one percent to Medicare physician pay rates, as Congress has repeatedly done in similar situations.¹⁵⁷ Another mounting concern is that in a time of rising national deficits, debts, and general economic woe the enacted plan does not account for new "hidden taxes" in coming years.¹⁵⁸ In particular, critics argue that the individual mandate constitutes a massive transfer of wealth of \$1.5 trillion from workers to private insurance companies, effectively a "hidden tax."¹⁵⁹ This must be balanced against the average \$1,000 in higher premiums that the average insured American family pays to compensate for the care of the uninsured in the absence of universal coverage. This constitutes yet another "hidden tax," which primarily operates in the absence of health care reform, especially as enacted.¹⁶⁰

A number of legal challenges loom before federal health care reform becomes fully effective. Idaho was the first state to enact legislation to block implementation of an individual mandate for health care coverage by the federal government, with over thirty states contemplating similar legislation.¹⁶¹ More immediately, litigation has already been jointly filed by Republican Attorneys General from thirteen states against the federal government, naming the Secretary of HHS as a defendant, to challenge the individual mandate provision as unconstitutional.¹⁶² The Attorneys General for Florida, South Carolina, Nebraska, Texas, Utah, Alabama, Louisiana, Michigan, Colorado, Pennsylvania, Washington, Idaho, and South Dakota filed a complaint in the U.S. District Court for the Northern District of Florida.¹⁶³ The litigation brief argues that the individual mandate provision is unconstitutional.¹⁶⁴ The multistate brief specifically states:

The Constitution nowhere authorizes the United States to mandate, either directly or under threat of penalty, that all citizens and legal residents have qualifying healthcare coverage. By imposing such a mandate, the Act exceeds the powers of the United States under Article I of the Constitution and violates the Tenth Amendment to the Constitution.¹⁶⁵

The brief also asserts that the federal government exceeds its authority under Article I, Section 8's Interstate Commerce Clause, the tax and spending clause, and any other Constitutional provision.¹⁶⁶

A separate lawsuit was filed by the Virginia Attorney General Ken Cuccinelli, in the U.S. District Court in the Eastern District of Virginia.¹⁶⁷ He contends, "if a person decides not to buy health insurance, that person – by definition – is not engaging in commerce, and therefore, is not subject to a federal mandate."¹⁶⁸ Many legal experts and the White House expect the courts to uphold the constitutionality of the health care reform law.¹⁶⁹ Anonymous White House administration officials asserted that constitutional law supports a broad grant of authority to Congress to regulate the nation under the Commerce Clause, especially under the favorable precedents from two cases.¹⁷⁰ *United States v. South-Eastern Underwriters Association* allegedly supports the notion of congressional regulation of insurance.¹⁷¹ *Gonzales v. Raich* held that "Congress can regulate purely intrastate activity that is not 'commercial,'"¹⁷² when failure to do so could "undercut" its regulation of the interstate market of that activity.¹⁷³

IV. Conclusion

The path to achieve health care reform involved a tremendously bitter political and policy debate.¹⁷⁴ Quite unfortunately, falsehoods and half-truths were pervasive, especially those that stated the plan would constitute a government takeover of private providers and insurance companies.¹⁷⁵ Not surprisingly, the ultimate shape of health care reform was at best an imperfect solution to American's problems, falling far short of a national consensus before passage. Over time, it is possible that the country will treasure the health care reform package, much as Medicare and Social Security have garnered broad-based support after contentious starts.

The debate over the future of health care reform will surely continue into the 2010 Congressional elections as Republicans seek to gain control of the House and Senate and at least modify, if not repeal, the newly enacted health care plan. One conclusion is inescapable: health care reform policy debates have only just begun. As the health care insurance exchanges are implemented across the country, there will no doubt be resistance, confusion, and unseen problems to be resolved. With the gradual infusion of nearly a trillion dollars in additional health care spending and thirty-two million more Americans consuming additional health care resources, the financing and operation of the health care system may be pushed to its limits. The result could be a fundamental restructuring of the health care system, particularly if costs from health inflation continue unabated or even expand. This means universal health care reform will be revisited in the near future.¹⁷⁶

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⁴ *Id.*

⁵ *Id.*

⁶ Paul Krugman, *The New York Times*, "Clinton, Obama, Insurance," February 4, 2008, available at <http://www.nytimes.com/2008/02/04/opinion/04krugman.html> (last visited Feb. 10, 2010).

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⁸ Barack Obama Official Campaign Website, "Reduce Costs and Save a Typical American Family up to \$2,500 as Reforms Phase in," available at http://www.barackobama.com/issues/healthcare/index_campaign.php#reduce_costs (last visited Mar. 30, 2010).

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- ¹⁵ *Id.*
- ¹⁶ *Id.*
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- ¹⁸ See Kaiser Family Foundation, *supra* note 12.
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- ²¹ Matthew Bigg and Nick Carey, Reuters, “Angry Americans Disrupt Town-Hall Healthcare Talks,” August 7, 2009, *available at* <http://www.reuters.com/article/idUSTRE5765QH20090807>.
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- ²⁴ *Id.*
- ²⁵ The White House, *The Obama Plan: Stability & Security for all Americans*, http://www.whitehouse.gov/issues/health_care/plan/ (summarizing Obama proposal) (*hereinafter* Obama Plan).
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- ²⁸ Kaiser Family Foundation, *supra* note 12.
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THE OTHER GREEN MOVEMENT: How D.C. CAN SENSIBLY REGULATE MEDICAL MARIJUANA & WHY IT MATTERS

Jacob Rahavi* and Robert Ziff†

After years of obstructing home rule in the District of Columbia, the federal government has reversed course on the issue of medical marijuana. First, the Department of Justice released a memorandum advising U.S. Attorneys to avoid prosecuting “individuals whose actions are in clear and unambiguous compliance with existing state laws providing for the medical use of marijuana.”¹ Then, in a critical step, the U.S. Congress repealed the Barr Amendment, which had prevented the District from enacting the Legalization of Marijuana for Medical Treatment Initiative of 1998 (“the Act”). Accordingly, the District of Columbia government (“the District”) must now create a regulatory scheme for the proper cultivation, sale, and distribution of marijuana for medical purposes. To succeed in its task, the District must strike a delicate balance between the patient’s right to access and the threat of abuse. This will require a series of controls designed to prevent non-medical use while ensuring reasonable access for suffering patients.

Regulation of Medical Marijuana in the Fifty States

Doctors have long recognized the medicinal value of marijuana in treating the symptoms of chronic diseases.² While it cannot cure anything, proper marijuana use is considered an effective treatment for, *inter alia*, the nausea, weight loss, and severe pain suffered by many cancer and HIV/AIDS patients. It also appears to mitigate the severe pain and discomfort related to other chronic ailments. Considering the District has the highest per capita rate of HIV/AIDS in the nation,³ it should come as no surprise that 69% of D.C. residents passed the Act by voter initiative in 1998.⁴

The Act grants seriously ill individuals the right to consume marijuana for medical purposes when recommended by a licensed physician.⁵ To facilitate the creation of a legal supply, it also permits D.C. residents

to organize and operate nonprofit corporations for the purpose of cultivating and distributing marijuana to qualified patients.⁶ The District must now create the necessary framework to license and regulate these dispensaries. Though the District may do so in accordance with its existing authority to regulate controlled substances,⁷ recent legislative activity suggests that the D.C. Council intends to amend the Act in order to create a more robust regulatory framework.⁸ Fortunately, D.C. is not the first actor in this arena. It follows a torrent of activity within the states, many of whom have already relaxed the prohibition on use and distribution of marijuana for qualified medical purposes. According to the Marijuana Policy Project, no less than thirty-six states have enacted “favorable” medical marijuana laws in the last thirty years.⁹ While many of these laws are symbolic or ineffectual, fifteen states provide patients with real protections for medical use,¹⁰ and a handful of states have affirmatively regulated the cultivation and distribution of medical marijuana by third parties.¹¹

Marijuana has long been classified as a Schedule I narcotic by act of Congress. This precludes reclassification to a lower schedule except by subsequent act of Congress. Such classification prevents any distribution as a prescription drug through conventional pharmacies.¹² So the states that are home to organized cultivation and distribution efforts — California, Colorado, Maine, Michigan, New Jersey, New Mexico, Oregon, and Rhode Island — permit the formation of marijuana dispensaries for patients who have a doctor’s recommendation. As each state’s regulatory framework is unique, each has addressed the balance between patient need and narcotic control with varying degrees of success. For instance, the law in both Colorado and Michigan does *not* expressly allow for the operation of dispensaries. Yet new for-profit dispensaries are rapidly emerging in both states anyway. Rather than address the issue directly, each state has effectively ignored it.¹³ Meanwhile in California, state law permits the establishment of collectives and cooperatives, but regulation of these establishments is relegated to local governments.¹⁴ Attitudes toward marijuana vary widely throughout California, which has led to varying

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interpretation of the governing law, confusion among dispensary operators and law enforcement alike, and a heated ongoing debate.¹⁵ Consequently, a patchwork of varying and ineffective practices — the blind-eye approach in Michigan/Colorado and the local approach in California — have created unnecessary and potentially consequential ambiguities.

On the opposite end of the spectrum, New Jersey and Rhode Island are currently implementing the most conservative plans for the establishment of dispensaries. Prospective applicants in Rhode Island are required to establish a number of qualifying factors (capability to run a nonprofit, capability to provide the necessary amount of marijuana, existence of a secure facility, *et cetera*) before winning one of a limited number of licenses.¹⁶ In New Jersey, dispensary applicants must undergo extensive background checks and are subject to strict monitoring and regulation by the government.¹⁷ The current proposal before the D.C. City Council — the Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010 (the “Amendment”)¹⁸ — falls within the more restrictive end of the spectrum.

A Proposal for Effective and Manageable Regulation in the District

While the Justice Department has reversed policy and stated that it will not prosecute individuals who comply with state law, the current environment in some states leaves open the possibility of criminal sanctions. In states where no clear regulatory framework exists, who can say what “unambiguous compliance” actually is? Contemporaneously, the lack of a robust regulatory framework raises the real possibility of abuse. While the level of abuse is currently unknown, such allegations have already spurred moratoriums on new dispensaries in some local communities in California, Colorado, and Michigan.¹⁹ Thus, the District would be wise to create a regulatory system that is both pointed and well defined without being overly burdensome to legitimate distributors and patients. A clearly defined set of regulations would allow dispensaries to follow the law and avoid severe federal penalties. Meanwhile, a serious attempt at regulation with emphasis on verifiability would minimize the real potential for abuse of the system. In this manner, the District can properly balance patients’ need for access with its desire for autonomy and security.

The Act, which was passed by the voters in 1998, was among the first wave of medical marijuana laws. Consequently, it lacks the benefits of the previous decade’s experience; and significant issues related to record keeping, verification, and security go largely

unaddressed. For that reason, the District should focus on filling these regulatory gaps in order to meet contemporary standards. Otherwise, the District risks further congressional interference²⁰ or criminal sanctions against its residents by the Department of Justice.²¹ As at least one council member has noted, “The more professional and controlled and evidence-based our system is, the greater likelihood it will be sustained going forward.”²²

A. Verification of Doctor Recommendations

The most effective way to balance patient need for access against the need for controlled distribution is the creation of a government-run registration system with identification cards for qualified patients. Although it is not called for in the Act, nearly every state with an effective medical marijuana regime maintains such a registry and the District would be wise to follow suit.²³ Indeed, the proposed Amendment would create just such a registry.²⁴ Identification cards benefit all interested parties by providing verifiable evidence of lawful possession. Specifically, they protect patients from unlawful arrest and serve as reliable evidence of the right to purchase from dispensaries.

The Act, in its current form, permits oral recommendations from physicians.²⁵ California is the sole state that permits this practice.²⁶ The inherent difficulty of verifying oral recommendations presents a substantial challenge for the District and may ultimately draw the ire of Congress. Perhaps for this reason, the proposed Amendment would require that all recommendations be written.²⁷ Since patients are already required to obtain a physician’s recommendation, obtaining it in written form should not be overly burdensome.

Implementation of the Act will necessitate the accumulation of records and patient privacy is a legitimate concern; and not everyone wants to be on a government sponsored list of marijuana users. This is especially true in a city full of federal government employees. For that reason, all patient records should be treated in the strictest of confidences. The database should be securely managed and access should be restricted to the limited number of persons who are expressly tasked with managing it. In this manner, the current Amendment is perhaps most deficient. It makes no reference to the confidential treatment of patient records.

B. Presumptive Quantity Restrictions

All medical marijuana states limit the quantity of usable marijuana and/or the number of plants that qualified patients may lawfully possess.²⁸ Knowing

“Implementation of the Act will necessitate the accumulation of records and patient privacy is a legitimate concern; and not everyone wants to be on a government sponsored list of marijuana users.”

“To ensure the sustainability of D.C.’s medical marijuana laws, the District should amend the Act to include authority to collect fees, so dispensaries will bear the burden of their own regulation.”

both the number of patients and presumptive per patient quantities enables regulators and suppliers to limit the amount of marijuana produced without causing supply interruptions. Here in D.C., the Act requires that “patients have access to a *sufficient quantity* of marijuana to assure that they can maintain their medical supply without any interruption.”²⁹ As such, the Act appears to permit reasonable restrictions on quantity. Other states to address this issue have implemented regulations that generally include presumptive caps on per patient quantities.³⁰ A typical presumptive limit is around two ounces and a handful of plants per patient. Similar regulations should be adopted by the District and incorporated into the registration process. The Amendment, if passed, would expressly create quantity restrictions.³¹ Where patients have a medical need for higher quantities — a situation that sometimes occurs where patients can only eat the medicine — their registration card should so indicate.

C. Dispensary Licensing Scheme

The District should also create a licensing scheme for dispensaries that is designed to provide an uninterrupted supply for patients while protecting the safety of the community. An effective licensing scheme would allow the District to mandate compliance with sound policies and conduct reasonable inspections and enforcement proceedings, administered by the D.C. Department of Health. Thus, dispensaries would be regulated in much the same way as pharmacies.

A number of sound regulations seem appropriate. Among other things, proper dispensary regulations in D.C. might address the character of board members and employees. For example, Rhode Island prohibits felons (with limited exception) from serving in any capacity at a dispensary.³² Also, a firewall should be created between dispensaries and recommending physicians in order to avoid any conflict of interest that may raise the suspicion of federal investigators. And dispensaries should maintain accessible audit-friendly records on inventories, sales, personnel, policies, and financial transactions. These records will assist the District’s regulatory efforts and demonstrate a dispensary’s strict adherence to local laws. Accordingly, dispensaries should expect to retain compliance counsel to ensure sufficient training of staff and record keeping, and to assess the appropriateness of internal policies and course corrections.

Dispensaries should also comply with a variety of reasonable restrictions directed toward the safety, security, and general well being of the community. These may include limited hours of operation, plenty

of outdoor lighting, and professional on-site security guards. Most importantly, all facilities should be monitored, securely constructed, and inaccessible to unauthorized persons.

The District may seek to prevent dispensaries from opening within certain proximity to schools. The proposed Amendment, for example, would prevent dispensaries from opening anywhere within 1000 feet of schools and youth centers.³³ However, the District should proceed cautiously. Due to, *inter alia*, the proliferation of charter schools, D.C. is bursting with school facilities. Consequently, businesses seeking alcohol distribution licenses in D.C. have already found it difficult to comply with similar restrictions. Overly regulating the location of dispensaries may relegate them to the outskirts of the city where they will be inaccessible to many patients. If the District’s aim is to prevent marijuana from being unintentionally marketed to minors, it could achieve a superior result through reasonable restrictions on signage and other advertising.

D. Funding of Regulatory Efforts

Administering D.C.’s medical marijuana regime will require funding to cover costs associated with licensing, inspections, and enforcement actions. However, the citizen drafted Act specifically exempts nonprofit dispensaries from paying sales taxes, use taxes, income taxes, and other local taxes. In addition, it makes no mention of fees specifically associated with dispensary regulations. To ensure the sustainability of D.C.’s medical marijuana laws, the District should amend the Act to include authority to collect fees, so dispensaries will bear the burden of their own regulation. The proposed Amendment addresses this issue by implementing a licensing fee for dispensaries and a sliding-scale registration fee for patients.³⁴ This seems wise so long as fees are kept at a reasonable level. Excessive fees may impact the ability of patients to purchase marijuana at a reasonable price.

Conclusion

Medical marijuana is an evolving area of law that has withstood fits and starts over the last decade. Due to the District of Columbia’s role as our nation’s seat of power, implementation of the Act may be its greatest challenge yet. But despite various arguments against implementation, nothing prevents the District from succeeding. After all, pharmacies have been filling prescriptions for dangerous and addictive substances without controversy for decades. Under the Act, marijuana would be just another medication in the physician’s toolbox. When effectively employed, it relieves some of the severe pain and suffering of the

chronically ill. Unlike the fifty states, however, D.C. remains subject to congressional oversight and control. Consequently, more permissive societal norms that exist in some states are unworkable in D.C.; and an overly lax and easily abused regulatory regime may persuade Congress to repeal the Act altogether. But if physicians, patients, and dispensaries work together in good faith with the District, there is no doubt that a sensible policy is attainable.

¹ Memorandum from David W. Ogden, Deputy Attorney General, to Selected United States Attorneys (Oct. 19, 2009), *available at* <http://www.justice.gov/opa/documents/medical-marijuana.pdf>.

² Report 3 from American Medical Association Council on Science and Public Health (I-09), *available at* <http://www.ama-assn.org/ama1/pub/upload/mm/443/csaph-rep3-a09.pdf>.

³ Dept. of Health and Human Services HIV/AIDS Surveillance Report Vol. 19, Table 16, *available at* www.cdc.gov/hiv/topics/surveillance/resources/reports/2007report/pdf/2007SurveillanceReport.pdf.

⁴ District of Columbia November 3, 1998 Election Results on Initiative Measure #59, *available at* www.dcboee.org/election_info/election_results/elec_1998/ini59_98.htm.

⁵ Legalization of Marijuana for Medical Treatment Initiative of 1998 § 1. *Id.* at § 7.

⁶ D.C. CODE § 48-903.01 *et. seq.* (2010).

⁷ District of Columbia Legalization of Marijuana for Medical Treatment Initiative Temporary Amendment Act of 2010, B18-0663 (Delaying the implementation of the Act until the effective date of the Amendment.); District of Columbia Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, B18-0622. This article was submitted for publication while B18-0622 was under consideration by the D.C. City Council. Subsequent amendments to the bill are likely. *See* Martin Austermuhle, *Changes to Medical Marijuana Legislation Likely Next Week*, DCIST, Mar. 24, 2010, *available at* http://mobile.dcist.com/2010/03/changes_to_legislation_that_would.php.

⁸ Marijuana Policy Project, *State by State Medical Marijuana Laws: How to Remove the Threat of Arrest*, 2 (2008) *available at* www.mpp.org/legislation/state-by-state-medical-marijuana-laws.html.

⁹ *See, e.g.*, AK, CA, CO, HI, MA, MD, MI, MT, NJ, NM, NV, OR, RI, VT, and WA.

¹⁰ *See, e.g.*, CA, MA, NJ, NM, OR, and RI.

¹¹ 21 U.S.C. § 812(b).

¹² Colorado Department of Public Health and the Environment statement on Medical Marijuana Registry, *available at* www.cdph.state.co.us/hs/Medicalmarijuana/Dispensaries%202.pdf; Michigan Department of Community Health, Frequently Asked Questions on Medical Marijuana Program, *available at* www.michigan.gov/mdch/0,1607,7-132-27417_51869_52140_--_,00.html.

¹³ CAL. HEALTH & SAF. CODE, § 11362.775 (2010).

¹⁴ John Hoeffel, *Confusion About Marijuana Sales Traced to California Law*, LOS ANGELES TIMES, Jan. 6, 2010.

¹⁵ Office of Health Professionals Regulation, Medical Marijuana Program, *available at* www.health.ri.gov/hsr/mmp/index.php.

¹⁶ New Jersey Compassionate Use Medical Marijuana Act, § 7 (2010).

¹⁷ District of Columbia Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, B18-0622.

¹⁸ *See, e.g.*, Genevieve Bookwalter, *Pot dispensary moratorium approved in Santa Cruz*, Santa Cruz Sentinel.

¹⁹ D.C. CODE § 1-206.01.

²⁰ *See* 21 USC § 841.

²¹ Sam Jewler, *Medical Marijuana Finally Heads for D.C.*, TIME, Jan. 27, 2010, *available at* www.time.com/time/nation/article/0,8599,1956673,00.html?iid=tsmodule.

²² *See* AK, CA, CO, HI, MA, MI, MT, NM, NV, OR, RI, and VT.

²³ B18-0622, Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, § 10, D.C. Council (D.C. 2010).

²⁴ The Act, § 5(a).

²⁵ CAL. HEALTH & SAF. CODE, § 11362.5(d).

²⁶ District of Columbia Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, § 2, R18-0622.

²⁷ *See* AK, CA, CO, HI, MA, MI, MT, NM, NV, OR, RI, VT, and WA.

²⁸ Legalization of Marijuana for Medical Treatment Initiative of 1998, § 5(a) (emphasis added).

²⁹ *See, e.g.*, MICH. COMP. LAWS §§ 333.26421–333.26430 (2008) (noting that Michigan, permits individual patients to have up to 2.5 ounces of usable marijuana and up to twelve plants in an enclosed and locked facility).

³⁰ District of Columbia Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, § 10, B18-0622.

³¹ The Edward O. Hawkins and Thomas C. Slater Medical Marijuana Act, § 21-28.6-12(i)(4) (Rhode Island, 2006).

³² District of Columbia Legalization of Marijuana for Medical Treatment Initiative Amendment Act of 2010, § 10, B18-0622.

³³ *Id.*

REEXAMINING MODELS OF DISABILITY AND APPLYING RATIONALITY, MORALITY, AND ETHICS TO SUPPORT DISABILITY RIGHTS IN CONTEXT OF GENETICS¹

Gary C. Norman, Esq.*

“People with or without disabilities have, and should have, a fundamental civil and human right of biological autonomy including private, personal decisions about the circumstances of procreation.”

“I do not feel obliged to believe that the same God who has endowed us with sense, reason, and intellect has intended us to forgo their use.”²

I. Introduction

The “brave new world”³ of genetic and assistive reproduction science and technology provides unrivaled opportunities like no other in history for individuals, either with or without disabilities, to engage in fundamental decisions of procreation, disease prevention and management, and child rearing. Procedures and therapies found in this brave new world are, *inter alia*: prenatal genetic testing diagnosis;⁴ trait selection, which includes germ line modification; and such therapies as stem cell research and Pharmacogenomics.⁵ Likewise, personalized medicine, which is narrowly targeting therapies based on genetics to address disease, constitutes a revolutionary advancement for medicine.⁶ These advancements outpace cultural, ethical, and legal structures and norms, and implicate a dichotomy between the better spirits and the woeful nature of civic society. Advocates, ethicists, legal professionals, and scholars possess concerns about the misuse of science and technology, especially inclusive of medicine, to sterilize, eradicate, and eliminate, or segregate and exclude, so-called undesirables.⁷ Persons with disabilities have all too often been considered as one of these categories of undesirable individuals, and have historically been prey to the nefarious eugenic agenda of some in society.⁸ Additionally, for many, parental choice not to procreate humans with disabilities, or to terminate pregnancies once a disability is detected, constitutes an alarming outgrowth because, even if this falls short of a eugenics agenda, stereotypes are perpetuated.⁹ In sum, should genetic and reproduction science and technology be applied to determine the human genome of fetal life?

In the view of myriad people with disabilities, the negative outgrowth of such application would include a host of actions from further segregation and discrimination to outright forced eradication.¹⁰ As such, the reemergence of the abhorrent period of history known as eugenics constitutes a concern.¹¹ Conversely, people with or without disabilities have, and should have, a fundamental civil and human right of biological autonomy including private, personal decisions about the circumstances of procreation.¹²

This article will discuss the brave new world of science and technology in light of its impact on people with disabilities. Specifically, the discussion in this article will focus on the prism of the models through which disability is recognized. If applied in a manner such that the best facets of both models of disability can bear forth, then the position of this author, a person with a vision disability, is that my colleagues in the disability civil rights movement should not reflexively excoriate genetic and assisted reproduction science and technology. However, safeguarding people with disabilities, who are a discrete and insular minority across the globe,¹³ against the negative potentialities of science and technology requires more than laudatory pronouncements. Two proposed prescriptions may have the affect of positively influencing the application of genetic and assisted reproduction science and technology within the United States, a world leader with respect to the rights of the disabled community.¹⁴ They are: (1) model legislation that sets a framework for this brave new world of science and technology in a pro-life, pro-disability rights context. A waiting period, such that individuals will subsequently engage in informed decision-making regarding an embryo or fetus with a disability or future possible disabling condition constitutes an integral component of this model legislation. And (2) measures to further evolve further cultural notions and attitudes about disability.

II. Review of Genetics and Assisted Reproduction

A wondrous “blue-print” can be discovered in each human being.¹⁵ Genotypes and phenotypes constitute

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key components of the make-up of people.¹⁶ In the 1990s, the federal government¹⁷ initiated an undertaking of historic proportions, the Human Genome Project, which private industries in competition joined, to identify this blueprint or “map.”¹⁸ The Human Genome Project, and the applications that have been developed and will continue to be developed from it, including the ability to control and manipulate the blueprint, is earth shattering, as it reveals intimate details about medical condition, disease, the predisposition for disease, identity, and family ancestry and history.¹⁹

The project is estimated to have cost three billion dollars.²⁰ Optimism about the ability of mapping the human genome and its applications abounded as the project spiraled forward at a startling tempo.²¹ At the conclusion of the Clinton administration, when the Human Genome Project approached its goal of mapping the genome, scientists and government and private leaders glowed with the potentiality for the new field of gene therapy, which is the treatment of a disease by introducing a corrective gene.²² The hope exclaimed by the White House was that the Human Genome Project would result in cures for some five thousand known hereditary conditions.²³ Furthermore, in 2003, the concomitant occurrences of “finalizing the sequencing of the DNA of the human genome” and the anniversary of the discovery of DNA took place.²⁴

Dr. Francis S. Collins, Director of the National Human Genome Research Institute and now head of the National Institutes of Health, exuded optimism in his testimony before a United States Senate subcommittee on the progress of the Human Genome Project and of its implications for society.²⁵ His testimony expressed that by 2010, “predictive genetic tests will exist for many common conditions where interventions can alleviate inherited risk.”²⁶ Likewise, by 2020, “gene-based designer drugs are likely to be available for conditions like diabetes [and] Alzheimer’s disease.”²⁷

As recently as 2003, sequencing genes cost exponential sums.²⁸ However, the goal is that within five years, sequencing and testing a gene in order to provide personalized medical therapies will cost only \$1,000, thereby spurring further development of genomics.²⁹ The tests, treatments, therapies, and applications, which are presently available in genetics and assisted reproduction, delineate into categories of pre-conception and post-conception.

Specifically, “[m]ost genetic testing does not diagnose physical injury or disease; rather, it...provides information about the possibility of a latent condition in an otherwise healthy person.”³⁰ Regarding pre-conception, genetic counseling constitutes a powerful option for parents, with or without disabilities, to detect disabilities or potential disabling conditions. Genetic counseling constitutes a health service utilized by families and performed by certified health professionals, such as specially trained nurses, the purpose of which, includes, enhanced knowledge of inheritable traits.³¹ Conditions may be observed in utero through such post-conception procedures as targeted blood testing and sampling, e.g., amniocentesis and ultrasound. These means can detect disabilities, such as intellectual disabilities.

For instance, “[i]n 2007, the American College of Obstetricians and Gynecologists recommended that all women be offered screening tests for Down syndrome, which causes...[developmental disabilities, i.e., substantially restricted cognitive functioning] and other health problems.

The current tests consist of a combination of blood tests and ultrasounds.”³² Preimplantation Genetic Diagnosis (PGD) constitutes another example of procedures utilized to control the traits of offspring.³³ As PGD involves the removal and genetic analysis of a single cell from each available embryo, a particular gene can be tested for, (e.g., the gene for Huntington’s disease) and selected for or against implantation.³⁴ Additional procedures include, once again, amniocentesis, chorionic villus sampling, and other methods.³⁵

Finally, advancements in knowledge about genetics will enable screening and testing of “embryos for the presence of gene variants, known as alleles, associated with a range of conditions through the use of a DNA microarray, a testing device that can screen for thousands of alleles at one time.”³⁶ As such, “[c]ombining these genetic advances with ART procedures will permit parents to select embryos based upon their potential future traits.”³⁷

Therefore, the ethical and legal issues caused by genetics strain the mind to be sure. The “newly acquired ability to map and understand...genetic traits” is a discovery that has “transform[ed] both science and society.”³⁸ As Judith Daar, a noted ethicist and scholar, has written, “[a]ssisted conception... is axiomatically complicated by its necessary introduction of third parties into the reproductive process.”³⁹ As such, the traditional two-party process has the issue of increased complexity.⁴⁰ Arguably, bias may be inserted into the process of procreation therefore.⁴¹ In sum, genetic and assisted reproduction science and technology can transform society in a way that either improves the human condition or that worsens bias, discrimination, and exclusion.

III. Medical Model versus Social Model of Disability

Arguably, disability originates from the effect of differing models – the medical and the social models.⁴² This article will discuss the models of disability as well as their historical milieu.⁴³

A. Medical Model

The medical model of disability dates back to the nineteenth and twentieth centuries, which experienced the rapid development of medicine and advancements in medical diagnosis, procedures, and technology.⁴⁴ These centuries also witnessed the corresponding emergence of the physician as a powerful actor in society.⁴⁵ Logically, a biological component exists at the core of this model.⁴⁶ People with disabilities constitute poor suffering patients, afflicted with impaired parts and disease.⁴⁷ Outcomes of the disabled are to be governed by diagnosis, prognosis, and therapeutics.⁴⁸ Arguably, eugenics constitutes the malevolent expression of this medical model of disability.⁴⁹

At this point, it is worth emphasizing that cultural stereotypes of the disabled abound. These stereotypes, many of which implicate the medical model, include the following:

- The disabled person as pitiable and pathetic (e.g., Tiny Tim in Charles Dickens’ *A Christmas Carol* and Porgy in George Gershwin’s *Porgy & Bess*).
- The disabled person as an object of violence (e.g., Joan Crawford in *Whatever Happened to Baby Jane?* and Audrey Hepburn in *Wait until Dark*).

- The disabled person as sinister and evil (e.g., Shakespeare's Richard III, and also Black Dog, Blind Pew and Long John Silver in Stephenson's *Treasure Island*).
- The disabled person as atmosphere or curio (e.g., the characters of Merrick in *The Elephant Man* and Half Soldier in *the Good, the Bad, and the Ugly*).
- The disabled person as super cripple (e.g. the central characters in *My Left Foot* and *Reach for the Sky*).
- The disabled person as an object of ridicule (e.g. the cartoon *Mr. Magoo* and Harpo Marx of the Marx Brothers).
- The disabled person as his or her own worst and only enemy (e.g. the central characters in *Coming Home* and *Born on the Fourth of July* and Lt. Dan, a newly wounded soldier, in *Forrest Gump*).
- The disabled person as a burden (e.g. in the recent British television drama *Keeping Tom Nice*).
- The disabled person as sexually abnormal (e.g. Hephaestus in Homer's *The Odyssey* and Lady Chatterley's husband in D.H. Lawrence's novel).⁵⁰

Additionally, ignorance imbued jocularity reinforces these stereotypes. For instance, a piece published in *Maxim*⁵¹ possessed the seeming intention of using the disabled as a punch line. These representations in mass media reflect that bias, discrimination, and prejudice are prevalent within the intimate, private contexts of courtship and marriage, sexual intercourse, and procreation.⁵² Women with disabilities disproportionately encounter discrimination and prejudice on these issues.⁵³ Disability law and policy scholars seem to accept summarily that the medical model, and its corollary the rehabilitation model,⁵⁴ constitute the reason for these continued notions and stereotypes.⁵⁵

Since the medical model focuses on the physical condition of the disabled, the argument posited against this model holds that it "relies on normative categories of 'disabled' and 'non-disabled,' and presumes that a person's disability . . . is 'a personal, medical problem, requiring but an individualized medical solution.' . . . The medical model views the physiological condition itself as the problem."⁵⁶ As far as this model might categorize individuals as the sum of their anatomical parts and impairments, instead of autonomous actors endowed with dignity, a concern exists about the reemergence of the eugenics movement. Before providing further discussion about the models of disability, exploring the topic of eugenics may prove helpful.

1. Eugenics

As one court explained, "[e]ugenics is defined as the science of improving the qualities of the human race by the careful selection of parents."⁵⁷ There is even so called "positive" and "negative" eugenics.⁵⁸

Additionally, contemplations of eugenics implicate automatically the specter of 1930's and 1940's Germany. Flashing in the mind therefore is: (1) torch ignited parades, (2) Kristallnacht, and (3) guards rounding up fellow human beings, inclusive of women and children, for mass slaughter.⁵⁹ Humans would be remiss to forget this history, as not doing so might cause a repeat of such terror. While the brothers and sisters of people

with disabilities, e.g., Jews, were the subject of horrific acts of evil and prejudice in Germany under the *Das Dritte Reich* or Third Empire, many forget that people with disabilities ostensibly constituted a training module for the Nazi regime even before there were organized concentration camps of terror and death – The Final Solution.⁶⁰

The article entitled, *Bioethics and Disability Rights: Conflicting Values and Perspectives*,⁶¹ in discussing the concern of people with disabilities about the application of genetic and assisted reproduction science and technology, provides a good and concise review of eugenics as it was first utilized to eradicate the disabled. Unfortunately, medical professionals who pledged to "do no harm," participated in the Nazi Action T-4 program, in which up to 100,000 children and adults with disabilities were euthanized.⁶² Arguably, people with disabilities met this horrific consequence because Germans thought them to be feeble, anatomically unworthy burdens on the state.⁶³

Today, a linkage exists among historical eugenics and pre-conception and post-conception genetic testing procedures.⁶⁴ The medical model, and its corollary, the rehabilitation model,⁶⁵ bear forth, especially in the context of sex and procreation.⁶⁶ As such, "[t]he eugenics legacy continues to linger as a cautionary note to the application of a public health model [i.e., a medical model] to advances in reprogenetic medicine."⁶⁷ Hence, one can understand that disability advocates typically criticize the medical model of disability because the focus of that model is of the disabled as ill and in need of patronage⁶⁸ and because of its potentiality to reinvigorate eugenics.⁶⁹

2. Counterpoint

However, medical intervention, even as facilitated by the brave new world of genetic and assisted reproduction science and technology, might conceivably aide the future life of people with disabilities. Notably, one morning when at a bed and breakfast in Pennsylvania, a couple recounted how their friend was able to utilize applications that have been derived from genetics to address a life-threatening kidney disease of her fetus that, if present after birth, would have had a high probability of mortality. The fetus, now a grown adult, has a distended kidney. In that circumstance, the medical procedure resulted in a positive outcome—the birth of a contributing human—whose in utero condition might be considered a disability. Moreover, as one author argued:

"Curing cancer; reversing paralysis; eliminating tuberculosis, leprosy, and malaria; and correcting the organic causes of many mental health conditions, for example, would seem to be achievements that nearly everyone would applaud enthusiastically. The elimination of polio, now found in only 4 countries in the world, is well within reach; why would anyone lament its final eradication?"⁷⁰

Furthermore, if comprehensive early intervention services funnel to infants as early on as possible, successful outcomes in rehabilitation and education increase in likelihood.⁷¹ Therefore, by detecting disabilities or the predisposition for disabilities early on, specifically when a fetus is in utero, parents with or without disabilities and society as a whole can engage in critical decisions and planning, to the consequential impact of all. Contrary to the accepted position of some,⁷² the medical paradigm can benefit people with disabilities.

B. Social Model

The belief that discrimination emerges not from disabilities as a medical condition or disease in their own degree but rather from societal attitudes and stereotypes, a belief that emerged during the twentieth century, constitutes the preferred construct of disability held by myriad scholars – the social model.⁷³ The author, Adam M. Samaha, provides a good description of the social model. He expresses that the definition of disability contained within the social model focuses on the “disadvantage” of people with disabilities and the root causes, which include, “architectural, social, and economic,” causes of such disadvantage.⁷⁴ Another definition of disability incorporated in this model is that people with disabilities constitute not the sum of their conditions and diseases but rather, in a certain sense, the victims of an environment that lacks reasonable accommodations.⁷⁵ In sum, whether people with disabilities are abnormal and must adhere to society, or whether a just and equal society should engage in affirmative actions to maximize the potential of such individuals, is a question that the social model addresses.⁷⁶

Additionally, the critical and on-going quest of realizing the noble concepts of equal civil and human rights set forth in the Declaration of Independence, which became a tour de force during the twentieth century, spurred the national and international disability civil rights movement.⁷⁷ Furthermore, the civil rights movements of the late 20th Century arguably caused people with disabilities to “recognize[] that their social positioning was strongly correlated with their exclusion from existing, legal, social, cultural, political, economic and structural arrangements . . . In this sense disabled and non-disabled people emerged as two distinct categories of citizens,”⁷⁸ each deserving protections. The philosophy of this model of disability is that, “analyzed limbs may not particularly limit a person’s mobility as much as attitudinal and societal barriers.”⁷⁹ Consequently, persons with disabilities, if provided the appropriate accommodations, modifications, or supports, can contribute equally to the collective.⁸⁰ In the United States, a panoply of statutes arguably embodies the social model of disability.

The Rehabilitation Act of 1973 (Rehabilitation Act), as amended,⁸¹ and the Americans with Disabilities Act of 1990 (ADA),⁸² as amended,⁸³ as well as other statutes, are argued to embody the social model of disability.⁸⁴ Additionally, the Genetic Information Nondiscrimination Act of 2008⁸⁵ (Genetic Act) can be considered to embody the social model of disability. These statutory schemes seek to establish an inclusive society for all.⁸⁶ Finally, the Convention on the Rights

and Dignity of Persons with Disabilities⁸⁷ and its optional protocol⁸⁸ constitute a reflection of the paradigm shift from the medical to the social model of disability.⁸⁹

1. Social Model: Domestic and International Protections

Equal access to and affordability of healthcare and rehabilitation services constitute critical components of the integration of people with disabilities.⁹⁰ In May 2009, the Secretary of the U.S. Department of Health and Human Services (HHS) announced,⁹¹ in commemoration of the landmark decision of the United States Supreme Court in *Olmstead v. L.C.*,⁹² that 2009 would constitute the “Year of Community Living.” Genetic testing and counseling arguably equals an important community-based support. Additionally, as insurance is a key reimbursement vehicle for healthcare, including genetics, civil rights protections against discrimination have been supplemented, if imperfectly, with the provisions of the Genetic Act.⁹³

Genetic disorders, which are either singular or multifactorial,⁹⁴ obviously result in impairments.⁹⁵ These impairments, if active or even potentially dormant but laden may, depending on their severity, qualify affected individuals as disabled.⁹⁶ Under the Rehabilitation Act,⁹⁷ and the ADA,⁹⁸ as originally enacted, “the ability to reproduce and bear children is a ‘major life activity’ that if substantially limited, may constitute a disability.”⁹⁹ Furthermore, as former Equal Employment Opportunity Commission (EEOC) Commissioner and Endowed Chair of Law, Paul Steven Miller, stated, “[c]early, the ADA covers people who have a manifested genetically related illness or disability that impairs a major life activity as well as those who have a record of a genetically related disability (e.g., someone who has recovered from cancer). The more challenging question is whether the ADA prohibits discrimination based on a diagnosed but asymptomatic genetic condition that does not substantially limit a major life activity.”¹⁰⁰ However, under the expansive provisions of the ADA Amendments Act of 2008, asymptomatic conditions or disorders may be disabilities.¹⁰¹

Scholars and advocates proclaim this set of amendments to the original ADA as a victory for the disabled.¹⁰² In advance of promulgating updated regulations to the ADA, the EEOC will acquire public input by means of town hall meetings hosted across the United States in 2009.¹⁰³ If impairment meets the definition of disability, then certain affirmative obligations protect the individual with those impairments.

“One can understand that disability advocates typically criticize the medical model of disability because the focus of that model is of the disabled as ill and in need of patronage and because of its potentiality to reinvigorate eugenics.”

“The Rehabilitation Act and the ADA translate the goal of creating a more decent, inclusive society for the disabled by imposing affirmative prohibitions against discrimination and by requiring rights of access and modification or accommodation on private and public actors.”

In short, the Rehabilitation Act and the ADA translate the goal of creating a more decent, inclusive society for the disabled by imposing affirmative prohibitions against discrimination and by requiring rights of access and modification or accommodation on private and public actors. The ADA expands on the principles and protections of the Rehabilitation Act into the non-federal public and private sectors. As such, principles under both the Rehabilitation Act and the ADA involve the same matter.¹⁰⁴

Medical offices, institutions, and facilities, which do not receive federal or state financial assistance, comprise places of public accommodation, covered by the provisions of Title III of the ADA.¹⁰⁵ If a state or local government or instrumentality thereof, operates them, then they constitute a public entity and are subject to the provisions of Title II of the ADA.¹⁰⁶ Furthermore, services and programs furnished or operated by a public entity in the context of healthcare can include, for example, state Medicaid programs.¹⁰⁷ A covered party, (i.e., a place of public accommodation or a public entity) must refrain from discrimination. In furtherance of this requirement, the covered party must provide reasonable accommodations or modifications to services, programs, policies and procedures, or provide auxiliary aides and services.¹⁰⁸ Additionally, the Rehabilitation Act, as well as Title II of the ADA, require that programs and activities receiving federal financial assistance, or that are part of state or local government must be administered “in the most integrated setting appropriate.”¹⁰⁹ The purpose behind this so-called “integration mandate,” is that a public entity or place of public accommodation may not deny a qualified person with a disability the opportunity to participate in programs or activities that are as equal to the able-bodied as possible, even if separate programs or activities would be, in the view of such public entity or place of public accommodation, best suited to the disabled. However, despite the passage of the ADA nineteen years ago, and the passage of the Rehabilitation Act before that, people with disabilities, especially women, continue to confront unawareness on the part of providers, programmatic and policy barriers (including, equal access to medical equipment and services, financing, and supports and assistance), and outright discrimination.¹¹⁰

Examples of inaccessible services, programs, and procedures, which women with disabilities confront, include: (1) inaccessible mammography and pelvic exam equipment, (2) overall inaccessible medical equipment, and (3) a lack of fertility and sexual health information.¹¹¹ Clearly, women with disabilities suffer health disparities because of their immutable

characteristics. The problem of health disparities originates from a myriad of root issues.

The 2004 symposium report on the health of women with disabilities, hosted by HHS, indicates that awareness about disabilities among providers is limited. The report states, “despite the increased awareness of women’s health, research to date has not adequately addressed the health concerns of women with disabilities.”¹¹² Moreover, providers typically receive no school or clinical-based training about people with disabilities, either as a whole or as related to sub-fields of medicine, such as women’s health.¹¹³ Medical and allied health schools simply do not possess curricula about disability, except as a reflection of illness and impairment to be cured.¹¹⁴ Consequently, attitudes among providers about disability generally range on the spectrum from the discriminatory to the patronizing.¹¹⁵ For instance, providers can sometimes be surprised that women with disabilities would be sexually active or would desire to procreate.¹¹⁶

Providers, who are generally concerned about the costs and time of regulatory compliance consequently fail to adhere to accessibility mandates because of these underlying beliefs and attitudes.¹¹⁷ A lack of appropriate communication by physicians causes access gaps to a range of minority populations, especially inclusive of women with disabilities.¹¹⁸ Inadequate communication causes these gaps because providers must be vigilant with their patients if they are to avoid errors or to provide meaningful consent.¹¹⁹ By having myopia about people with disabilities, providers are less likely to engage in appropriate communication.¹²⁰ This worsens the consequential power imbalance between the patient with a disability and a provider.¹²¹ Once again, providers, concerned with issues of time and profit margins, tend to limit focus on communication to patients, with or without disabilities.¹²² Inadequate communication, coupled with unequal coverage in the public and private insurance systems, punctuate health disparities.

Reimbursement schemes, especially those furnished through Medicare and Medicaid, are a continued barrier that inhibits broad access to genetic testing and counseling for people with disabilities.¹²³ The HHS Advisory Committee on Genetics, Health, and Society urged action on prior recommendations, namely its 2006 report,¹²⁴ concerning gaps in reimbursement.¹²⁵ Additionally, the United States is a multi-payer based health insurance system, which many Americans cannot afford.¹²⁶ The problem of access disparities worsens under such a multi-payer system when chronic conditions rise to the level of a

disability.¹²⁷ Moreover, a lack of robust community support and services for persons with disabilities and their families compounds the issue of health disparities.¹²⁸ Disability activists lobby Congress on the principle that people with disabilities receive due attention during the reform of American healthcare.¹²⁹ Namely, they advocate the need for better access to community-based supports, coverage parity, and accessibility of Durable Medical Equipment and medical facilities.¹³⁰

Despite these issues, hope exists as regulatory and legislative approaches have been initiated to address discrimination based on the genetic code. In 2000, President Clinton issued Executive Order No. 13145 to prohibit discrimination against federal employees based on genetic information.¹³¹ In 2008, Congress passed and President Bush signed the Genetic Act to address actual or possible gaps in the coverage of statutory schemes, such as the ADA, as to health insurance.¹³²

The Genetic Act seeks to protect individuals from discrimination based on information derived from genetics, namely, genetic tests and counseling, and family medical history. It covers only asymptomatic individuals amending several statutory schemes, including the Social Security Act (Medicare supplemental policies), the Health Insurance Accountability and Portability Act of 1996 and Title VII of the Civil Rights Act.¹³³ The Genetic Act prohibits insurers and employers from excluding eligibility, limiting, or increasing premiums for group insurance, based on preexisting conditions or as a matter of underwriting, and employers, labor unions, or joint management and labor committees from rendering adverse employment decisions based on the genetic code.¹³⁴ The Genetic Act deserves criticism as its provisions fail to address genetic discrimination in life, disability, and long-term care insurance.¹³⁵ Nor do its provisions address other issues, where affirmative language would have been helpful in safeguarding civil rights. For instance, section 208 of the Genetic Act specifically precludes the critical cause of action of disparate impact with which to remedy violations.¹³⁶ In sum, litigation and various forms of alternative dispute resolution will test if the Genetic Act will be effective in combating discrimination.

The new international framework of the Convention on the Rights of Persons with Disabilities and its Optional Protocol, which builds on the positive protections of the ADA, will prove critical globally as civic societies seek to promote the benefits of science and technology while striving against negative applications of science and technology, such as the reemergence of eugenics for the more than 650,000,000 people with disabilities on the planet.¹³⁷ In 2006, the United Nations General Assembly adopted these historic covenants. Scholars Lord and Stein describe that the Convention possesses several general principles and articles, including, “articles of universal application, articles addressing substantive rights, and articles establishing implementation and monitoring schemes.”¹³⁸ The Convention is a comprehensive human rights covenant with affirmative civil, political, and social rights mandates on state parties, or governments.¹³⁹ Specifically, Articles 25 and 26 of the Convention require state parties to engage in actions, such that people with disabilities enjoy equal access to healthcare and rehabilitation services.¹⁴⁰ Explicitly, Article 25 provides that state parties will ensure equal, accessible, and affordable healthcare services, reimbursement systems, and insurance to persons with disabilities, “including in the area of sexual and reproductive health and population-based public health programs”.¹⁴¹ An optional protocol

fortifies the Convention, and that serves as an implementation vehicle with communication and complaint processes to redress the rights set forth in the covenant.¹⁴²

In light of the foregoing, women with disabilities are less likely to receive appropriate gynecological and other health services and examinations.¹⁴³ Therefore, women with disabilities sustain rates of poorer health, especially in terms of reproductive health.¹⁴⁴ Clear inadequacies, as they relate to the protection of people with disabilities, in the brave new world of genetics penetrate existing civil rights frameworks. Consequently, protections in such statutory schemes as the ADA¹⁴⁵ and the Genetic Act¹⁴⁶ constitute starting points which should serve as bulwarks against the negatives of genetic and assisted reproduction science and technology. Moreover, the Convention, which is influenced by the ADA, may be a helpful galvanizer of dialogue, if not substantive legislation, on these issues.¹⁴⁷

C. Criticizing The Social Model: Both Models Have A Role

Clearly, the social paradigm of disability operates with a pro-disability focus. The normative orientation of this paradigm is that people with disabilities deserve equal rights, and the above-mentioned civil rights panoply embodies this orientation. To the extent that this paradigm integrates the historically excluded into civic society, we should applaud the same. However, the review of the models of disability cannot stop here.

The article, *What Good Is the Social Model of Disability?*,¹⁴⁸ provides a refreshing insight into, even perhaps critique of, the social model of disability or the application thereof. The article expresses that the social model is a way to describe disability, but falls short of an actual policy response.¹⁴⁹ Therefore, qualitatively categorizing the medical model and its corollary, the rehabilitation model,¹⁵⁰ as deleterious, and praising the social model of disability, is simplistic. Much more exists to the issue.

When the medical and social model are juxtaposed, condemning the medical paradigm while praising the social paradigm falls short of a workable basis for explaining disability based discrimination. Even the medical paradigm can result in positive outcomes, that is, children – a laudatory magical experience whether disabilities are implicated or not. As pro-disability rights as the social paradigm may be, especially in the inclusion and integration mandates of positive legislation, people with disabilities continue to encounter bias, discrimination, and prejudice in society. Moreover, there is an inherent flaw with qualitatively categorizing these paradigms as such, because neither of them possess measures of goodness or wrongfulness – they are mere explanations and constructs.

Disability, on the one hand, possesses a medical facet, which may necessitate medical attention and even cure. On the other hand, disability implicates the manner in which civic society upholds its better spirits and normative imperatives of the equality of individuals, even if such individuals may not be able to walk up the stairs or see the film screen at the drive-in on a Saturday night. Therefore, society ultimately determines the potential either for the implementation of the morally positive, or for the detriment of the historically excluded and marginalized.

Consequently, merging these models in a way that incorporates each of their better components in furtherance of civil rights of people with disabilities should constitute the searching review and weighty task of scholars and policy-makers. Profound injustice will occur if science and

technology lacks a pro-disability and pro-life perspective.¹⁵¹ Obviously, the eugenics fad of the twentieth century is a clear example of how science and technology can punctuate prejudice.¹⁵² The question that remains is what ultimate course of conduct or remedial measures should be undertaken, such that society advances scientifically but also progressively.

IV. Analysis

The Minnesota Supreme Court indicated, in resolving whether malpractice should be extended to circumstances involving genetic diagnosis and counseling, that the “practical reality of the field of genetic testing and counseling” is that it “not affect[s] only the patient. Both the patient and her family can benefit from accurate testing and diagnosis. And conversely, both the patient and her family can be harmed by. . . testing and diagnosis.”¹⁵³ Parents with or without disabilities increasingly confront, and must respond to, the dilemmas posed by procreation. The choices presented to such parents include: (1) avoid pregnancy in the fear that offspring will be born with active or future disabling conditions or disorders, (2) conceive utilizing donor egg or sperm from an individual who is not a carrier, (3) proceed with a pregnancy, but undergo a prenatal diagnostic test (possibly terminating the pregnancy if it reveals a gene mutation), or (4) accept the possibility that offspring could be born with a disability.¹⁵⁴

Determinations from an array of options increasingly enabled by genetic and assisted reproduction science and technology must be executed in light of underlying societal moral norms, legal systems, and ethical considerations. In this regard, several options clearly fall within the positive side or are morally noteworthy, while arguably at least one option, (as described below), falls within the negative. In the words of one author, “[I]aw probably should not make . . . intimate decisions [about such issues as procreation], but it can shape the social world in which intimate decisions are made.”¹⁵⁵ The ethos, which must consequently govern any discussion about genetics, is that all life, disabled or not, is precious and demands reverence.

People with disabilities need not, and should not, as a matter of reflex, excoriate this brave new world of science and technology. Conversely, people with disabilities are justified to denounce issues posed by genetic and assisted reproduction science and technology, when such science and technology have the impact of hindering their social inclusion and civil rights. In light of this divergence of approaches, options provided by genetic and assisted reproduction science and technology may be proper as long as parents, with or without disabilities, are better equipped by such options to engage in informed decision-making regarding the procreation of a potential child with a disability. However, terminating a pregnancy after which a condition or disorder is identified through genetic testing is repugnant.¹⁵⁶

In the United States, ethical decisions regarding procreation often fall within the context of the rights based framework.¹⁵⁷ Many condemn the choice to terminate a pregnancy because of the detection of a disability or the predisposition for a disability as selective abortion.¹⁵⁸ As such, the better view is that any of the religious,¹⁵⁹ natural law,¹⁶⁰ or Kantian¹⁶¹ frameworks found in bioethics should be applied especially when it means balancing the rights of the person on the one hand, while on the other, safeguarding against continued societal discrimination.

As the Maryland Court of Appeals correctly implied in *Kassama v. Magat*,¹⁶² it is human nature to crave life, not to extinguish such life, even if there are arguably burdens imposed by disabilities. For all that, life offers, it cannot be stated that a life without disabilities is any more socially benevolent than one with disabilities.¹⁶³ Furthermore, attempting to determine the relative value of a life, based on a query of “what is the best life or the best child” is “fraught with bias and ambiguity.”¹⁶⁴ Notably, the late Pontiff, Pope John Paul II, aptly expressed as long ago as 1991 the need for science and religion, morality, and ethics to be interconnected in human advancement. Pope John Paul II expressed, when confronting the dilemmas posed by advancements in science and technology,¹⁶⁵ “progress, particularly in the field of genetics, keeps conscience on the alert and stimulates ethical reflection. This progress cannot be limited to technical aspects which one could consider morally neutral, because it directly concerns the human person in regard to his most valuable possession: his very structure as a person.”¹⁶⁶ Therefore, science has a role to play in improving the quality of life of our species. Human existence is, however, more than the blueprint of life. “Science considers the world and the human person on the horizontal level, the level of physical/chemical processes and of quantifiable matter. Religious faith, on the other hand, considers the vertical level: the level of the human person’s transcendent origin, dignity, and destiny: the level of the . . . person in [a] . . . relationship with God.”¹⁶⁷ In specific regard to science and technology, Kathy McReynolds, Ph.D., offered a noteworthy position paper, which indicates that scientific applications can be consistent with moral and religious imperatives. Namely, by acquiring wisdom about the blueprint of life, this enables parents to prepare for a child with a disability or future disabling condition.¹⁶⁸ Therefore, religion, moral philosophy, and ethics must provide conscience to our scientific and technological advancements.¹⁶⁹ In practical terms, the input and contributions of theologians and leaders of differing faiths, such as Pope John Paul II, as well as moral philosophers, and ethicists, are critical.

Proponents of the enduring legacy of *Roe v. Wade*,¹⁷⁰ as affirmed and refined by *Planned Parenthood of Pennsylvania v. Casey*,¹⁷¹ hold that, as abortion falls within the right to privacy, such right should not be curtailed by the state — no matter what the circumstances.¹⁷² If upholding the principles of *Roe*, even as refined in *Casey*, is at stake, then the proponent of the rights based framework would argue that the potential for human life must relinquish to that of the individual, i.e., the woman seeking an abortion.¹⁷³ As the Tennessee Supreme Court wrote in *Davis v. Davis*,¹⁷⁴ “[a]s embryos develop; they are accorded more respect than mere human cells because of their burgeoning potential for life. But, even after viability, they are not given legal status equivalent to that of a person . . . born.”¹⁷⁵ In the view of feminists, however, embryos and fetuses, even if they deserve heightened status, do not ultimately arise to the level of a life. Abortions are protected, and this is a right that is not to be infringed—even in the context of partial birth abortion, a post-viability procedure. Arguably, the rights based point of view would seem to implicate that somehow rights have no minimum thresholds, and no upper limits. Rights, even in the context of abortion, have reasonable limits that must give way to the compelling interest of the state in protecting the potentiality for human life.¹⁷⁶ Consequently, abortion, recognized as a right, will erode other rights if unregulated.¹⁷⁷

The problem occurs when humans are treated as the mere flotsam of the rights based framework. When humans, even at the stage of pre-viability,

do not receive the reverence they deserve, then our species as a whole reduces to a commodity, rather than as a gift of the creator. The reduction of humans to the level of widgets constitutes the practical outgrowth of this lack of respect.¹⁷⁸ That is clearly unfortunate, no matter how one defines and describes the deity-inspired origins of our species. Even if one does not accept the existence of a creator, one would need to acknowledge that a rational actor, not all rights-based expressions, such as abortion, is morally appropriate if they diminish the equality of others. Specifically, proponents of abortion are unlikely to have had the experience of living with a disability and confronting the ubiquitous bias, discrimination, and prejudice buffeted by an array of actors in society. Proponents must consider how, on the one hand, protecting what they interpret as a right protected under the United States Constitution, might at the same time winnow away at other hard-won achievements in civil, political and social rights.

Scholars in disability law and policy, even those who hail from the feminist perspective, increasingly propound questions about abortions that target embryos or fetuses that have the potentiality for disabilities. As one such scholar noted:

“[W]hat did perturb me was the way in which my serious objections to abortion on the grounds of fetal abnormality were interpreted as an assault on choice, rather than seen for what they really are — an engagement with the ethical questions surrounding such abortions, and a vital challenge leveled against social prejudices about disability.”¹⁷⁹

The author poignantly expresses that, “so long as selective abortion exists,” “prejudices [will be given] legitimacy.”¹⁸⁰ Additionally, commentators argue that, while precise data may be non-existent, rates of abortions are higher when prenatal genetic testing is utilized to detect disabilities or the predisposition for disabilities.¹⁸¹ Selective abortions appear to be encouraged particularly by medical professionals at the stage of pre-viability.¹⁸² Selective abortions thusly cause concern among disability advocates and scholars that people with disabilities, as a fetal populace, will be preemptively screened for and terminated.¹⁸³ Clearly, this punctuates rather than eliminates bias, discrimination, and prejudice held by such powerful actors in civic society as medical professionals.¹⁸⁴ Notably, “[t]his selective elimination of fetuses and embryos with disability-related traits is seen as the ultimate expression of prejudice, the elimination of an undesirable social trait through science and medicine.”¹⁸⁵ As far as this implements the malevolent facet of the medical model, this is an arguable expression of eugenics.¹⁸⁶

Likewise, disability advocates and scholars have posited certain noteworthy arguments, the ‘disability critique,’ against selective abortions. They are in pertinent part:

1. Expressivity,
2. Traits versus Persons, and
3. Disability Identity.¹⁸⁷

Another argument is that, by degrading the value and identity of persons with disabilities, people with disabilities will fall prey to healthcare rationing.¹⁸⁸ That is, because accommodating people with disabilities and addressing their underlying diseases may cost more to society than able-

bodied individuals cost, and because genetic tests can screen-out these suppose burdensome individuals; people with disabilities will be summarily rationed out of the equation.¹⁸⁹

In some circumstances, however, parents may not be in the position to afford a child with special needs. Bias and prejudice, especially as fostered by the medical profession engender this reaction.¹⁹⁰ However, procreating and rearing all children, regardless of disabilities or the potential for future disabling conditions, constitutes an expensive endeavor. In 2006, when declining to extend consequential damages in the law of negligence to genetic counseling and testing, the Ohio Supreme Court wrote that, regardless of disabilities, “significant expense is associated with rearing any child.”¹⁹¹

Finally, people with disabilities may be labeled as possessing a culture which stems from shared experiences in combating discrimination and encountering environments that often lack reasonable accommodations.¹⁹² To the extent there is a disability culture, this does not logically equate to altering offspring in utero to increase disorders or conditions, or the predisposition for disorders or conditions in furtherance of the social model of disability. Any subpopulation of disabilities might seek to apply genetic and assisted reproduction science and technology to augment the likelihood of a future disability in offspring. For instance, “[a] survey published in 2006 indicates that at least a few IVF [in vitro fertilization] centers have assisted in selecting for a ‘disability’ such as deafness or dwarfism.”¹⁹³ Specifically, a documented segment of the deaf, who view themselves as holding a distinct culture, are noted for their desire to apply genetic and assisted science and technology to ensure the viability of their community.¹⁹⁴

The rights of the individual must relinquish, in some instances, to the state, such as its enactment or promulgation of positive moral or religious influenced regulation. Judith F. Daar points out, when it concerns the “procreative liberty,”¹⁹⁵ “[t]he question for constitutional purposes is whether any . . . barriers [to such liberty] rise to the level of state action and if so whether they pose an undue burden on procreation.”¹⁹⁶ On the one hand, where state action is implicated in the process of protecting classes of historically excluded and marginalized individuals, and on the other, is not very intrusive to a liberty interest, who can legitimately argue that such state action fails the test of strict scrutiny?¹⁹⁷ Furthermore, legislative pronouncements do not transition from the page to substantive action by a whim. Thusly, Policy or other measures often spur a change in the culture of citizens, such that compliance with substantive legislation is achieved. In the award-winning fictional television series of *The West Wing*, President Jed Bartlett recognizes this principle when he expressed at a campaign stop in Iowa that the American people have changed their laws and must change their hearts.¹⁹⁸ In sum, this article discusses model legislation and a set of policy measures.

V. Remedies

Draft “model” legislation and a set of policy measures are proposed below.

A. Legislative Remedy

*The Model Defense of the Disabled Fetus Act*¹⁹⁹

A. Preamble

The policy of this state is that all life, whether at its earliest development, its quickening or during gestation, or after birth, inclusive of children and older adults, with or without disabilities, has, and is and ought to be endowed with, sanctity, respect, and dignity.²⁰⁰ The fetus, either with or without known, detectable impairments, defects, disabilities, now or prospectively existing, can rightly be contemplated as possessing potential sentence.²⁰¹

Technology and science are not value-neutral.²⁰² Wondrous, magnanimous intentions, but also evil proclivities of humans imbue technology and science.²⁰³ Particularly, the milieu of technological and scientific advancements in genetics and assisted reproduction seemingly offers a false sense of omniscience, power, and control.²⁰⁴ Serious religious, moral, legal and ethical questions for civic society, including, but not limited to, eugenics, emanates when humans, imperfect creatures, utilize the profound to alter the blueprint of life.²⁰⁵

Women perceive that they receive encouraged, or in some instances counseled to undergo abortions.²⁰⁶ This is especially true in the circumstance of disabilities.²⁰⁷ The policy of this state is to realize the benefits of genetic and reproductive technology and science while, at the same time, safeguarding against, and as applicable, forbidding outcomes, practices, procedures, services, or therapies, which may worsen societal prejudice, exclusion, discrimination, and bias.

Genetic and assisted reproductive technology and science are encouraged, funded, and incentivized as far as they are utilized, developed, and applied to address, if possible, cure, or alleviate the medical facets of impairments, defects, deficiencies, or conditions, which, now or in the future, may rise to the level of a disability. At no time, however, will science and technology be utilized, developed, or applied in a way such that the affects of historical social, political, and cultural prejudice, exclusion, discrimination, and bias are worsened, promoted, and enhanced. Finally, the policy of this state is that the movement, as far as it acts lawfully, to support human life, inclusive of opposition to abortion and selective abortion, is commendable.²⁰⁸

B. In accordance with the compelling interest of the state in protecting the potentiality for human life²⁰⁹ — either with or without disabilities

1. There shall be a right of conscience; neither liability as a cause of action, nor discrimination, disqualification, coercion, for any person, acting individually or in association, in this state, for a failure to suggest, sell, mention, propose, proscribe, recommend or refer for, or discuss an abortion, (including a late tri-semester “partial birth abortion”), especially where wondrous advancements in science and technology, peering into the body, disclose a disability or potentially future disabling condition will attach.²¹⁰
2. There shall be a prohibition to abortions, where such abortions, (including a late tri-semester “partial birth abortion”), are

specifically administered, proscribed, recommended or referred, or sold to prevent, cure, or ameliorate any impairment, disease, defect, deficiency, or condition, which may or may not presently or in the future, rise to the level of a disability as defined under federal law and the laws of this state.²¹¹

3. However, abortions may be performed by a properly licensed medical professional, and in an appropriately accredited and licensed medical facility, institution or hospital,²¹² if they are:
 - a. To save, protect, or preserve the life of a woman experiencing a medical crisis or emergency situation, or
 - b. To remedy an incident or criminal offense of sexual abuse, incest, or rape as defined under the laws of this state.
 - c. However, under subsection “a” providers shall make reasonable medical efforts under the circumstances to preserve both the life of the mother and her unborn fetus in a manner consistent with conventional medical practice.²¹³
 - d. And in the circumstance of subsection “b,” providers shall only perform an abortion, once such provider has referred such pregnant patient to a medical social worker or other allied healthcare professional where the option for and the services related to adoption is discussed and counseled.

C. Causes of Action Or Claims

1. The cause of action or claim of wrongful birth is prohibited,²¹⁴ and
2. The cause of action or claim of wrongful life is prohibited; but,²¹⁵
3. This subsection shall not preclude causes of action based on arguments that, but for a wrongful act or omission, maternal death or injury would not have occurred, or that impairment, disease, defect, deficiency, disability, or condition of an individual, prior to birth, would have been prevented, cured or ameliorated in a manner that preserved the health and life of the affected individual.²¹⁶

D. Additional Prohibitions

The following additional actions respecting genetics and assisted reproduction are prohibited under this Act:

1. Create a human being, perform any procedure or provide, prescribe or administer any therapy, service, or medication that would ensure or increase the probability that an embryo will be of a particular sex, or that would identify the sex of an in vitro embryo, except to treat, diagnose, or address a sex-linked disorder or disease²¹⁷
2. Alter the genome of a cell of a human being or in vitro embryo such that the alteration is capable of being transmitted to descendants²¹⁸
3. Utilize the rapidly developing applications of genetics and assisted reproduction, (e.g., IVF), specifically to create or caused to be created a fertilized oosite for the purpose of treating the impairments, disabilities, disease, defects, or conditions of another child, or for the purpose of perpetuating disabilities or disability culture.²¹⁹

E. Encouraged, Incentivized, And Required Mandatory Actions

To ensure that abortions are truly informed, contemplated, and are the last option in all general circumstances, especially where the developing advancements in genetics, inclusive of genetic counseling and testing, and assisted reproduction, may discover or may cause the discovery of impairments, defects, deficiencies, or conditions, which may now or in the future rise to the level of a disability, the following actions, in the compelling interest of protecting human life, are encouraged, incentivized, and required:

1. Any woman, before she undergoes an abortion with respect to the existence or future existence of a disability of the unborn embryo or fetus, except where such abortion is necessary to preserve her health or safety, will be required to wait a period of one week for such an abortion.²²⁰ During this period, all medical professionals involved with the abortion are required to:
 - a. Provide the woman with information and examples about and of successful people with disabilities. A roster containing the contact information for area non-profits and agencies of and for people with disabilities is to be kept on file at the facility, institution, or hospital.²²¹
 - b. In addition to the passive roster above, which staff at the institution, hospital, or facility, is to provide, a confidential meeting by such woman with a family with disabilities is to be facilitated promptly. A disability liaison at the institution, hospital, or facility, which is to work in tandem with the medical staff, will be established for this purpose.
 - c. The scope of the position of disability liaison will include:
 - i. Providing the woman with information, contacts, and resources or referrals to support services, such as respite care, parent education and training, parent-to-parent counseling, homemaker services, and other services that enables families to maintain and provide quality care to children in their homes.²²²
 - ii. Informing the pregnant woman of the numerous public and private agencies, (inclusive of medical assistance), and services, which are available to assist her during her pregnancy and after the birth of her child, if she chooses not to have an abortion.²²³

F.

The woman, if she wishes to keep her child but is fearful of rearing a child with then or future existing disabilities, must be provided with information, resources, and referral to adoption or foster care, agencies, options, and programs therewith, before an abortion may be performed.²²⁴

G.

Who so ever seeks genetic counseling and testing in order to detect or diagnose a currently or prospectively existing impairment, defect, deficiency, or condition that may rise to a disability, for the purposes of, planning, designing, or acquiring early intervention services, including

developmental training and specialized social or medical therapies, is allowed a tax credit annually to account for the added costs of rearing a child with a disability.

B. Cultural Measures

Correspondence conveyed during the transition to the administration of President Obama suggested continued dialogue on these issues through a national summit on the impact of genetics on the disabled.²²⁵ To this end, it is critical to note that the National Council on Disability will host a national summit on disability policy in July 2010.²²⁶ At this summit, delegates will discuss healthcare services, systems, and technology.²²⁷ Additionally, recommendations which could potentially advance the better aspects of the models of disability in the context of this brave new world of science and technology, are as follows: (1) Congress needs to ratify²²⁸ the Convention²²⁹ and its Optional Protocol,²³⁰ (2) applicable federal agencies and departments should expand on the provisions of the Genetic Act by promulgating regulations and policies that, to the fullest extent possible, without being arbitrary and capricious,²³¹ are broader than the statute, and (3) Congress should pass, with the assistance and input of activists and scholars, a joint resolution indicating support for evidence-based and ethical-based genetic and assisted reproduction science and technology, on the one hand, but that, on the other, equally denounces its negative implications, namely, eugenics. Furthermore, HHS can engage in the vital task of consciousness enhancement of providers about people with disabilities, through increased training about and enforcement of civil rights provisions. Finally, HHS, possibly in partnership with organizations such as the American Medical Association, should utilize its full range of policy options to encourage the design and to mandate curriculum at medical schools for medical students as well as professional development for providers on disability.²³²

VI. Conclusion

Society must consequently grapple with, and will continue to grapple with, the ethical, legal, and moral issues implicated by genetic and assisted reproduction science and technology long into the future.²³³ Particularly, one class of individuals who are likely either to benefit or be negatively affected by this new world posed by science and technology are people with disabilities. A science-based dystopia, where some are equal, but those who have the correct genetic make-up are more equal,²³⁴ will occur if society is not to engage in affirmative actions. In an Orwellian sense, where such dystopia exists, “one who has the genetic code for four legs is good, but one who has the code for two legs is better.”²³⁵ However, when developed in a regime of appropriate regulatory promulgation, based on public negotiation and input, involving all segments of civic society secular leaders and institutions as well as ethical, moral, and religious leaders and institutions—science and technology has the power to enable the better facets of each of the models of disability to improve the quality of life and equality of opportunity of people with disabilities.

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² See DR. GABRIEL ROBINS, GOOD QUOTATIONS BY FAMOUS PEOPLE (1994-2009), <http://www.cs.virginia.edu/~robins/quotes.html> (last visited Mar. 21, 2010) (quoting Galileo Galilei).

³ See WILLIAM SHAKESPEARE, THE TEMPEST, Act 5, Scene 1 (1611), available at www.william-shakespeare.info/script-text-the-tempest.htm.

⁴ See UNITED METHODIST CHURCH TASKFORCE, SPIRITUAL DISCERNMENT: A GUIDE FOR GENETIC AND REPRODUCTIVE TECHNOLOGIES, 18 (2008) (providing a good explanation of science in terms of the laity to this field, setting forth ethical and religious issues, and providing recommendations for Methodists that seek to balance the fruits that could be derived from genetics while safeguarding the dignity of humans).

⁵ See Human Genome Project, Pharmacogenomics: Medicine and the New Genetics, http://www.ornl.gov/sci/techresources/Human_Genome/medicine/pharma.shtml (last visited Mar. 21, 2010) (Pharmacogenomics is the study of how the genetic makeup (genotype) affects how the body responds to medication. In my view, this is probably one of the promising outgrowths of genetics, which can improve the health of people with disabilities without necessarily jeopardizing the civil rights of such persons). www.ornl.gov/sci/techresources/Human_genome/medicine/medicine.shtml (last visited July 7, 2009).

⁶ See Robert S. Boyd, *Genome Advances Promise Personalized Medical Treatment*, MCCCLATCHY NEWSPAPERS, Nov. 16, 2009, available at <http://www.mcclatchydc.com/2009/11/16/78960/genome-advances-promise-personalized.html>; Meredith Simons, *Medicine Tailored to Your Genes*, SEATTLE POST-INTELLIGENCER, Nov. 16, 2009, available at http://www.seattlepi.com/health/412335_taioredmeds1116.html.

⁷ See, e.g., Denise Avar, Ph.D., HUMAN GENETICS RESEARCH AND PRACTICE: IMPLICATIONS FOR PEOPLE WITH DISABILITIES, Jan. 14, 2002, available at <http://www.un.org/esa/socdev/enable/disid2001e.htm> (stating “[t]here is the potential for this impact to be positive, providing new treatments and supporting people’s choices about their health and reproduction. However, in light of the widespread discrimination faced by people with disabilities, there is danger that these developments could be used in ways that restrict rather than enhance the rights and choices of people with disabilities and their families.”); Edward J. Larson, *The Meaning of Human Gene Testing for Disability Rights*, 70 U. CIN. L. REV. 913 (2002).

⁸ See *Buck v. Bell*, 274 U.S. 200, 207 (1927) (Holmes, J., opinion) (upholding the constitutionality of the compulsory sterilization of a person with a developmental disability, stating “...It is better for all the world if, instead of waiting to execute degenerate offspring for crime or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes....Three generations of imbeciles are enough.”). See generally, Roberta L. Cepko, *Involuntary Sterilization of Women*, 8 BERKELEY’S WOMEN’S L.J. 122 (1993); Posting of Theresa Walsh Giarrusso to <http://www.ajc.com/health/content/shared-blogs/ajc/parenting/entries/20> (In 2001, as a sign of social evolution by Americans, the Virginia General Assembly expressed its regrets for playing a part in the eugenics movement).

⁹ But see *In re Romero*, 790 P.2d. 819, 822 (Colo. 1990) (stating “...The decision whether to bear or beget a child is a constitutionally protected choice...,” (questioning *Buck v. Bell*)).

¹⁰ Larson, *supra* note 7, at 914-15.

¹¹ *Id.* at 915-19, 932-33. (The author describes the awful role of the United States in the eugenics movement with respect to persons with disabilities and

the period propaganda that extolled the benefits of non-creation or even death for the disabled).

¹² See *Roe v. Wade*, 410 U.S. 113 (1973); *Romero*, 790 P.2d at 821 (reasoning that women have a level of autonomy concerning their body and the decision to procreate).

¹³ See Convention on the Rights of Persons with Disabilities, opened for signature (Mar. 30, 2007), 46 I.L.M. 433.

¹⁴ E.g., Posting of Gary C. Norman to <http://blog.gmfus.org/author/gnorman/> (Jul. 29, 2008, 15:49 EST).

¹⁵ See Amy Adams, M.S., Genetics 101: Overview of Genetics, www.genetichealth.com/G101_Genetics_Demystified.shtml (Last visited Mar. 21, 2010) (noting that the building blocks of life can be contemplated as part of a descending litany. There are: 1. chromosomes, 2. genes, and 3. Deoxyribonucleic Acid or DNA, and 4. nucleotides. DNA, which is composed of four types of bases, designated A (adenine), T (thymine), G (guanine), and C (cytosine), plus proteins, equal a chromosome. In each chromosome, there are genes).

¹⁶ See RICHARD LEWONTIN, THE GENOTYPE/PHENOTYPE DISTINCTION, *Stanford Encyclopedia of Philosophy* (Edward N. Zalta ed., 2008), available at <http://plato.stanford.edu/archives/fall2008/entries/genotype-phenotype/>.

¹⁷ Namely the National Institutes of Health and the Department of Energy, as well as a myriad of international partners, such as, the United Kingdom.

¹⁸ See Adams, *supra* note 15; see also Larson, *supra* note 7, at 913; Patricia Alten, *GINA: a Genetic Information Nondiscrimination Solution In Search Of a Problem*, 61 FLA. L. REV. 379, 382 (2009).

¹⁹ See The Future of Genomics, Hearing before Subcomm. on Health, of the H. Comm. on Energy & Commerce, 108th Cong. (2003) (statement of Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, National Institutes of Health, Department of Health & Human Services), available at <http://www.genome.gov/11007447> [hereinafter *Future of Genomics*].

²⁰ Alexander Van Voorhees, Note, *Truth in Testing Laws: A Shot in the Arm For designer Gene Tests*, HEALTH MATRIX J. OF L. & MED. 797, 797 (2006).

²¹ Alten, *supra* note 18, at 382-83 (citing S. Rep. No. 110-48, at 5 (2007)).

²² Press Release, The White House, President Clinton Announces the Completion of the First Survey of the Entire Human Genome, Hails Public and Private Efforts Leading to the Historic Achievements (June 25, 2000), http://www.ornl.gov/sci/techresources/Human_Genome/project/clinton1.shtml (last visited June 29, 2009).

²³ See *id.*

²⁴ See *Future of Genomics*, *supra* note 19.

²⁵ See *id.*

²⁶ See *id.*

²⁷ See *id.*

²⁸ See Boyd, *supra* note 6, at 2.

²⁹ See *id.*

³⁰ See Voorhees, *supra* note 20, at 816.

³¹ See Nancy Arnett, *Genetic Counseling: Every day new discoveries unlock medical mysteries. How does this affect your family?*, CHILD BIRTH SOLUTIONS, INC., <http://www.childbirthsolutions.com/articles/preconception/geneticcounseling/index.php> (last visited Mar. 21, 2010).

³² See Rob Stein, *New Safety, New Concerns in Tests for Down Syndrome*, WASH. POST, Feb. 23, 2009, at A1, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/02/23/AR2009022302837.html>.

³³ See Janet Malek, *Symposium, Disabilities and the Duties of Potential Parents*, 2 ST. LOUIS J. OF HEALTH L. & POL’Y. 119, 121 (2008).

³⁴ See *id.* at 121.

³⁵ See *id.*

³⁶ See Jaime King, *Predicting Probability: Regulating the Future of Preimplantation Genetic Screening*, 8 YALE J. HEALTH POL’Y. L. & ETHICS 283, 286 (2008).

³⁷ See *id.*

³⁸ See Alten, *supra* note 18, at 382 (stating the project “supported an Ethical, Legal and Social Implications research program to address the many complex issues that might arise from this science”).

³⁹ Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 21 (2008).

⁴⁰ See *id.*

- ⁴¹ See *id.*
- ⁴² See e.g., Janet E. Lord & Michael Ashley Stein, *Social Rights and the Relational Value of the Rights to Participate in Sport, Recreation, and Play*, 27 B. U. INT'L. L. J. 249, 252-56 (2009); see also Debra Kaplan, THE DEFINITION OF DISABILITY – PERSPECTIVE OF THE DISABILITY COMMUNITY, The Center for an Accessible Society, <http://www.accessiblesociety.org/topics/demographics-identity/dkaplanpaper.htm> (last visited June 24, 2009).
- ⁴³ See Lord & Stein, *supra* note 42, at 254-55.
- ⁴⁴ See Kaplan, *supra* note 42.
- ⁴⁵ See *id.*
- ⁴⁶ See Bradley A. Areheart, *When Disability Isn't "Just Right": The Entrenchment of the Medical Model of Disability and the Goldilocks Dilemma*, 83 IND. L. J. 181, 186-87 (2008) (stating “[A]dherence to the notion of disability as biological inability is precisely what enables the conclusion that accommodations push the market’s balance beyond equilibrium. More generally, adherence to the medical model encourages the view that disability rights are ‘special,’ akin to some form of charity for biological losers. In short, under the medical model, a person’s disability is her own personal misfortune-devoid of social cause or responsibility. From this perspective, the medical model has the...capacity to fragment the disability community by stressing the individual physiological traits that differentiate disabled persons, rather than the common societal obstacles that unite them.”).
- ⁴⁷ See Lord & Stein, *supra* note 42, at 254-55; Kaplan, *supra* note 42.
- ⁴⁸ *Id.*
- ⁴⁹ See Areheart, *supra* note 46, at 186 (citing Paul T. Jaeger & Cynthia Ann Bowman, UNDERSTANDING DISABILITY: INCLUSION, ACCESS, DIVERSITY, AND CIVIL RIGHTS 100 (2005)).
- ⁵⁰ See David Ruebain, What Is Prejudice As Relates to Disability Anti-Discrimination Law?, http://www.dredf.org/international/paper_ruebain.html (last visited Sept. 4, 2009).
- ⁵¹ See Elizabeth F. Emens, *Intimate Discrimination: The State's Role in the Accidents of Sex and Love*, 122 HARVARD L. REV. 1307, 1329-30 (2009) (stating “Laughing at disability can cause offense, making it a prime target for the Maxim humor page, which apparently trades in the shock value, or rebellious frisson, of saying “un-PC” things.”).
- ⁵² E.g., Laura Hershey, *Women with Disabilities: Health, Reproduction, and Sexuality*, INTERNATIONAL ENCYCLOPEDIA OF WOMEN: GLOBAL WOMEN'S ISSUES AND KNOWLEDGE (Routledge Press 2000), available at <http://www.cripcommentary.com/women.html>.
- ⁵³ See *id.*
- ⁵⁴ See Nicholas A. Dorsey, Note, *Mandatory Reassignment Under the ADA: The Circuit Split And Need For A Socio-Political Understanding Of Disability*, 94 CORNELL L. REV. 443, 455 (2009) (stating, “[t]he rehabilitation model is essentially a modern application of the medical model. Like the medical model, the rehabilitation model locates the difficulties faced by a disabled person within the disabled individual — rehabilitation is needed to cure the individual’s defects.”).
- ⁵⁵ E.g., Areheart, *supra* note 46, at 181.
- ⁵⁶ See *id.* at 185-86.
- ⁵⁷ See *In re Romero*, 790 P2d. at 821.
- ⁵⁸ See *id.*
- ⁵⁹ See generally, Wikipedia, Kristallnacht, <http://en.wikipedia.org/wiki/Kristallnacht#Kristallnacht> (last visited Sept. 24, 2009).
- ⁶⁰ See United States Holocaust Memorial Museum, Frequently-Asked Questions: What is the origin of the word ‘Holocaust’?, <http://www.ushmm.org/research/library/faq/details.php?topic=01#02> (last visited Oct. 1, 2009).
- ⁶¹ Ron Amundson & Shari Tresky, *Bioethics and Disability Rights: Conflicting Values and Perspectives*, (5) (2-3) J. OF BIOETHICAL INQUIRY 111-23 (2008).
- ⁶² *Id.*
- ⁶³ *Id.*
- ⁶⁴ See Voorhees, *supra* note 20, at 802.
- ⁶⁵ Kaplan, *supra* note 42.
- ⁶⁶ See, Lord & Stein, *supra* note 42, at 254-55.
- ⁶⁷ Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past-Present, and Future?*, 36 CONN. L. REV. 125, 131-32 (2003).
- ⁶⁸ See Kaplan, *supra* note 42.
- ⁶⁹ See Mark P. Moster, *Cultures of Death, Old and New*, 33: 4 HUM. LIFE REV. 54 (, 2007) (stating, “[t]he Nazi example makes plain that macro political and social forces can easily be used to harm people with disabilities. It is also a historical touchstone that can inform our understanding of some perceptions of disabilities now largely accepted in advanced technological societies—such as those that allow and/or encourage the abortion of preborn children with identifiable anomalies, and those that propose euthanasia of newborn or even older children with disabilities.”).
- ⁷⁰ Robert L. Burgdorf, Jr., *Restoring The ADA And Beyond: Disability in the 21st Century*, 13 TEX. J. CIV. LIBERTIES & CIV. R. 241, 323 (2008).
- ⁷¹ See Deborah D. Hatton et. al., *Infants and Toddlers with Vision Impairments: Suggestions for Interventionists*, ERIC CLEARINGHOUSE ON DISABILITIES AND GIFTED EDUCATION (2002), available at www.ericdigests.org/2003-5/infants.htm; *Easter Seals, Inc., Easter Seals : Focusing on the Needs of Infants and Toddlers with Disabilities*, [www.easterseals.com/site/PageServer?...early intervention](http://www.easterseals.com/site/PageServer?...early%20intervention) (last visited July 7, 2009).
- ⁷² See Kaplan, *supra* note 42.
- ⁷³ See Glenn Cohen, *Intentional Diminishment, The Non-identity Problem, and Legal Liability*, 60 U.C. HASTINGS L. J. 347 (2008); see also Larson, *supra* note 7, at 935-36.
- ⁷⁴ Adam M. Samaha, *What Good Is The Social Model of Disability*, 74 U. CHI. L. REV. 1251, 1251 (2007).
- ⁷⁵ See *id.*; see also Isabel Karin & Roxanne Mykitiuk, *Going Out On a Limb: Prosthetics, Normalcy and Disputing the Therapy/Enhancement Distinction*, 16 Med. L. Rev. 413, 418 (2008).
- ⁷⁶ See *id.*
- ⁷⁷ E.g., Disapedia, Social Model, www.disapedia.com/index.php?title=Social_Model (last visited June 25, 2009).
- ⁷⁸ Gabriella M. Hanrahan, Ph.D. Candidate, A Social Model of Disability and the Restructuring of Ireland’s Disability Employment Services through the Service of Supported Employment, [http://www.nda.ie/cntmgmtnew.nsf/0/A3CFE76BE6EE5B7080257117005B2A1B/\\$File/disability_research_conference_18.htm](http://www.nda.ie/cntmgmtnew.nsf/0/A3CFE76BE6EE5B7080257117005B2A1B/$File/disability_research_conference_18.htm) (last visited June 25, 2009).
- ⁷⁹ Kaplan, *supra* note 42.
- ⁸⁰ *Id.*
- ⁸¹ Rehabilitation Act, 29 U.S.C.A §701. (West 2009).
- ⁸² Americans with Disabilities Act, 42 U.S.C.A §12101 (West 2009).
- ⁸³ Americans with Disabilities Act Amendments of 2008, Pub. L. No. 110-325, 122 Stat. 3553 (codified at scattered sections of 42 U.S.C.).
- ⁸⁴ E.g., Michael Ashley Stein and Michael E. Waterstone, *Disability, Disparate Impact, and Class Actions*, 56 DUKE L. J. 861, 887 (2006).
- ⁸⁵ Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29, and 42 U.S.C.) [hereinafter *Genetic Act*].
- ⁸⁶ E.g., Jeffrey Scott Ranen, Note, *Was Blind But Now I See: The Argument for ADA Applicability to the Internet*, 22 B.C. THIRD WORLD L.J. 389, 392-93 (2002).
- ⁸⁷ Convention on the Rights of Persons with Disabilities, opened for signature (Mar. 30, 2007), 46 I.L.M. 433.
- ⁸⁸ Optional Protocol to the Convention on the Rights and Dignity of Persons with Disabilities opened for signature (Mar. 30, 2007), 46 I.L.M. 433.
- ⁸⁹ See Lord & Stein *supra* note 42 at 254.
- ⁹⁰ See e.g., Letter from John R. Vaughn, Chair of the Nat’l Council on Disability to The White House (Mar. 31, 2009), available at http://www.ncd.gov/newsroom/publications/2009/Progress_Report.doc.
- ⁹¹ See Press Release, Dept of Health and Human Serv., HHS Announces Initiatives in Support of “Year of Community Living” (June 22, 2009), available at www.hhs.gov/news/press/2009pres/06/20090622b.html.
- ⁹² 527 U.S. 581 (1999) (holding that the unnecessary segregation of individuals with disabilities in institutions may constitute discrimination, based on disability under Title II of the ADA. The Court concluded that, under Title II of the ADA, unnecessary institutional segregation constitutes discrimination *per se*, which cannot be justified by a lack of funding. States may be required to provide community-based services, rather than, institutional placements as a consequence of the integration mandate. The Court remanded the decision to the lower courts for further proceedings.).
- ⁹³ 122 Stat. 881.
- ⁹⁴ Genetics in Wisconsin, What Causes Genetic Disease? http://www.slh.wisc.edu/genetics/basics_disease.dot (last visited Oct. 23, 2009).
- ⁹⁵ See *id.*
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- ⁹⁸ 42 U.S.C.A § 12101.
- ⁹⁹ See *Bragdon v. Abbot*, 524 U.S. 624, 638, 643 (1998) (stating “[r]eproduction falls well within the phrase ‘major life activity.’ Reproduction and the sexual dynamics surrounding it are central to the life process itself”).
- ¹⁰⁰ Paul Steven Miller, *Genetic Discrimination in the Workplace*, in *Contemporary Issues in Business Ethics*, (Joseph R. DesJardins & John J. McCall, eds., Wadsworth, 2000 Fourth Edition) available at www.ornl.gov/hgmis/publicat/hgn/.../09workplace.shtml.
- ¹⁰¹ See Americans with Disabilities Act Amendments of 2008, 122 Stat. 353 (expanding the “regarded as” prong for the definition of “disability”).
- ¹⁰² E.g., ASSOCIATION ON HIGHER EDUCATION AND DISABILITY, STATEMENT OF THE MANAGERS TO ACCOMPANY S. 3406, ADA AMENDMENTS OF 2008, available at <http://www.ahead.org/uploads/docs/resources/ada/Senate%20Managers%20Report.doc>.
- ¹⁰³ See EQUAL EMPLOYMENT OPPORTUNITY COMM’N, ADA AMENDMENTS ACT OF 2008 – TOWN HALL MEETINGS, <http://www.eeoc.gov/ada/adaaa-townhall.html> (last visited Oct. 25, 2009).
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- ¹⁰⁵ See 42 U.S.C. § 12181(7); 28 C.F.R. § 36.104 (2009).
- ¹⁰⁶ Letter of John Wodatch, Dir., Office of the Americans with Disabilities Act, Civil Rights Div, Dep’t. of Justice to Nat’l. Ass’n. of Rehab. Facilities (Sept. 21, 1992), available at www.usdoj.gov/crt/foia/tal260.txt.
- ¹⁰⁷ See Elizabeth Pendo, *Disability, Equipment Barriers, and Women’s Health: Using the ADA to Provide Meaningful Access*, 2 ST. LOUIS U. J. OF HEALTH L. & POL’Y. 15, 31 (2008).
- ¹⁰⁸ See *id.* at 15.
- ¹⁰⁹ See Friedman & Norman, *supra* note 104, at 348-49.
- ¹¹⁰ E.g., Adrienne Asch, *Forward, Disability, Reproduction, and Parenting*, 2 ST. LOUIS U. J. OF HEALTH L. & POL’Y 1, 6 (2008) (stating “[a]lthough the Rehabilitation Act and the ADA require that healthcare institutions, programs, and offices be accessible, but few actually are.”); Disability Rights and Education Defense Fund, *HEALTHCARE: ACCESS TO CARE*, <http://www.dredf.org/healthcare/healthcare.shtml> (last visited Jul. 8, 2009); Corbett Joan O’Tool, *Book Review, Welner’s Guide to the Care of Women with Disabilities: A Comprehensive Guide to Care*, DISABILITY WORLD June-Aug. 2004, http://www.disabilityworld.org/06-08_04/women/bookreview.shtml (last visited Jul. 1, 2009) (quoting Sandra L. Welner, M.D. and Florence Haseltine, M.D., Ph.D., *WELNER’S GUIDE TO THE CARE OF WOMEN WITH DISABILITIES: A COMPREHENSIVE GUIDE TO CARE*, 373 (Lippincott Williams and Wilkins Publishers 2003)).
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- ¹¹² *Id.*
- ¹¹³ See *id.*
- ¹¹⁴ See *id.*
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- ¹¹⁶ Heather Becker, PhD et al., *Reproductive health care experiences of women with physical disabilities: A Qualitative Study*, in *Archives of Physical Medicine and Rehabilitation* 78 ARCHIVES OF PHYSICAL MEDICINE AND REHABILITATION S22 (1997).
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- ¹¹⁸ See *Health Information Not Communicated Well to Minority Populations*, *University of Missouri Researcher Finds*, U.S. Fed. News 2009 WLNR 21663721 (Oct. 30, 2009).
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- ¹²¹ *Id.*
- ¹²² N.K. Seyden et al., *Enhancing Medical Students’ Attitudes and Knowledge About Disabilities*, <http://disability.ucdavis.edu/program/seyden.pdf> (last visited Oct. 23, 2009).
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- ¹²⁹ Disability Coalition for Healthcare Reform, *Building a Movement for Access and Choice*, Information Sheet, <http://www.paraquad.org/Policy/HealthcareReformInfoSheet.html> (last visited Nov. 19, 2009).
- ¹³⁰ *Id.*
- ¹³¹ Exec. Order No. 13145, 65 Fed. Reg. 6,877 (2000) (This Order was a good starting point, but needed to be followed by other more substantive action; as such orders do not create substantive rights vis-à-vis the federal government).
- ¹³² See generally, Dep’t. of Health & Human Servs., *Genetic Information Nondiscrimination Act of 2008*, Fact Sheet (last updated June 8, 2009), available at www.genome.gov/24519851. See also, Genetic Act, *supra* note 85.
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- ¹³⁴ *Id.*
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- ¹³⁶ Genetic Act, *supra* note 85, at 916.
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- ¹³⁹ *Id.*
- ¹⁴⁰ Convention, *supra* note 87, at Art. 25-26.
- ¹⁴¹ *Id.*
- ¹⁴² Lord & Stein, *supra* note 43, at 261-62.
- ¹⁴³ Pendo, *supra* note 107, at 22-24, 26.
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- ¹⁴⁷ See generally, Gary C. Norman, *Reflections on Transatlantic Disability Policy*, German Marshall Fund U.S. Blog (Nov. 2, 2009), <http://blog.gmfus.org/2009/11/02/reflections-on-transatlantic-disability-policy/>.
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- ¹⁵⁰ Dorsey, *supra* note 54.
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- ¹⁵⁶ See Amy Harmon, *Genetic Testing + Abortion = ???*, N.Y. Times 2007 WLNR 9958036 (May 13, 2007) at §4. (The liberty interest in substantive due process, which includes the right to privacy, namely abortions, is even controversial among people of the same political spectrum, that is, liberals.)
- ¹⁵⁷ See, Mallika Kaur Sarkaria, Comment, *Lessons from Punjab’s “Missing Girls”: Toward a Global Feminist Perspective on “Choice” in Abortion*, 97 Cal. L. Rev. 905, 938 (2009) (citing Nivedita Menon, *Abortion and the Law: Questions for Feminism*, 6 CANADIAN J. WOMEN & L. 103, 105 (1993) (“The ‘choice’ rhetoric reflects a liberal rights approach. Choice is a quintessential liberal value, representing respect for individual autonomy.”)).

- ¹⁵⁸ E.g., Martha A. Field, *Killing "The Handicapped"—Before and After Birth*, 16 HARV. WOMEN'S L. J. 79, 80-81 (1999); Deborah Kaplan & Marsha Saxton, *Disability Community and Identity: Perceptions of Prenatal Screening*, in *Our Bodies Ourselves* (2005) available at www.geneticsandsociety.org/article.php?id=2003 ("In an era which offers access to improved health, longevity, social mobility, and a political voice for disabled citizens, it is ironic that the growth of the new reproductive and genetic technologies...now provides the possibility of eliminating categories of people with certain kinds of disabilities, such as Down Syndrome...muscular dystrophy, sickle cell anemia and hundreds of other conditions. The central message from those who resist selective abortion is that there is something deeply valuable, and profoundly human...in meeting and loving a child or adult with a disability. The contributions of human beings cannot be judged by how they fit into the mold of normalcy . . .").
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- ¹⁶¹ *Id.*
- ¹⁶² *Kassama v. Magat*, 368 Md. 113 at 139, 142-43.
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- ¹⁶⁴ Marta Kolthoff, M.D., *Commentary, Assisted Reproduction and Primum Non Nocere*, 9(9) VIRTUAL MENTOR 605 (Sept. 2007) (citing Michael Parker, *The Best Possible Child*, 33(5) J. MED. ETHICS 279-83 (2007)).
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- ¹⁶⁸ Kathy McReynolds, Ph.D., *Prenatal Genetic Testing and Disability*, Pos. Paper (Updated Apr. 8, 2009), available at http://www.joniandfriends.org/Prenatal_Genetic_Testing.pdf.
- ¹⁶⁹ *Id.*
- ¹⁷⁰ *Roe v. Wade*, 410 U.S. 113 (1973) (this author suggests that women probably have, or perhaps should have, a protected constitutional interest to an abortion up to the point where a fetus is viable medically outside of the womb. While it is understandable why the Court grounded the holding of *Roe* in the substantive due process of the 14th Amendment. Arguably, the better approach would have been based on the enumerated rights reserved to the people of the United States in the 9th Amendment).
- ¹⁷¹ *Parenthood of Pennsylvanla. v. Casey*, 505 U.S. 833 (1992) (plurality opinion).
- ¹⁷² Compare David. A. Fahrenthold & Carlyle Murphy, *Abortion under Fire*, WASH POST 2003 WLNR 15454301, Jan. 23, 2003, at 1A and Robert W. Bloom & Eva M. Moore, *Editorial, Crisis Pregnancy Centers Operate on Moral Precepts Not Science*, Balt. Sun 2009 WLNR 23257057, Nov. 17, 2009, at 21A, with Edward F. O'Brien, *Editorial, Don't Punish Pro-lifers*, Balt. Sun 2009 WLNR 22244559, Nov. 5, 2009, at 15A.
- ¹⁷³ *Id.*
- ¹⁷⁴ *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).
- ¹⁷⁵ *Id.* at 595.
- ¹⁷⁶ E.g., *Roe v. Wade*, 410 U.S. 113, 153-56 (1973).
- ¹⁷⁷ *Id.*
- ¹⁷⁸ See e.g., Victor E. Frankle, *Man's Search for Meaning*, Wash. Square Press (Simon & Schuster N.Y. Ed. 1963) ("It did not really matter what we expected from life, but rather what life expected from us. We needed to stop asking about the meaning of life, and instead to think of ourselves as those who were being questioned by life—daily and hourly. Our answer must consist, not in talk and meditation, but in right action and in right conduct. Life ultimately means taking the responsibility to find the right answer to its problems and to fulfill the tasks which it constantly sets for each individual."); Elie Wiesel, *Night* (Bantam Books 1982).
- ¹⁷⁹ Victoria Al-Sharqi, *Choice and disability – The F-Word: Are feminist pro-choice politics on selective abortions sidelining the concern of disabled people? Victoria Al-Sharqi argues the case*, The F-Word Compellation (Updated Dec. 1, 2008), http://www.thefword.org.uk/features/2008/12/recently_i_stum.
- ¹⁸⁰ *Id.*
- ¹⁸¹ *Geneinfo—Genetic testing and disabilities*, available at www.geocities.com/geneinfo/facts/disabilities.html (last visited Jul. 8, 2009).
- ¹⁸² See, *Head to Head: Abortion Limit Cut*, BBC News (Last updated May 20, 2008), available at http://news.bbc.co.uk/2/hi/uk_news/politics/7410475.stm.
- ¹⁸³ Tim Stainton, *Missing the Forest for the Trees? A Disability Rights Take on Genetics: Commentary on Stowe et al.* (13) (2) J. on Developmental Disabilities (2007), available at <http://www.oadd.org/publications/journal/issues/vol13no2/download/stainton.pdf>.
- ¹⁸⁴ *Id.*
- ¹⁸⁵ *Id.*
- ¹⁸⁶ *Id.*
- ¹⁸⁷ *Id.*
- ¹⁸⁸ Amy Harmon, *Ideas and Trends; The Problem with an Almost Perfect Genetic World*, N.Y. TIMES 2005 WLNR 18734710, May 20, 2005, at §4.
- ¹⁸⁹ *Id.*
- ¹⁹⁰ *Moster*, *supra* note 69.
- ¹⁹¹ *Schirmer v. Mt. Auburn Obstetrics & Gynecologic Assoc.*, 108 Ohio St. 3d 494, 504-05 (Ohio 2006).
- ¹⁹² *Kaplan*, *supra* note 42.
- ¹⁹³ Judith F. Daar, *Symposium, Embryonic Genetics*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y. 81, 84 (2008) (Citing Susanna Burich et Al., *Genetic Testing of Embryos: Practices and Perspectives of U.S. In Vitro Fertilization Clinics*, 89 FERTILITY & STERILITY 1053, 1055 (2008)).
- ¹⁹⁴ See Areheart, *supra* note 46, at 186-87 (citing Linda MacDonald Glenn, *Using PGD to Select for Disability* (Sept. 12, 2008), <http://stanford.wellsphere.com/bioethics-article/using-pgd-to-select-for-disability/340084>) ("...adherence to the notion of disability as biological inability is precisely what enables the conclusion that accommodations push the market's balance beyond equilibrium. More generally, adherence to the medical model encourages the view that disability rights are 'special,' akin to some form of charity for biological losers. In short, under the medical model, a person's disability is her own personal misfortune-devoid of social cause or responsibility. From this perspective, the medical model has the...capacity to fragment the disability community by stressing the individual physiological traits that differentiate disabled persons, rather than the common societal obstacles that unite them.")).
- ¹⁹⁵ Daar, *supra* note 39, at 53.
- ¹⁹⁶ *Id.*
- ¹⁹⁷ *Greenville Women's Clinic v. Bryant*, 222 F.3d 157 (S.C.), August 15, 2000) (citing *Planned Parenthood v. Casey*, 505 U.S. at 874 ("the Regulation does not 'strike at the [abortion] right itself'")).
- ¹⁹⁸ See generally, *The West Wing: In This White House* (Warner Bros. Television broadcast Oct. 25, 2000).
- ¹⁹⁹ While the legislation put forth in this section of the article is individually authored. Such model legislation has a connection to legislation co-sponsored by United States Senators Sam Brownback (R. Kansas) and Edward Kennedy (D. Mass.)—The Pre-natally and Post-natally Diagnosed Conditions Act. Arguably, the legislation introduced in 2007 is not as reaching as the model legislation put forth herein. However, the proposed legislation by the Senators emphasizes the need for resources to inform those facing these situations to consult with actual people with disabilities, rather than following the sometimes harsh encouragement of medical professionals to abort. Office of Sen. Sam Brownback, BROWNBACK, KENNEDY REINTRODUCE PRE-NATALLY AND POST-NATALLY DIAGNOSED CONDITIONS AWARENESS ACT, Press Release (Jul. 18, 2007), available at <http://brownback.senate.gov/pressapp/record.cfm?id=279251>; see also, George Will, *Judges vs. Lawmakers on Abortion and Disability, It's Time To Ulter The Balance*, Kansas City Star 2005 WLNR 22873255 (Apr. 16, 2005) at B7.
- ²⁰⁰ E.g., Randy Alcorn, *What Makes a Human Life "Meaningful"?*, in *Pro-life Issues* Ch. 7, 48-53 (2008), available at http://www.epm.org/artman2/publish/prolife_issues/What_Makes_a_Human_Life_Meaningful.shtml.
- ²⁰¹ *Id.*
- ²⁰² Philip L. Bereano, Ph.D., J.D., *Does Genetic Research Threaten Our Civil Liberties?* ActionBioscience.org (2000), available at <http://www.actionbioscience.org/genomic/bereano.html>.
- ²⁰³ *Id.*
- ²⁰⁴ *Id.*

- ²⁰⁵ *Id.*
- ²⁰⁶ See generally, Pa. Consolidated Stat. Ann. §3202(b)(1) (1982 and 2009 Vol.).
- ²⁰⁷ *Id.*
- ²⁰⁸ Tenn. Right to Life, *Abortion*, Policy Statement (1999-2005), available at http://tennesseerighttolife.org/about_us/about_us_policy.htm.
- ²⁰⁹ *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Gonzales v. Carhart*, 127 S. Ct. 1610 (2007).
- ²¹⁰ E.g., Okla. Stat. Ann. §1-568 West (2006 and Supp. 2009); PA. CONS. STAT. ANN. §3202(d) (West 1982 and Supp. 2009).
- ²¹¹ MINNS. ST. ANN. §145.424(3) (West 1982).
- ²¹² *Roe v. Wade*, 410 U.S. 113, at 163-64 (“Examples of permissible state regulation in this area are requirements as to the qualifications of the person who is to perform the abortion; as to the licensure of that person; as to the facility in which the procedure is to be performed, that is, whether it must be a hospital or may be a clinic . . . ; as to the licensing of the facility”).
- ²¹³ Women’s Health and Life Protection Act, §4, H.B. 1215, 81st Leg., 1st Spec. Sess. (S.D. 2006), available at <http://news.findlaw.com/cnn/docs/abortion/sdabortionlaw06.html>.
- ²¹⁴ ME. REV. STAT. ANN. tit. x, §2931 (2009).
- ²¹⁵ *Id.*
- ²¹⁶ *Id.*
- ²¹⁷ Assisted Human Reproduction Act 2004, available at <http://laws.justice.gc.ca/en/ShowFullDoc/cs/A-13.4/20090818/en?noCookie>.
- ²¹⁸ *Id.*
- ²¹⁹ *Id.*
- ²²⁰ Some courts have upheld waiting periods. See, e.g., *Cincinnati Women’s Serv., Inc. v. Taft*, 468 F.3d 361, 372-74 (6th Cir. 2006); *Fargo Women’s Health Org. v. Schafer*, 18 F.3d 526, 532-34 (N.D. 1994), February 10, 1994; *Utah Women’s Clinic, Inc. v. Leavitt*, 844 F. Supp. 1482 (D. Utah, 1994); *Woman’s Choice-East Side Women’s Clinic v. Newman*, 305 F.3d 684, 684 (Ind. 2002) (“*Casey* also found the twenty-four hour waiting period was not an undue burden, reasoning that ‘important decisions will be more informed and deliberate’ if made after some period of reflection . . . Again, the Court looked to the exception for medical emergencies and record evidence that in the vast majority of cases a twenty-four hour delay does not create an appreciable health risk. Recognizing that in practice there is a substantial obstacle in a mandatory twenty-four hour waiting period, the Court found a closer question was whether the waiting period will increase the exposure of women seeking abortions to harassment and hostility of anti-abortion protesters. *Casey* held that these findings, while troublesome, did not demonstrate that the waiting period constituted an undue burden.”). Admittedly, no court has been presented with the question of a waiting period of one week, however.
- ²²¹ See generally, FLA. STAT. ANN. §393.064 (2009).
- ²²² *Id.* at 393.064(2).
- ²²³ See generally, TENN. CODE ANN. §39-15-202(b)(5) (West 2009); WIS. STAT. ANN. §253.10(L)(2)(c) (West 2009).
- ²²⁴ *Id.*
- ²²⁵ Letter from American Association of People with Disabilities et al to Melody Barnes, Assistant to the President for Domestic Policy, Presidential Transition Team and Lisa Brown, Staff Secretary, Presidential Transition Team (Dec. 23, 2008), available at <http://jfactivist.typepad.com/jfactivist/2008/12/index.html>.
- ²²⁶ National Council on Disability, *NCD National Summit on Disability Policy 2010: ADA 1990-2010 Retrospective and Future Policy Directions*, available at <http://www.neweditions.net/ncd2010/index.html> (Last visited Oct. 23, 2009).
- ²²⁷ *Id.*
- ²²⁸ In the summer of 2009, President Obama pledged that his administration would sign, and his Ambassador to the United Nations, Ms. Susan Rice, Ph.D. signed, the Convention at a ceremony. Myriad members of the disability community attended; among them, were the President of the Am. Foundation for the Blind. Congress must next ratify the Convention by a super majority. As the Senate is controlled by Democrats, this is anticipated. See, Remarks of Susan Rice, Ambassador to the United States Mission to the United Nations & White House Senior Advisor Valerie Garrett at U.N. Headquarters (Jul. 2009), available at www.usunnewyork.usmission.gov/press.../20090730_156.html.
- ²²⁹ Convention, *supra* note 87.
- ²³⁰ Protocol, *supra* note 88.
- ²³¹ See, e.g., *Thomas Jefferson University v. Shalala*, 512 U.S. 504 (1994) (discussing the standard, as applied in the context of regulatory promulgation of the HHS).
- ²³² E.g., Disability Rights and Education Defense Fund, *Healthcare Outcomes for People with Disabilities*, Healthcare Access Br., available at http://www.dredf.org/healthcare/Access_Brief.pdf (Last visited Jul. 8, 2009).
- ²³³ Donald Elliott, *Symposium, The Genome and the Law: Should Increased Genetic Law Change the Law?* 25 HARV. L. J. & PUB. POL’Y. 61, 61 (2001) (“[H]ow should our law change in light of increasing knowledge of the human genome? That will be a central question occupying legal thought in coming decades as progress in genetic changes not only our understanding of human nature but, also our ability to manipulate human nature.”).
- ²³⁴ See, Michael Schmid, *The Orwellian Language of Big Government*, Pol’y. Paper No. 152 (June 22, 2004), <http://www.ntu.org/main/press.php?PressID=604>.
- ²³⁵ *Id.*; see also, *George Orwell’s Animal Farm: Lessons for Today* (Oct. 2006), available at <http://www.stentorian.com/animfarm.html>.

REGULATING SECONDHAND TOBACCO SMOKE IN THE AMERICAS: A COMPARISON OF THE TOP DOWN AND BOTTOM UP APPROACHES IN BRAZIL AND THE UNITED STATES

Leigh Warren*

I. Introduction

The tobacco epidemic has emerged as one of the major public health disasters of the twentieth century.¹ According to the World Health Organization (WHO), the tobacco epidemic killed 100 million people worldwide in the last century, and the twenty-first century could claim one billion more.² These deaths include the 600,000 nonsmokers who die annually from “passive smoking” or inhaling secondhand tobacco smoke (SHS). Tobacco use continues to be the single most preventable cause of death in the world today.³

For nonsmokers, the tobacco epidemic has been a human rights tragedy. Their involuntary exposure to SHS in the workplace and other public venues violates their fundamental right to a safe and clean environment and the internationally recognized right to health. No safe levels of exposure to SHS exist, even in ventilated areas.⁴ There is no question that SHS is a carcinogen and that SHS exposure increases the risk of lung cancer, cardiovascular disease, and respiratory illnesses in nonsmokers.⁵

The violation of nonsmokers’ human rights is a global phenomenon, surpassing all economic and geographic boundaries, but SHS disproportionately impacts the poor and vulnerable. WHO estimates that by 2030 there will be more than eight million tobacco-related deaths per year worldwide and eighty percent of those deaths will be in the developing world.⁶ Furthermore, the tobacco epidemic will cause the most harm to low-income households and countries.⁷ Children are particularly vulnerable to the adverse health effects of SHS. Numerous studies suggest that their exposure to SHS may cause leukemia, brain tumors, respiratory diseases, and sudden infant death syndrome.⁸ Additional vulnerable groups include pregnant women,

who cannot protect their fetuses from SHS exposure, and those working in the hospitality industry, whose jobs hold them captive to the toxic fumes of customers’ cigarette smoke daily.

The Framework Convention on Tobacco Control (FCTC) established a global commitment to ending the tobacco epidemic.⁹ Article 8 of the FCTC calls for universal protection from exposure to SHS in all public indoor places. Accordingly, Article 8 imposes a duty on governments to enact legislation to protect individuals against SHS because it threatens fundamental rights and freedoms.¹⁰

Almost five years after the FCTC entered into force in 2005, information on global progress toward a smoke-free world is now available. The global report card is rather dismal, but select countries have adopted legislation answering the call of Article 8. Among the Pan American States, Brazil and the United States have pursued exemplary, though opposite, legal approaches. Brazil has focused on comprehensive federal legislation followed by decentralization to the local level (“top down”), while the United States has emphasized local legislation, slowly making inroads at the federal level (“bottom up”). In both approaches, the assertion of human rights has advanced judicial and legislative efforts.

This article presents a comparative analysis of the legal approaches to regulate SHS in Brazil and the United States. Part II reviews the FCTC, its objective to achieve smoke-free public places, and the legal framework supporting freedom from SHS as a human right. Parts III and IV examine Brazil’s top down and the United States’ bottom up approaches to regulating SHS through legislative and judicial measures. Part V presents a comparative analysis of the two approaches and offers recommendations based on lessons learned from each approach. Because neither approach is perfect, Part V also discusses the role that the Inter-American Commission on Human Rights (IACHR) and the Inter-American Court on Human Rights can play to protect the fundamental right of nonsmokers to a smoke-free environment, regardless of their domestic laws.

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II. Secondhand Tobacco Smoke: A Human Rights Perspective

A. The Framework Convention on Tobacco Control and SHS

By the 1990s, the catastrophic and global consequences of the tobacco epidemic prompted the international public health community to take action. WHO responded by establishing the FCTC, the first treaty negotiated under WHO’s authority. The FCTC garnered astounding global commitment, boasting 168 signatories and 167 current Parties.¹¹ It entered into effect on February 27, 2005 and legally binds eighty-seven percent of WHO Member States.

What the FCTC accomplished in breadth, it sacrificed in depth to garner wide global support.¹² The framework-convention protocol imposes light obligations, long-term deadlines, and aspirational liabilities. It also lacks realistic enforcement for noncompliance. Signatory countries need only “strive in good faith to ratify [the Convention], and show political commitment not to undermine the [Convention’s] objectives.”¹³ Thus the FCTC garnered many signatures in exchange for shallow commitment.

Nonetheless, the FCTC provides clear goals for its Parties and guidelines for achieving them. The FCTC sets forth core-reduction provisions relating to the supply and demand of tobacco (Articles 6-17) and mechanisms for Parties’ cooperation and exchange of information (Articles 20 and 22). In addition, Parties must report their progress toward fulfilling the core-reduction goals (Article 21). Given the flexibility of the framework convention, Parties can essentially set their own pace toward tobacco control, and reporting is voluntary in practice. In 2008, 81 countries (out of the expected 129) reported to WHO on their progress toward implementing the FCTC. The WHO summary of the Parties’ 2008 reports indicates that countries vary widely in their efforts and progress toward fulfilling the core reduction goals.¹⁴

Among the FCTC’s core reduction provisions is Article 8, which calls for protection from exposure to tobacco smoke in all enclosed public places:

Each Party shall adopt and implement in areas of existing national jurisdiction as determined by national law and actively promote at other jurisdictional levels the adoption and implementation of effective legislative, executive, and administrative and/or other measures, providing for protection from exposure to tobacco smoke in indoor

workplaces, public transport, indoor public places, and, as appropriate, other public places.

According to public health officials, “protection from exposure to tobacco smoke” means no smoking in public indoor spaces. In 2007, the U.S. Surgeon General issued a report concluding that SHS cannot be effectively controlled by technical measures; a total ban on indoor smoking is necessary to protect nonsmokers.¹⁵ WHO also formally acknowledged that ventilation techniques do not adequately control SHS indoors to the extent called for in Article 8.¹⁶ Therefore, Article 8 calls for a total ban on smoking in enclosed public spaces.

For many WHO Member States, the goal of protecting nonsmokers from SHS is remote. Based on available data from 179 WHO Member States and one territory, WHO reports that:

- Only sixteen countries, representing five percent of the world’s population, have comprehensive smoke-free laws;
- More than half of countries, accounting for nearly two-thirds of the world’s population, allow smoking in government offices, workplaces, and other indoor places; and
- The overwhelming majority of countries have no smoke-free laws, very limited laws, or ineffective enforcement.¹⁷

Therefore, Article 8 remains an aspirational standard among the international community. Existing legislation and enforcement are inadequate, and countries have been slow to make improvements. In short, the tobacco epidemic is winning the global battle against SHS at the expense of nonsmokers’ health.

B. Freedom from SHS as a Human Right

The FCTC does more than impose an obligation on states to protect against exposure to SHS. It implicitly recognizes a fundamental right to be free from SHS and links it with “the right of all people to the highest standard of health.”¹⁸ Moreover, WHO’s guidelines on the implementation of Article 8 further clarifies that Parties’ duties to protect from tobacco smoke is “grounded in fundamental human rights and freedoms,” such as the rights to life and health.¹⁹ These rights are recognized in international legal instruments, including the Convention on the Rights of the Child (CRC), the Convention on Elimination of all Forms of Discrimination against Women (CEDAW), and the International Covenant on Economic, Social and Cultural Rights (ICESCR), as well as in the preamble to the FCTC.²⁰

Legal scholars recognize that the right to be free from SHS derives from a trio of internationally recognized human rights: the right to life, the right to health, and the right to freedom of information.²¹ The Pan American Health Organization (PAHO)²² further supports that freedom from tobacco smoke is encompassed by the rights to life, health, humane treatment, and fifteen additional internationally recognized human rights and fundamental freedoms.²³ Linking freedom from SHS to international human rights amplifies and strengthens that “smoke-free” right in several ways.

First, the smoke-free right becomes incorporated into United Nations (U.N.) treaties recognizing fundamental rights to life, health, and humane treatment.²⁴ So linked, the smoke-free right becomes legally enforceable in countries where these treaties have been ratified. These treaties generally have stronger enforcement mechanisms than the FCTC’s flexible convention framework. In addition, the smoke-free right becomes enforceable through more legal instruments than just the FCTC. Thus linking the smoke-free right to human rights treaties amplifies and strengthens its enforceability.²⁵

Second, the smoke-free right becomes enforceable even in countries that have not ratified the FCTC or U.N. treaties, assuming broader geographical scope.²⁶ By fitting the smoke-free right under the umbrella of the rights to life and health, the smoke-free right becomes incorporated into well-established international customary law. This body of law imposes binding obligations on countries even when they have not ratified particular legal instruments.²⁷ Again, the effect is to amplify, strengthen, and geographically expand the smoke-free right beyond the confines of the FCTC.

Third, linkage to international human rights treaties creates additional fora where the smoke-free may be enforced.²⁸ These international courts and institutions include the United Nations Committee on Economic, Social, and Cultural Rights, the United Nations Human Rights Committee, the European Court of Human Rights, the IACHR, and the Inter-American Court of Human Rights (Inter-American Court). The IACHR and the Inter-American Court will be discussed in more detail in Part V.

In summary, the right to a smoke-free environment derives from fundamental human rights, such as the rights to life, health, humane treatment, and freedom of information. These rights are recognized in U.N. human-rights treaties and international customary law. Thus the smoke-free right is stronger and more widely enforceable than the weak confines of the FCTC.

C. Brazil and the United States: Two Models in the Americas

Within the Americas, Brazil and the United States serve as models for countries regulating SHS. These two “Model States” have made substantial progress in reducing the burden of SHS on their citizens. Their accomplishments have not come easy. Both countries are homes to powerful tobacco industries that have infiltrated their social, economic, and political infrastructures. Yet the Model States have persisted, and PAHO recently hailed their “significant and fast” progress in reducing exposure to SHS.²⁹

Brazil and the United States are leaders in various tobacco industries. Brazil is the world leader in tobacco leaf export and the second-largest tobacco leaf producer.³⁰ Its states depend heavily on tobacco industries to support local economies and tax revenue.³¹ The United States is the third-largest exporter of manufactured cigarettes, the third-largest tobacco leaf importer, and home to the largest transnational tobacco company, Altria/Philip Morris.³²

Due to their proximity to tobacco companies, the Model States’ anti-tobacco reforms have endured relentless interference by the tobacco industry. The influence of tobacco companies weakened the Model States’ positions during FCTC negotiations.³³ The United States’ subsequent failure to ratify the FCTC and Brazil’s delay in doing so are largely attributed to industry influence.³⁴ Moreover, tobacco companies have donated huge sums to policymakers in the United States. For example, between 1997 and 2007, they contributed \$34.7 million to federal candidates, political parties, and political action committees.³⁵ In 2008, tobacco companies made four million dollars in campaign contributions to federal candidates and political action committees, and spent twenty-nine million dollars to lobby Congress.³⁶ Political contributions are less transparent in Brazil,³⁷ but tobacco lobbying there is “vigorous.”³⁸ In both Model States, the tobacco lobbies have a stranglehold on high-level policymakers.

The tobacco industry has influenced scientific communities as well, stymieing efforts to determine the adverse health effects of SHS. At the international level, tobacco companies sought to undermine a large-scale epidemiological study on the relationship between SHS and lung cancer.³⁹ Using undercover tactics, tobacco officials gained access to details about the study. The tobacco companies then launched a media campaign and conducted counter-research designed to undercut the study’s finding that SHS caused lung cancer.⁴⁰ In Latin America, top tobacco

“By fitting the smoke-free right under the umbrella of the rights to life and health, the smoke-free right becomes incorporated into well-established international customary law.”

companies launched the “Latin Project.”⁴¹ They recruited scientists to study non-tobacco pollutants and sponsored scientific conferences to downplay the risks of SHS, all under the guise of legitimate science.⁴² These biased and bogus arguments were presented to policymakers through scientific channels to frustrate regulation of SHS. Similar tactics were used in the United States. For example, tobacco companies legally challenged a report by the US Environmental Protection Agency (EPA) identifying SHS as a carcinogen, specifically for lung cancer.⁴³ Although the EPA report had no direct regulatory effect, it galvanized the public health community and state legislators toward anti-smoking reforms. The case was ultimately dismissed because the EPA’s publication of the report was not subject to judicial review.⁴⁴

Despite the tobacco industry’s tactics, the Model States have launched legislative initiatives to regulate SHS. Brazil has focused on federal legislation, followed by decentralization to the state and local levels — the “top down” approach. The United States, on the other hand, has made far more progress at the state and local levels, with little federal legislation — the “bottom up” approach.

Neither the top down nor the bottom up approach is perfect. In both countries, many public places remain unregulated for SHS.⁴⁵ As frontrunners in the global smoke-free movement, the Model States have grappled with legal and political hurdles to a greater extent than many of their fellow American States. Because of their diametric approaches, the Model States have jointly encountered a wide range of issues that likely await their American neighbors. Only sixty percent of PAHO Member States have ratified the FCTC and exposure to SHS remains universal and high in those countries.⁴⁶ The lessons learned from Brazil and the United States provide much-needed instruction on tackling typical legal and political hurdles. Brazil and the United States serve as Model States for their successes and their shortcomings in regulating SHS. Their legal approaches are discussed separately in the following sections.

III. Brazil: Top Down Approach to Regulating SHS

Brazil is a world leader in the fight against the tobacco epidemic. The country ratified the FCTC in 2005 and passed national legislation addressing most of its goals.⁴⁷ Brazil’s restrictions on tobacco advertising, among the strictest and most comprehensive in the world, set a standard for international best practices.⁴⁸ Brazil’s anti-tobacco commitment is bolstered by the nation’s constitutional right to health.⁴⁹ Moreover, Brazil has ratified the ICESCR, which explicitly encompasses the international right to health (“enjoyment of the highest attainable standard of physical and mental health”).⁵⁰ According to General Comment No. 14 of the ICESCR, the right to health includes the right to healthy natural and workplace environments, which requires the “prevention and reduction of the population’s exposure to harmful substances such as . . . harmful chemicals or other detrimental environmental conditions.”⁵¹

The hallmark of Brazil’s smoke-free initiative is federal legislation. Implementation at the state and local levels has proven difficult due to lack of regulatory coordination, inadequate local resources, and courts’ struggle to interpret federal law. State and local smoke-free laws have only just begun to surface, and their constitutionality is not yet settled.

Despite its difficulties, top down legislation, in conjunction with Brazil’s overall tobacco control program, has accomplished much in protecting Brazilian citizens from SHS. SHS exposure in the nation’s public and private spaces has decreased dramatically, owing to the over fifty percent reduction in overall prevalence of adult smoking since 1989 and the continuing decrease in household smoking.⁵² Nonetheless, many Brazilians remain unprotected and seven deaths per day in Brazil are attributable to SHS.⁵³ Furthermore, SHS in Brazil may disproportionately impact the less educated and less affluent, evidenced by the higher prevalence of smoking in their households.⁵⁴

A. Federal Law

In 1996, Brazil passed Federal Law No. 9294 (Law 9294), which prohibits the use of cigarettes, cigarillos, cigars, pipes, or any other tobacco product in enclosed collective areas, private or public, except in areas designated exclusively for smoking, which must be isolated and properly ventilated.⁵⁵ While commendable for its universal applicability, Law 9294 does not meet the smoke-free standard of Article 8 of the FCTC, which prohibits smoking in all public indoor areas. The exception for designated smoking areas vastly weakens the law, since no ventilation techniques are known to protect against SHS.⁵⁶ The only places where smoking is entirely banned in Brazil are in aircraft, other public transportation, and facilities owned by the Ministry of Health.⁵⁷

Law 9294 has also proven difficult to enforce because courts differ on how to interpret “areas designated exclusively for smoking.” According to a 2009 report by the O’Neill Institute, one interpretation holds that designated smoking rooms cannot be used to serve food or drinks, or for any other purpose.⁵⁸ Under another interpretation, designated smoking areas are simply areas for smoking, without restriction on services or activities offered there.⁵⁹ These interpretations are vastly different — the former would bring the hospitality industry to a halt, whereas the latter would permit business as usual. The regulation promulgated under Law 9294 (Decree 2018) does little to clarify the definitions of “enclosed collective areas” and “areas designated exclusively for smoking.”⁶⁰

There is general agreement that Law 9294 and Decree 2018 need to be clarified, but attempts stalled until recently. The Agência Nacional de Vigilância Sanitária (the National Health Surveillance Agency, ANVISA) is responsible for issuing regulations under Law 9294 and it drafted a proposed regulation (ANVISA Resolution No. 527 (2006)) to clarify Decree 2018.⁶¹ Simultaneously, the Instituto Nacional de Câncer (the National Cancer Institute (INCA) within the Ministry of Health) proposed a draft amendment of Law 9294 for the National Congress’s consideration. ANVISA withdrew its resolution in view of INCA’s draft amendment, which languished at the end of 2009.⁶² For a while, tobacco-control efforts reached a stalemate on the legislative and regulatory fronts.

The stalemate may soon resolve due to recent progress toward additional federal legislation. In March 2010, the Brazilian Senate’s Committee on Constitution, Justice, and Citizenship (JCC) approved a proposed bill (PLS 315/08) that would amend Law 9294 to require 100% smoke-free public spaces.⁶³ Numerous public health and medical organizations showed support for the bill,⁶⁴ and, according to the JCC rapporteur, the amendment would finally align Brazil’s federal laws with the FCTC’s Article 8

objective. Following the JCC's favorable vote, the bill must be approved by the Brazilian Commission for Social Affairs before being considered by Congress.⁶⁵

In addition to formal legislation, two interministerial ordinances establish nonbinding recommendations on smoking restrictions in Brazil's indoor spaces.⁶⁶ First, Interministerial Ordinance 3257 recommends measures to restrict smoking in workplaces and determines the designation of smoking areas, which must be isolated and properly ventilated. This Ordinance, passed in 1988, long predates Law 9294 and is less important than Decree 2018. Interministerial Ordinance 1498 recommends that health and teaching institutions implement tobacco-free environment programs and award certificates to those entities with exemplary tobacco-control policies.

B. State and Local Law

Progress toward smoke-free environments at the state and local levels has been slow. To effectively implement Law 9294, state and local officials require clear guidance on how to enforce ill-defined "designated smoking areas." Decree 2018 has not served that purpose well and either ANVISA's proposed regulation or INCA's proposed legislative amendment, whichever passes, will be much welcomed. In the meantime, ANVISA is developing guidelines on how to apply Law 9294 and public agents were trained to implement the law in 2006.⁶⁷

Whether ANVISA will be able to provide meaningful guidance is questionable. Law 9294 calls for properly ventilated designated smoking areas in enclosed spaces – an oxymoron in light of later scientific evidence. It is now well accepted in the public health community that no ventilation controls can protect nonsmokers against SHS in enclosed spaces. State and local legislators may have to wait for an amendment to Law 9294 before trying to implement it in a significant way.

In the meantime, some states and municipalities have initiated their own smoke-free laws and programs. Their progress is difficult to quantify because there are no databases of state and municipal laws related to tobacco control.⁶⁸ From what little information is known, tobacco-control coverage varies and the majority of implementation programs are concentrated in three of Brazil's twenty-six states.⁶⁹

In August 2009, São Paulo, Brazil's most populous and economically prominent state, passed a law (São Paulo Law No. 13541) banning smoking in enclosed public spaces with no exception for designated smoking areas.⁷⁰ The São Paulo law exceeds the reach of Law 9294 and provides the full protection guaranteed by Article 8 of the FCTC. Noncompliance results in monetary penalties and closure of the establishment upon a repeat offense.⁷¹ Although São Paulo has attempted such a ban before, it failed due to weak enforcement and public apathy.⁷² This time around, São Paulo reports over ninety-nine percent compliance by its pubs, restaurants, and hotels.⁷³ Although the law prompted a litany of lawsuits, state courts have so far upheld the law.⁷⁴

The São Paulo law is a revolutionary test case for Brazil that may spur more rapid progress. No doubt many states and municipalities are watching to see how courts resolve the preemption issue (i.e., whether states' and municipalities' strict smoke-free laws are preempted by the weak federal law). Many state and municipal laws have been challenged as preempted

and thus unconstitutional by the hospitality industry (often a front for tobacco companies).⁷⁵ A non-governmental organization (Aliança de Controle do Tabagismo (ACT)) recently commissioned a legal analysis on the preemption issue, which was presented to the Interministerial National Commission for FCTC Implementation (CONICQ).⁷⁶

INCA's tobacco control program supplements legislative initiatives, but it has faltered recently. INCA coordinates the federal tobacco program with state and local anti-tobacco regulations and activities. INCA acted as an intermediary in the first agreements between the National Health Fund and State Health Secretariats in 1999.⁷⁷ From these agreements, states and municipalities developed smoking control programs and established a network of focal points in major cities. This network started to localize tobacco control efforts, but progress waned due to high turnover of trained staff for political reasons.⁷⁸ Furthermore, the program abruptly lost funding when the mechanism INCA had used to transfer federal funds to states and municipalities was eliminated.⁷⁹ INCA has pledged to revive its efforts to assist municipal implementation of Law 9294.⁸⁰

C. Summary of Brazil's Top Down Legal Approach

In summary, Brazil's top down approach consists mainly of a weak federal law that is difficult for courts to interpret and thus not locally enforced. Federal regulations have done little to clarify the law, and further progress has been frustrated by lack of coordination between the two bodies sharing authority for federal tobacco programs. Limited though it may be, the success of the federal tobacco program thus far is due in large part to its management by a public health agency that is isolated from the tobacco lobby and political pressures. States and municipalities have begun to enact strict smoke-free laws, but their status will remain unclear until the Brazilian Supreme Court decides whether they are preempted by the weak federal law.

IV. United States: Bottom Up Approach to Regulating SHS

The United States' bottom up approach consists mainly of municipal and state smoke-free laws, which are not uniform throughout the country. SHS regulation at the federal level is sparse due to the strength of the tobacco lobby. Overall, the bottom up approach has significantly reduced nonsmokers' exposure to SHS since 1986, evidenced by survey and epidemiological data.⁸¹ Regulatory gaps still expose many vulnerable groups to high levels of SHS, including children, certain ethnic groups (in particular, blacks and Hispanic women), low-income individuals, and workers in the hospitality and transportation industries.⁸²

A. Local Law

Of the three levels of government in the United States, local ordinances afford the best protection against SHS. The city or county officials responsible for enacting ordinances are far more responsive to their local boards of health and residents than the tobacco industry. These local ordinances are usually well known in their communities and enforced by local officers. Furthermore, the independence and dispersed locations of the 3000+ municipalities that restrict smoking keep the tobacco industry at bay.⁸³

Local ordinances vary in their coverage of smoke-free facilities. Generally, they require one or more of 100% percent smoke-free workplaces, 100% smoke-free restaurants, and 100% smoke-free freestanding bars.⁸⁴ Some municipalities also restrict smoking in outdoor areas (e.g., near building entrances and windows, parks, beaches, or sporting and entertainment venues).⁸⁵ These local laws vary in substance, but Americans' for Nonsmokers' Rights provides a model ordinance that guides most jurisdictions tackling the issue.⁸⁶ The model ordinance guarantees "the right of nonsmokers to breathe smoke-free air."⁸⁷ The model ordinance also finds support in the smoke-free laws of the international community.⁸⁸

Although it is not common practice local governments can channel international treaties directly to their communities, even when those treaties not ratified in the United States. For example, the City of San Francisco has adopted an ordinance implementing CEDAW⁸⁹ and the New York City Human Rights Law incorporates CEDAW and Committee on the Elimination of Racial Discrimination.⁹⁰ In theory, city governments could adopt Article 8 of the FCTC (relating to SHS).

Local ordinances represent the "bottom" of the bottom up approach and provide a strong base for nonsmokers' rights. Unfortunately, they also are vulnerable to preemption by more relaxed federal and states laws. Federal preemption has not truly threatened local ordinances due to the tobacco industry's ability to frustrate higher-level legislation. The more Congress frees itself from the grip of Big Tobacco, the greater the threat that a more lenient federal law will preempt local smoke-free laws.

Preemption by state law presents a more immediate and continuing threat. Currently thirteen states have smoke-free laws with preemptive provisions, which may offer more or less protection than existing local laws.⁹¹ Some local ordinances have survived preemption challenges under state law; others have not. State courts have found implied preemption based on statutes silent on preemption, ambiguous or conflicting preemption clauses, collections of state statutes (all silent on preemption), or state constitutions.⁹² Only explicit non-preemption clauses in state statutes guarantee that a local smoke-free ordinance will stand.

It is important to resolve preemption issues as soon as possible, since that threat alone can chill local smoke-free efforts. For example, after a smoke-free law in San Jose survived a preemption challenge by the California State Department of Health a network of local ordinances were rapidly enacted throughout the state.⁹³ These local smoke-free laws filled the gaps in the state law, making California the first Article 8-compliant state. Thus, although preemption threatens local laws, resolving the issue can galvanize rapid progress toward smoke-free environments.

B. State Law

States protect their residents from SHS using statutes, constitutions, and common law. While state smoke-free laws are becoming more common, many do not meet the FCTC's Article 8 standard. State common law helps to fill the gaps, and state courts are often receptive to creative legal theories incorporating fundamental rights.

1. State Statutes and Constitutions

States have enacted laws to restrict SHS in various institutional settings (e.g., correctional facilities, child care and juvenile centers, hospitals,

and adult residential care facilities).⁹⁴ Currently twenty-seven states, Washington, DC, and Puerto Rico have passed smoke-free laws that cover restaurants and bars.⁹⁵ Four additional states have smoke-free laws that cover restaurants but exempt stand-alone bars. Only fifteen states and Puerto Rico have enacted one hundred percent smoke-free laws for all state-regulated casinos and gaming facilities.

Several states offer constitutional protection from SHS. Florida's constitution specifically recites a smoke-free provision but permits exceptions (e.g., stand-alone bars).⁹⁶ Montana's constitution recognizes a broader "right to a clean and healthful environment" as an inalienable right.⁹⁷ Similarly, the New York state constitution imposes an obligation on the state to protect and promote the health of its inhabitants.⁹⁸ Such a broad, health-related constitutional right is also helpful as a legal tool to protect against SHS. State courts can, and often do, look to international human rights treaties (ratified or not) to interpret their own constitutions and statutes.⁹⁹

State courts may also apply more general statutes to protect the right to a smoke-free environment, aided by interpretative tools of their choosing, including international human rights norms. For example, in *In re Julie Anne*, a child custody proceeding, a Court of Common Pleas relied on Ohio's "best interest of the child" statute and the doctrine of *parens patriae* (state acts as "parent of the nation") to restrain parents and others from smoking in a child's presence.¹⁰⁰ To determine what was in the "best interest" of the child, the court looked to the CRC (not ratified by the United States but serving as international customary law) and its finding that imposes a "duty as a matter of human rights to reduce children's compelled exposure to tobacco smoke."¹⁰¹ The court also relied on U.S. Supreme Court cases suggesting that smoking is not a fundamental right and took judicial notice of overwhelming scientific evidence that SHS causes and aggravates diseases in children.¹⁰² Using this powerful doctrinal combination, the court prohibited SHS from the child's presence in private residences and motor vehicles, arguably exceeding the FCTC's Article 8 standard. *In re Julie Anne* embodies a child's right to a smoke-free home.

State statutes, in combination with local laws, go a long way to protect residents from SHS. According to the Americans for Nonsmoker's Rights Foundation, seventy-one percent of the U.S. population is covered by a state, or local law requiring smoke-free workplaces, restaurants, or bars; forty-one percent of the U.S. population is covered by laws that require all three venues to be smoke-free.¹⁰³ Still, substantial gaps in official laws require courts to look elsewhere for legal doctrine.

2. State Common Law

Courts have relied on state common law to find the right to a smoke-free workplace and rental residence. The common-law approach is powerful because it allows courts to consider evolving social and cultural values, including society's increasing disdain for SHS.¹⁰⁴ At the same time, common law may compromise human rights when society does not fully recognize them. Nonetheless, because of their receptiveness to creative legal theories, state courts can provide a favorable forum for implementing human rights.¹⁰⁵

Courts have applied common law to protect an employee's right to a smoke-free environment, though remedies are limited. In *Shimp v. New Jersey Bell Telephone Co.*, the Superior Court of New Jersey recognized the common-

law right to a safe working environment and ordered the employer to prohibit smoking in working and customer-service areas.¹⁰⁶ Ground-breaking as the case was in 1976, the court limited the smoke-free right by stating that employees “should have a reasonably accessible area in which to smoke” at work, such as the lunchroom and lounge.¹⁰⁷ Similarly, in *Smith v. Western Electric Co.*, the Missouri Court of Appeals allowed an employee to proceed with a claim that his employer breached a common-law duty to provide a reasonably safe workplace by permitting smoking.¹⁰⁸ The court found an injunction to be the appropriate remedy because monetary damages could not compensate for the health effects of SHS.¹⁰⁹

In the *Shimp* and *Smith* cases, preemption threatened the viability of the nonsmoker-employees’ claims. Fortunately, the only federal law arguably preempting states’ abilities to regulate SHS contained a nonpreemption clause.¹¹⁰ The *Shimp* and *Smith* courts held that the nonpreemption clause of the Occupational Safety and Health Act (OSH Act) did not preempt a common law claim asserting the right to a safe working environment.¹¹¹

In another notable case, *Gainsborough St. Realty Trust v. Haile*, a Massachusetts housing court recognized a tenant’s common-law right to quiet enjoyment in a rented residence. In *Gainsborough*, the landlord breached the covenant of quiet enjoyment by failing to prevent smoke from seeping in from an adjacent unit. The court awarded the tenant withheld rent (\$4350) but rejected the tenant’s claim for damages for smoke-induced asthma (six million dollars), citing failure to prove causation.¹¹²

Finally, state courts may also consult international human rights treaties to determine the limits of positive rights under state common law or use customary international norms when developing state common law.¹¹³

C. Federal Law

The United States has neither ratified the FCTC nor enacted comprehensive federal legislation to control SHS. Narrow federal laws prohibit smoking on domestic and international airline flights and in enclosed areas of school facilities.¹¹⁴ Under executive order, smoking is prohibited in all interior spaces and nearby outdoor areas owned, rented, or leased by the Executive Branch.¹¹⁵

No federal regulations control indoor smoking. The Occupational Safety and Health Administration (OSHA) once proposed a rule to regulate environmental tobacco smoke, citing authority from the OSH Act.¹¹⁶ OSHA withdrew the proposed rule seven years later, in view of the numerous state and local smoke-free laws passed in the interim.¹¹⁷ An advocacy group that initially challenged OSHA’s failure to issue a final rule dropped its claim

for fear that OSHA would issue a weak rule preempting strong existing and future state and local laws.¹¹⁸ The EPA has no authority to regulate indoor air quality, though it can provide guidance. For example, the agency’s 1992 report classifying SHS as a carcinogen is frequently cited in state court cases and state and local anti-smoking laws.

Recently Congress passed a comprehensive law granting the Food and Drug Administration authority to regulate tobacco products (the Family Smoking Prevention and Tobacco Control and Federal Retirement Reform Act of 2009).¹¹⁹ Although the Act does not address SHS, it is nonetheless noteworthy because it represents what Congress can practically accomplish, given the powerful tobacco lobby. The Act favors the tobacco industry on certain issues, for example, by partially preempting state and local laws and staffing the scientific advisory committee with tobacco industry representatives.¹²⁰ If Congress were to enact legislation restricting indoor smoking, the tobacco lobby and preemption remain real threats. It is hard to say whether such legislation would be an advance or a setback for the smoke-free movement.

Federal case law addressing SHS exposure is likewise limited. The Americans with Disabilities Act (ADA) has supported some successful claims, but the doctrine that has emerged provides limited protection to nonsmokers.¹²¹ An ADA plaintiff must show an existing disability (e.g., asthma or a respiratory condition) and thus must have been exposed to SHS for a substantial time and sustained significant physical harm. The U.S. Supreme Court addressed the issue in *Helling v. McKinney*, holding that a prisoner’s exposure to unreasonable levels of SHS supported a viable claim under the Eighth Amendment (prohibiting cruel and unusual punishment).¹²² Finally, federal courts are generally unreceptive toward arguments derived from international human rights treaties (most of which have not been ratified by the United States), even when offered as persuasive authority.¹²³

Summary of the United States’ Bottom up Legal Approach

In summary, the United States’ bottom up approach emphasizes state and local codified laws, supplemented by state common law establishing the right to live and work in smoke-free environments. State courts have embraced rights-based arguments, considering fundamental rights from various sources, including international human rights treaties as persuasive or interpretive authority. Compared to their state counterparts, federal statutes and case law offer very limited protection from SHS. If federal statutory law were to emerge, it would likely be weakened by the tobacco lobby and threaten preemption of stronger state and local smoke-free laws.

V. Evaluation of the Top Down and Bottom Up Approaches

A. Legal Analysis and Recommendations

The above discussion highlights the differences and similarities between Brazil's top down and the United States' bottom up approaches. On the one hand, Brazil's framework is top heavy, dominated by a universal, though weak, federal law. Courts have been preoccupied with interpreting the ambiguous federal law and have done little to advance nonsmokers' rights. The United States, on the other hand, has a pyramid-type framework, with a strong base of local and state laws but sparse federal legislation. State courts have advanced nonsmokers' rights through nonstatutory authorities. Beyond these differences, Brazil and the United States have similarly struggled with the preemption threat and influence of the tobacco lobby at the federal level.

The comparative analysis of Brazil's and the United States' approaches may be summarized as follows:

Brazil: Top Down Approach	United States: Bottom Up Approach
Top: Universal, though weak, smoke-free law permitting designated smoking areas. FCTC ratified.	Top: Smattering of federal smoke-free measures covering small portion of population. FCTC not ratified.
Bottom: Few local and state smoke-free laws, though more are emerging.	Bottom: Strong network of local and state smoke-free laws, though not uniform throughout the country.
Courts: Interpretive difficulties prevent implementation of federal smoke-free law.	Courts: State courts advance nonsmokers' rights by relying on nonstatutory authority.
Preemption: Threat that state and local laws are preempted by existing federal law, an issue to be settled by Brazil's Supreme Court.	Preemption: Some local laws have been preempted by state laws. Threat that state and local laws will be preempted by future federal law.
Tobacco Lobby managed by sequestering tobacco control program in remote, federal public health body (INCA).	Tobacco Lobby managed by concentrating smoke-free initiatives in local authorities responsive to local public health boards.

In view of the lessons learned from the Model States, the following recommendations are offered to assist other Pan American States in their smoke-free initiatives:

Recommendation #1: Plan for Preemption

Regardless of whether the top down or bottom up approach is used, lower levels of government have more practical freedom to enact smoke-free laws because they are more remote from the tobacco lobby and cooperate closely with public health officials. Local laws will likely exceed the protection from SHS afforded by state and federal laws and regulations. As such, preemption of local laws is a predictable issue.

Therefore, it is important to plan for preemption. First, if a federal or state law or regulation is pending, public health advocates should urge that an explicit preemption clause be included to permit municipalities to act with certainty.¹²⁴ Second, if such legislation or regulation already exists, the preemption question should be resolved as soon as possible so that uncertainty does not chill local legislation. Historically, the preemption issue is settled *ex post* when the ordinance is challenged in court. But an *ex ante* approach is advisable when planning ordinances. Local officials can request guidance or advisory opinions on preemption from federal and state legislators and regulators. While such feedback is nonbinding, it could signal legislators' and regulators' positions early on and possibly suppress a preemption challenge later. Third, local authorities should examine higher-level statutes and regulations, along with interpretive court decisions,

to identify possible preemption issues.¹²⁵ If a statute or regulation is ambiguous, it may be possible to tailor the language of an ordinance to increase its chances of surviving a preemption challenge.

Recommendation #2: Sequester the Primary Regulators from the Tobacco Lobby

History instructs that wherever the tobacco lobby concentrates its efforts, legislative efforts falter. Brazil managed to overcome this legislative suppression by focusing regulatory efforts in a public health agency (INCA) out of the tobacco lobby's reach.¹²⁶ The United States achieved the same by diffusing regulatory efforts over thousands of municipal authorities too numerous for the tobacco lobby to fight. In both cases, these regulatory "safe harbors" enabled smoke-free initiatives to flourish.

Recommendation #3: Connect the Top and the Bottom Through Fundamental Rights

Article 8 of the FCTC represents the "top" or highest-level authority calling for a smoke-free world, supported by the international community. Article 8 articulates the strongest declaration of the fundamental right to a smoke-free environment, linking it to the right to health in human rights treaties and international customary law. The strength of the smoke-free right is compromised by the aspirational nature of the FCTC.

At the "bottom" are local laws, representing the lowest level of authority. These laws have the virtue of being practical and enforceable.

The top and the bottom should be connected to combine the virtues of both. Accordingly, Article 8 of the FCTC should be directly incorporated into local smoke-free ordinances. There is no legal reason why this cannot be done. PAHO has offered model federal legislation on tobacco control for the Pan American States.¹²⁷ Similarly, a model ordinance incorporating Article 8 should be available as well.

Recommendation #4: Build Legal Doctrine in Receptive Courts

Courts can provide a forum to advance nonsmokers' rights when legislative measures falter. In countries where international human rights treaties have been codified in domestic statutes, courts may extend the enforceable right to health to protect nonsmokers' right to a smoke-free environment. In countries where the international right to health is not explicitly incorporated into domestic laws, courts may still be receptive to the use of international customary law as persuasive or interpretive authority. For example, courts may use treaties to interpret domestic statutes or constitutions embodying a right to health, or to define a positive right to health in nonstatutory law. This approach would provide legal precedent for using international customary law to bolster the right to a smoke-free environment. Furthermore, the use of these treaties in court decisions strengthens their place in international customary law, making them more available to support future claims to a smoke-free right.

Recommendation #5: Use Scientific Research on SHS to Identify Legal Approaches.

The two Model States successfully used the results of scientific research to advance SHS reforms. In Brazil, federal laws and regulations gained support as scientific research revealed the harmful effects of SHS. In the United States, state laws, local ordinances, and judicial opinions similarly cited scientific findings and publications on SHS.

Ongoing research on SHS continues to provide evidence that may support novel legal approaches. For example, scientists have recently discovered that certain nonsmokers, identifiable by particular genetic markers, are more susceptible to developing lung cancer.¹²⁸ Further research may confirm that certain individuals are disproportionately harmed by SHS. As such, they may form a "vulnerable group" warranting heightened protection under international human rights laws. Their genetic predisposition to lung cancer may qualify as a "disability" under the ADA, allowing them to obtain an injunction against smoking in the workplace before sustaining harm from SHS.

In addition, researchers recently discovered that residual nicotine from tobacco smoke adsorbed to indoor surfaces react to form new carcinogenic substances – in essence, "thirdhand smoke."¹²⁹ According to the researchers, thirdhand smoke presents a previously unappreciated health hazard through dermal exposure, dust inhalation, and ingestion.¹³⁰ If further research reveals significant health consequences, exposure to thirdhand smoke may support new legal theories. For example, a nonsmoker harmed by exposure to thirdhand smoke may be able to bring a claim against a former smoker-tenant or former smoker-owner of a used car.

B. Inter-American Commission and Court on Human Rights

Brazil's top down and the United States' bottom up approaches have enabled rapid and significant progress toward smoke-free environments. But both approaches leave gaps, due to incomplete regulatory schemes and ineffective enforcement efforts. As a result, many individuals in the Model States are involuntarily exposed to SHS on a regular basis. By failing to guarantee a smoke-free environment for all, these States violate the internationally recognized right to health.

When American States fail to protect human rights, the Inter-American System provides a forum for aggrieved individuals. The System consists of the Inter-American Commission on Human Rights and the Inter-American Court on Human Rights. Its jurisdiction is established by the American Convention on Human Rights ("American Convention") and the American Declaration on the Rights and Duties of Man ("American Declaration").¹³¹ The Commission's primary purpose is to address human rights violations in the thirty-five Member States of the Organization of American States (OAS).¹³²

Under the Inter-American System, an aggrieved individual must first exhaust remedies under domestic law.¹³³ If the individual is denied domestic remedies, he may file a petition with the Commission against the Member State allegedly violating a human right recognized by the American Convention.¹³⁴ The Commission investigates the case and works with the parties to reach an amicable settlement.¹³⁵ If that fails and the Commission finds a human rights violation, the Commission may make recommendations binding on the State Party and monitor for compliance or refer the case to the Court.¹³⁶ If appropriate, the Court considers the case and issues a judgment legally binding on Member States that have ratified the American Convention.

Not all Member States have ratified the American Convention. Currently 24 out of 35 OAS countries are parties to the Convention, and 11 are nonparties. For non-Convention Party States, the Commission applies the American Declaration. The Declaration is not a legal, binding document but defines rights recognized by international customary law (at least in part¹³⁷), including the right to life.¹³⁸ The Commission may still make recommendations, but they are not binding on non-Convention Party States.¹³⁹ These cases also cannot be referred to the Court, though they can be published in the Commission's annual report. The publication alone can be helpful to reveal a human-rights problem and prompt dialog to address it.

The Inter-American System has not explicitly recognized exposure to SHS as a human-rights violation. Neither the Commission nor the Court has faced the issue directly. However, they must recognize the right to life under Article 4 of the American Convention (or Article I of the American Declaration). Recently, the Court's interpretation has evolved to encompass the right to a "dignified life" or "dignified existence," and, implicitly, the right to health.¹⁴⁰ The Court clarified the positive right to a dignified life and the State's affirmative duty to protect that right, particularly for vulnerable groups in *Yakye Axa Indigenous Community v. Paraguay* and *Sawhoyamaya Indigenous Community v. Paraguay*.¹⁴¹

In *Ximines-Lopes v. Brazil*,¹⁴² the Court elaborated on the State's affirmative duty to protect the right to a dignified life. There, the Court established States' affirmative duty to regulate public healthcare systems that threaten the right to a dignified life.¹⁴³ The scope of the *Ximines-Lopes* duty to regulate public healthcare is not yet clear. It has been viewed in light of General Comment No. 14 of the ICESCR, clarifying States' duties to protect the right to health: "Violations of the right to health can occur through the direct action of States or other entities insufficiently regulated by the States."¹⁴⁴ Thus *Ximines-Lopes* and General Comment No. 14 suggest that "a state should not be liable for a human rights violation if there are adequate state guidelines and monitoring."¹⁴⁵

Under the standard of *Yakye Axa*, *Sawhoyamax*, and *Ximines-Lopes*, a right-to-life violation requires that (i) state authorities knew or should have known about a situation posing an immediate and certain risk to life (knowledge requirement); and (ii) state authorities failed to take necessary measures to prevent or avoid such risk within the scope of their authority (state inaction),¹⁴⁶ where (iii) that authority may be derived from Article 2 of the American Convention,¹⁴⁷ not necessarily from domestic legislation.¹⁴⁸

Already supported by the human-rights community, the case for recognizing the right to a smoke-free environment under Article 4 is now more compelling under the Court's broadened view of the right to life.¹⁴⁹ Applying the standard for a right-to-life violation in this context, the knowledge requirement is satisfied, as OAS Member States certainly know of the internationally publicized, life-threatening effects of SHS. State inaction is apparent in particular States, since many have failed to adopt or enforce adequate measures to protect the right to a smoke-free environment. This inaction leaves many vulnerable groups (e.g., women, children, and the poor) at risk for life-threatening conditions. Even in the absence of domestic authority, States are obligated to use their authority under Article 2 of the American Convention to regulate SHS.

If the right to a smoke-free environment were recognized under Article 4, the Commission could require certain actions by a State that has failed to protect that right. For example, the Commission could require a State to regulate environments where SHS threatens vulnerable groups. This outcome could prompt a State to adopt or enforce legislation to regulate SHS.

Brazil and the United States serve as Model States for considering right-to-life violations in the Inter-American System. Brazil represents the 24 OAS States that have ratified the American Convention, while the United States represents the 11 non-Convention Party States. Because the right-to-life analysis is conducted differently for Convention Party and non-Convention Party States, they are considered separately here.

Brazil as a Model for Convention Party States

Brazil ratified the American Convention, and, accordingly, the Inter-American Commission may apply the right-to-life standard of Article 2, demand compliance with the Commission's recommendations, and refer the case to the Inter-American Court, if necessary. A petition could be filed by a Brazilian individual whose right to health has been violated due to SHS exposure and who was unable to obtain an adequate remedy under domestic laws. Assuming the Commission recognized the right to a smoke-free environment under Article 4, the Court's right-to-dignified-

life doctrine would be applied as follows: (i) Brazilian state officials *have knowledge* that Law 9294 does not adequately protect nonsmokers from SHS since, according to its own Ministry of Health, designated smoking areas (ventilated or not) do not work as protective measures;¹⁵⁰ and (ii) the State has *failed to take necessary actions* to protect the right to life by failing to enforce Law 9294 in most municipalities. (The state of São Paulo and the handful of smoke-free municipalities are the exception in Brazil.) Furthermore, even if Law 9294 were fully enforced throughout the country, Brazil still fails to fulfill the *Ximines-Lopes* duty to regulate public health. That sole federal law regulating SHS permits designated smoking areas in enclosed public spaces, which, even when ventilated, fail to protect nonsmokers from SHS.

If the Commission found a right-to-life violation, it could recommend legislative or regulatory actions with which Brazil must comply. For example, the Commission could recommend that Brazil amend Law 9294 to require a smoke-free environment for all public indoor spaces in their entirety (no designated smoking areas). If Brazil did not comply with the recommendation, the case could be referred to the Court for a binding legal judgment.

The United States as a Model for Non-Convention Party States

The United States signed the American Convention but never ratified it or incorporated it into national law. (Both measures are required to enforce an international convention in the dualist system followed by the United States.) As such, while the Commission could consider a petition against the United States, the Commission would apply the American Declaration and could only make nonbinding recommendations to rectify a human rights violation.

Assuming the Commission recognized the right to a smoke-free environment under Article 1 of the American Declaration, the Commission could apply the right-to-dignified-life doctrine as international customary law: (i) U.S. state officials *have knowledge* that its citizens are exposed to levels of SHS in public spaces that cause numerous life-threatening conditions, evidenced by the U.S. Surgeon General's 2006 Report; and (ii) the State has *failed to take necessary actions* to protect the right to life by failing to adopt nationwide legislation restricting SHS in all public spaces. Indeed, the lack of federal legislation is evidence that the United States has not even attempted to fulfill the *Ximines-Lopes* duty to regulate public health.

If the Commission found a right-to-life violation, it could recommend legislative or regulatory actions, though they would not bind the United States. Still, the case could be published in the Commission's annual report. The mere recognition that inadequate protection from SHS violates the right to life would create a foothold in international customary law. The publication could also assist advocacy groups in the United States and elsewhere to legally support their arguments for stronger regulation of SHS.

Summary

The Inter-American System promises a powerful means to address human rights violations associated with SHS. Given the Court's recent expansion of the right to life, vulnerable individuals may pursue a new forum when OAS Member States have failed to protect their right to a smoke-free environment. Furthermore, the Inter-American Commission and Court can prompt states to adopt or strengthen their efforts to regulate SHS.

VI. Conclusion

For nonsmokers, secondhand smoke represents an unjust public health threat and a human rights tragedy. Article 8 of the Framework Convention on Tobacco Control declares the right to a smoke-free environment and calls on States to protect that right. Sadly, the smoke-free standard of Article 8 remains an aspirational goal for many countries.

Brazil and the United States have made outstanding progress in regulating secondhand smoke and thus serve as Model States for countries embarking on smoke-free initiatives. The Model States have pursued diametric legal approaches (top down and bottom up, respectively), and, between the two of them, have tested a range of regulatory tactics. Successful tactics include the sequestration of regulators from the tobacco lobby, the use of rights-based arguments in receptive courts, and the involvement of public health officials in regulatory efforts. In both approaches, preemption by weak federal law and the influence of tobacco industry at the federal level present substantial challenges.

Neither Brazil's top down nor the United States' bottom up approach is perfect. The Inter-American System provides a forum to assert the right to a smoke-free environment when domestic laws fall short. The Inter-American Court on Human Rights recently expanded the scope of the right to life in the American Convention on Human Rights, suggesting that States may have an affirmative duty to protect the right to a smoke-free environment.

By understanding the successes and challenges of regulating secondhand smoke, States can eventually fulfill the goal of guaranteeing a smoke-free environment to all of their citizens.

¹ Roemer, et al., *Origins of the WHO Framework Convention on Tobacco Control*, Am. J. Pub. Health 2005, 95(6): 936-938.

² WHO Report on the Global Tobacco Epidemic 2008 – The MPOWER Package, at 6, available at <http://www.int/tobacco/mpower/2008/en/index.html> [hereinafter “WHO MPOWER 2008 Report”].

³ *Id.* at 8.

⁴ WHO Guidelines for implementation: Article 5.3, Article 8, Article 11, Article 13 (2009), at 23, available at <http://www.who.int/fctc/guidelines/en> [hereinafter “FCTC Implementation Guidelines”].

⁵ See generally *The Health Consequences of Involuntary Exposure to Tobacco Smoke: A Report of the Surgeon General* (2006), at Chapter 2 [hereinafter “2006 Surgeon General Report”].

⁶ WHO MPOWER 2008 Report, *supra* note 2, at 7.

⁷ *Id.* at 12.

⁸ See generally 2006 Surgeon General Report, *supra* note 5, at Chapters 5 and 6.

⁹ WHO Framework Convention on Tobacco Control, May 21, 2003 [hereinafter “FCTC”].

¹⁰ FCTC Implementation Guidelines, *supra* note 4, at 20.

¹¹ Statistics reported by WHO, last updated October 22, 2009, available at http://www.who.int/fctc/signatories_parties/en/index.html.

¹² David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence* (2000) at 188-192.

¹³ FCTC, *supra* note 9, at vi.

¹⁴ WHO Reports of the Parties received by the Convention Secretariat and progress made internationally in implementation of the Convention, Second Summary Report (October 14, 2008), available at http://www.who.int/fctc/reporting/summary_analysis/en/index.html.

¹⁵ 2006 Surgeon General Report, *supra* note 5, at 634-650.

¹⁶ Conference of the Parties to the WHO FCTC, Decision FCTC/COP1(15) (March 23, 2006), at 47, available at http://apps.who.int/gb/fctc/PDF/cop1/FCTC_COP1_DIV8-en.pdf; see also FCTC Implementation Guidelines, *supra* note 4, at 23.

¹⁷ WHO MPOWER 2008 Report, *supra* note 2, at 46.

¹⁸ FCTC, *supra* note 9, at v.

¹⁹ FCTC Implementation Guidelines, *supra* note 4, at 19-20 (“The duty to protection from tobacco smoke, embodied in the text of Article 8, is grounded in fundamental human rights and freedoms. Given the dangers of breathing second-hand tobacco smoke, the duty to protect from tobacco smoke is implicit in, *inter alia*, the right to life and the right to the highest attainable standard of health, as recognized in many international legal instruments . . .”).

²⁰ *Id.*

²¹ Rangita de Silva de Alwis and Richard Daynard, *Reconceptualizing Human Rights to Challenge Tobacco*, 17 Mich. St. J. Int'l L. 291, 293 (2008–2009); Melissa E. Crow, *Smokescreens and State Responsibility: Using Human Rights Strategies to Promote Global Tobacco Control* (2004), at 211.

²² PAHO serves as WHO's Regional Office for the Americas.

²³ PAHO, *Exposure to Secondhand Tobacco Smoke in the Americas: A Human Rights Perspective* (May 2006), available at <http://new.paho.org/hq/index.php?lang=en>, under Health and Human Rights.

²⁴ de Alwis and Daynard, *supra* note 22, at 297-298; *id.* at 16.

²⁵ See *id.* at 300.

²⁶ *Id.* at 300-301.

²⁷ *Id.* at 301.

²⁸ Melissa E. Crow, *Smokescreens and State Responsibility: Using Human Rights Strategies to Promote Global Tobacco Control*, 29 Yale J. Int'l L. 209, 230-246 (2004).

²⁹ PAHO Strategic Plan 2008-2012 Amended (DRAFT), Official Doc. No. 328, at page 8 (noting significant progress made recently in Brazil and Uruguay, as well as the United States, Canada, and Argentina at the subnational level) [hereinafter “PAHO Strategic Plan”].

³⁰ Omar Shafey, et al., *The Tobacco Atlas* (3rd ed. 2009), at 49 and 52 [hereinafter “Tobacco Atlas”].

³¹ The O'Neill Institute, Campaign for Tobacco-Free Kids, and ACTbr, Shadow Report to the Periodic Report of the Government of Brazil, *Preventing, and Reducing Tobacco Use in Brazil: Pending Tasks*, United Nations Committee on Economic, Social, and Cultural Rights, 42nd Session Period (May 4-22, 2009) [hereinafter “O'Neill Report”], at 12; Food and Agriculture Organization of the United Nations, *Issues in the Global Tobacco Economy* (2003), at Chapter 2, available at <http://www.fao.org/docrep/006/y4997e/y4997e04.htm>.

³² Tobacco Atlas, *supra* note 31, at 50-53. Note that Philip Morris International split from Altria in March 2008.

³³ Yves Beigbeder, *Tobacco, the Perfect Foe*, in *International Public Health* (2004), at 140-41.

³⁴ Thomas E. Novotny and Hadii M. Mamudu, The World Bank, *Progression of Tobacco Control Policies: Lessons from the United States and Implications for Global Action* (May 2008), at 32-34 [hereinafter “2008 World Bank Report”]; Stella A. Bialous, *Brazil: Growers' Lobby Stalls FCTC, Tobacco Control* 2004, 13: 323-24.

³⁵ Tobacco Atlas, *supra* note 31, at 60.

³⁶ Statistics reported at <http://www.opensecrets.org>.

³⁷ *Brazil and Tobacco Use: A Hard Nut to Crack*, Bulletin of the World Health Organization (Nov. 2009), 87(11), available at <http://www.who.int/bulletin/volumes/87/11/09-031109/en/print.html> [hereinafter “2009 WHO Bulletin”].

³⁸ Luisa M. da Costa e Silva Goldfarb, *Government Leadership in Tobacco Control: Brazil's Experience*, in *Tobacco Control Policy: Strategies, Successes, and Setbacks* (2003), at 40, available at <http://www1.worldbank.org/tobacco/pdf/2850-Ch03.pdf>.

³⁹ Elisa K. Ong and Stanton A. Glantz, *Tobacco industry efforts subverting International Agency for Research on Cancer's second-hand smoke study*, *The Lancet* 2000, 355: 1253-59.

⁴⁰ *Id.* at 1255-56.

⁴¹ Joaquin Barnoya and Stanton A. Glantz, *Tobacco industry success in preventing regulation of SHS in Latin America: The “Latin Project,”* *Tobacco Control* 2002, 11: 305-14.

⁴² See generally *id.*

⁴³ See 2006 Surgeon General Report, *supra* note 5, at 576 (providing an account of the legal challenge to the EPA's report).

- ⁴⁴ *Flue-Cured Tobacco Coop. Stabilization Corp. v. U.S. Envtl. Prot. Agency*, 313 F.3d 852, 862 (4th Cir. 2002).
- ⁴⁵ WHO Report on the Global Tobacco Epidemic 2009: Implementing Smoke-Free Environments, at Appendix V, available at http://www.who.int/tobacco/mpower/2009/Appendix_V_table_1.pdf [hereinafter “WHO 2009 Report”].
- ⁴⁶ PAHO Strategic Plan, *supra* note 30, at page 8, para. 25.
- ⁴⁷ Instituto Nacional de Câncer (INCA), Tobacco and Other Cancer Risk Factors Control Program, Program Outcomes, Chapter 3 at 2-8, available at <http://www.inca.gov.br/english/tobacco/programstate.pdf> [hereinafter “INCA Program Outcomes”].
- ⁴⁸ Roberto Iglesias et al., *Tobacco Control in Brazil*, World Bank, HNP Discussion Paper (August 2007), at xii, available at <http://siteresources.worldbank.org/BRAZILEXTN/Resources/TobaccoControlinBrazilenglishFinal.pdf?resourceurlname=TobaccoControlinBrazilenglishFinal.pdf> [hereinafter “2007 World Bank Report”].
- ⁴⁹ Brazil Const., art. 196 (1988) (“Health is a right of all and a duty of the State and shall be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards and at the universal and equal access to actions and services for its promotion, protection and recovery.”).
- ⁵⁰ International Covenant on Economic, Social, and Cultural Rights, art. 12(1).
- ⁵¹ International Covenant on Economic, Social, and Cultural Rights, General Comment No. 14, art. 12(2)(b) (Nov. 8, 2000).
- ⁵² WHO 2009 Report, *supra* note 46, at 84, Table 1.0.2 (reporting 14% adult daily smoking in 2006, down from 34% in 1989), available at http://www.who.int/tobacco/mpower/2009/Appendix_V_table_1.pdf. See also 2007 World Bank Report, *supra* note 49, at 13 and 25 (reporting an increase in nonsmoking households from 66% in 1995 to 73% in 2002).
- ⁵³ Statistics made available by Ministry of Health of Brazil, INCA, available at <http://www.inca.gov.br>. See also INCA’s official press release in Portuguese (Aug. 22, 2008), available at http://www.inca.gov.br/releases/press_release_view.asp?ID=1855.
- ⁵⁴ 2007 World Bank Report, *supra* note 53, at 27.
- ⁵⁵ Brazil Federal Law No. 9294 (1996), art. 2.
- ⁵⁶ 2006 Surgeon General Report, *supra* note 5, at 649.
- ⁵⁷ Federal Law No. 10167 (2000) (amending Federal Law No. 9294); Ministry of Health Ordinance No. 2818 (1998).
- ⁵⁸ O’Neill Report, *supra* note 32, at 9.
- ⁵⁹ *Id.*
- ⁶⁰ *Id.* at 9-10.
- ⁶¹ *Id.*
- ⁶² *Id.*
- ⁶³ See press release at <http://bibliotecademedicina.com.br/blog/?p=471>lang=en>.
- ⁶⁴ See press release at <http://bibliotecademedicina.com.br/blog/?p=466>lang=en> (listing sixteen Brazilian organizations that sent motions in support of PL 315 and noting that 20 international public-health organizations sent letters to Brazilian senators to support the bill).
- ⁶⁵ *Id.*
- ⁶⁶ INCA Program Outcomes, *supra* note 48 at 4.
- ⁶⁷ 2007 World Bank Report, *supra* note 53, at 65.
- ⁶⁸ *Id.* at 68.
- ⁶⁹ *Id.* at 69.
- ⁷⁰ São Paulo Law No. 13541 (May 7, 2009).
- ⁷¹ Stella Aguinaga Bialous and Stella Martins, Tobacco Control 2009, 18: 341, available at <http://tobaccocontrol.bmj.com/content/18/5/341.full.pdf> (noting fines of \$435 to \$870 for first offense, doubled fines for second offense, 48-hour closure for third offense, and 30-day closure for fourth offense).
- ⁷² John Dunn and Ronaldo R. Laranjeira, *Smoke don’t smoke – two steps forward, one step back*, Psych. Bull. (1996), 20: 688-89, available at <http://pb.rpsych.org/cgi/reprint/20/11/688.pdf>.
- ⁷³ 2009 WHO Bulletin, *supra* note 38, at 805.
- ⁷⁴ David Simpson, *Tobacco Control* 2009, 18(5): 341-44, available at <http://tobaccocontrol.bmj.com/content/18/5/341.full.pdf>.
- ⁷⁵ *Id.*; 2009 WHO Bulletin, *supra* note 38.
- ⁷⁶ HealthBridge, *Strengthening FCTC Implementation in Brazil: Final Narrative and Financial Report* (April 2007), at 4, available at http://www.healthbridge.ca/tobacco_brazil_e.cfm.
- ⁷⁷ 2007 World Bank Report, *supra* note 53, at 61.
- ⁷⁸ *Id.* at 70-71.
- ⁷⁹ *Id.* at xii.
- ⁸⁰ http://www.inca.gov.br/english/tobacco_control.html
- ⁸¹ See generally 2006 Surgeon General Report, *supra* note 5, at Chapter 4 (“Prevalence of Exposure to Secondhand Smoke”).
- ⁸² See generally *id.* at 133, 137-38, 650, and Chapters 4 and 6 (“Respiratory Effects in Children from Exposure to SHS”).
- ⁸³ According to the Americans for Nonsmokers’ Rights Foundation (ANRF), as of October 2009, 3052 municipalities in the US have local laws in effect that restrict where smoking is allowed, and 1678 municipalities have a local law in effect that restricts smoking in one or more outdoor areas (e.g., near building entrances and windows, parks, beaches, and sporting and entertainment venues). Overview List – How many Smoke-free Laws? (October 2009), available at www.no-smoke.org/pdf/mediaordlist.pdf [hereinafter “ANR Overview List”].
- ⁸⁴ A listing of municipalities with 100% smoke-free laws is available at <http://www.no-smoke.org/pdf/100ordlistabs.pdf>.
- ⁸⁵ ANR Overview List, *supra* note 89.
- ⁸⁶ George P. Smith, *Cigarette Smoking as a Public Health Hazard: Crafting Common Law and Legislative Strategies for Abatement*, 11 Mich. St. U. J. Med. & L. 251, 296 (2007).
- ⁸⁷ Americans for Nonsmokers Rights, *Model Ordinance Prohibiting Smoking in All Workplaces and Public Places (100% Smoke-free)*, (May 2009), available at <http://no-smoke.org/document.php?id=229>.
- ⁸⁸ *Id.* at 2 and 4 (referring to the smoke-free laws of Canada, Bhutan, France, Ireland, New Zealand, Norway, Singapore, Uruguay, England, Northern Ireland, Scotland, and Wales).
- ⁸⁹ San Francisco, Cal., Admin. Code, Chap. 12K (Apr. 13, 1998).
- ⁹⁰ The New York City Human Rights Law, New York City, Admin. Code, Title 8 (May 2006).
- ⁹¹ Americans for Nonsmokers’ Rights maintains a list of preemptive states at <http://www.no-smoke.org/pdf/preemptionmap.pdf> and a Preemption Watch website tracking preemptive state bills at <http://www.protectglobalcontrol.org/resource.php?id=9587>. The website notes one preemptive bill pending as of December 11, 2009, though it would not weaken local laws.
- ⁹² O’Connor et al., *Preemption of Local Smoke-Free Air Ordinances: The Implications of Judicial Opinions for Meeting National Health Objective, Incidental Findings in Human Subjects Research* (Summer 2008), 403-11.
- ⁹³ International Agency for Research on Cancer, *Handbooks of Cancer Prevention*, Vol. 13, Evaluating the Effectiveness of Smoke-free Policies 68-69 (WHO Press 2009), available at <http://www.iarc.fr/en/publications/pdfs-online/prev/handbook13/handbook13.pdf>.
- ⁹⁴ See Environmental Laws: Pollution: Regulations Restricting Smoking in Indoor Areas, state-by-state analysis (Thomson Reuters/West, 50-state survey, July 2009).
- ⁹⁵ ANR Overview List, *supra* note 89.
- ⁹⁶ Fla. Const., art. X, § 20 (2002).
- ⁹⁷ Mont. Const., art. 2, § 4 (1889).
- ⁹⁸ New York Const., art. XVII, § 3 (1938).
- ⁹⁹ Gabrielidis, *Human Rights Begin at Home: A Policy Analysis of Litigating International Human Rights in U.S. State Courts*, 12 Buff. Hum. Rts. L. Rev. 139, 175-77 (2002).
- ¹⁰⁰ *In re Julie Anne*, 780 N.E.2d 635 (Ohio Ct. Com. Pl. 2002) (*sua sponte* raising the issue of whether parents and others should be restrained from smoking in the presence of a child, answering in the affirmative, and ordering parents to restrain themselves and other from smoking in the child’s presence).
- ¹⁰¹ *Id.* at 639-40.
- ¹⁰² *Id.* at 653-55 (citing *Helling v. McKinney*, 509 U.S. 25 (1993)).
- ¹⁰³ ANR Overview List, *supra* note 89.
- ¹⁰⁴ Smith, *supra* note 92, at 260-62.
- ¹⁰⁵ Gabrielidis, *supra* note 105, at 169.
- ¹⁰⁶ *Shimp v. New Jersey Bell Tel. Co.*, 368 A.2d 408, 413, 415-16 (N.J. Super. Ct. 1976).

¹⁰⁷ *Id.* at 416.

¹⁰⁸ *Smith v. W. Elec. Co.*, 643 S.W.2d 10, 13-14 (Mo. Ct. App. 1982) (remanding and reversing trial court's dismissal for failure to state a claim upon which relief could be granted).

¹⁰⁹ *Id.* at 13.

¹¹⁰ The Occupational Safety and Health Act of 1970, § 18(a), 29 U.S.C. § 653(b)(4) ("Nothing in this Act shall be construed to supersede or in any manner affect any workmen's compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.").

¹¹¹ *Shimp*, 368 A.2d at 410-11; *Smith*, 643 S.W.2d at 13-14.

¹¹² 50-58 *Gainsborough St. Realty Trust v. Haile*, No. 98-02279, 13.4 Tobacco Products Litigation Reporter 2.302 (Boston Housing Court, 1998), summarized in 12-4 Mealey's Litig. Rep. Tobacco 15 (1998).

¹¹³ See Judith Resnik, *Law's Migration: American Exceptionalism, Silent Dialogues, and Federalism's Multiple Ports of Entry*, 115 Yale L. J. 1564 (2006).

¹¹⁴ 14 C.F.R. Part 252 (Federal Aviation Administration's smoking ban on air carriers); No Child Left Behind Act of 2001, P.L. 107-110, 115 Stat. 1425 (Jan. 8, 2002), at §§ 4301-4304.

¹¹⁵ Exec. Order No. 13,058, 65 Fed. Reg. 43451 (Aug. 13, 1997).

¹¹⁶ Indoor Air Quality, 59 Fed. Reg. 15968 (Apr. 5, 1994).

¹¹⁷ Indoor Air Quality, 66 Fed. Reg. 64946 (Dec. 17, 2001).

¹¹⁸ Action on Smoking and Health, Press Release, Dec. 14, 2001, available at <http://no-smoking.org/nov01/11-19-01-5.html>.

¹¹⁹ Pub. L. No. 111-13, 123 STAT. 1776 (2009).

¹²⁰ See sec. 203, § 5 (permitting states and localities to ban or restrict the time, place, and manner, but not content, of advertising or promotions of cigarettes), sec. 916 (Preservation of State and Local Authority), and sec. 917 (requiring two representatives of the tobacco manufacturing industry on the Tobacco Products Scientific Advisory Committee, one specifically representing small business interests and one representing tobacco growers, albeit as nonvoting members).

¹²¹ Edward L. Sweda, *Lawsuits and SHS*, Tobacco Control 2004, 13(Suppl. 1): i61-i66.

¹²² *Helling v. McKinney*, 509 US 25, 35 (1993) (affirming that prisoner stated a cause of action under the Eighth Amendment and remanding to district court to allow prisoner an opportunity to prove his allegations).

¹²³ Gabrielidis, *supra* note 105, at 153-160.

¹²⁴ O'Connor, *supra* note 98, at 407 (noting recommendations that tobacco control and public health advocates should include an explicit nonpreemption clause in proposed smoke-free legislation).

¹²⁵ See *id.* at 408.

¹²⁶ See 2007 World Bank Report 2007, *supra* note 53, at 60 (noting that having INCA manage the tobacco-control program likely protected it from political pressures exerted by the government and the tobacco industry, due to INCA's location outside the capital); see also Goldfarb, *supra* note 39, at 44 (noting that when the Brazil's tobacco-control program was transferred from INCA to the capital from 1990 to 1992, tobacco-control efforts stalled until it was transferred back to INCA).

¹²⁷ PAHO, *Developing Legislation for Tobacco Control: Template and Guidelines* (May 2002), available at http://www.paho.org/English/HPP/HPM/TOH/tobacco_legislation.htm.

¹²⁸ Yafei Li et al., *Genetic variants and risk of lung cancer in never smokers: a genome-wide association study*, *Lancet Oncology* 2010, 11: 321-330.

¹²⁹ Mohamad Sleiman et al., *Formation of carcinogens indoors by surface-mediated reactions of nicotine with nitrous acid, leading to potential thirdhand smoke hazards*, *Proc. Nat. Acad. Sci.* 2010, published ahead of print on February 8, 2010, available at <http://www.pnas.org/content/early/2010/02/04/0912820107.full.pdf+html>.

¹³⁰ *Id.* (Abstract).

¹³¹ American Convention on Human Rights, Nov. 22, 1969, art. 33, 1144 U.N.T.S. 143 [hereinafter "ACHR"]; American Declaration of the Rights and Duties of Man, OAS Res. XXX, International Conference of American States, 9th Conf., OAS Doc. OEA/ser. L./V/I.4 rev. (1948), reprinted in *Organization of American States, Handbook of Existing Rules Pertaining to Human Rights* 15, OAS Doc. OEA/ser. L./V/II.23, doc. 21 rev. 5 (1978).

¹³² ACHR, *supra* note 113, art. 41.

¹³³ *Id.* art. 46.

¹³⁴ *Id.* art. 44, 1144 U.N.T.S. at 155. Articles 3-25 of the American Convention list recognized civil and political rights recognized by all ratifying Member States. Article 26 states economic, social, and cultural rights recognized by some ratifying Member States.

¹³⁵ *Id.* art. 48.

¹³⁶ *Id.* arts. 50 and 51.

¹³⁷ See Inter-Am. Ct. H.R. Basic Documents Pertaining to Human Rights in the Inter-American System at 7, OEA/Ser.L.V/II.82 doc.6 rev.1 (2003) (including the American Declaration as a basic document under Inter-American law).

¹³⁸ Am. Declaration of the Rights and Duties of Man, O.A.S. Res. XXX, adopted by the 9th Int'l Conference of the American States (1948), reprinted in *Basic Documents Pertaining to Human Rights in the Inter-American System*, OEA/Ser.L.V/II.82 doc. 6 rev. 1 at 17 (1992), art. I.

¹³⁹ See Statute of the Inter-American Commission on Human Rights, OAS Res. 447, 9th Reg. Sess., art. 20 (1979) (granting the Inter-American Commission jurisdiction to examine communications regarding governments that are not parties to the ACHR and to make appropriate recommendations).

¹⁴⁰ Steven R. Keener and Javier Vasquez, *A Life Worth Living: Enforcement of the Right to Health Through the Right to Life in the Inter-American Court of Human Rights*, 40 Colum. Hum. Rts. L. Rev. 595, 618-19 (2009).

¹⁴¹ *Yakye Axa Indigenous Comty. v. Paraguay*, 2005 Inter-Am. Ct. H.R. (ser. C) No. 125 (June 17, 2005), ¶¶ 161-62; *Sahoyamaya Indigenous Comty. v. Paraguay*, 2006 Inter-Am. Ct. H.R. (ser. C) No. 146 (Mar. 29, 2006), ¶ 153.

¹⁴² *Ximenes-Lopes v. Brazil*, 2006 Inter-Am. Ct. H.R. (ser. C) No. 149 (July 4, 2006), ¶¶ 89-90.

¹⁴³ *Id.*

¹⁴⁴ Keener and Vasquez, *supra* note 146 at 623.

¹⁴⁵ *Id.*

¹⁴⁶ See *Sahoyamaya*, 2006 Inter-Am. Ct. H.R. (ser. C) No. 146 (Mar. 29, 2006), ¶ 155; see also *id.* at 614-15 (summarizing the standard set forth in *Sahoyamaya*).

¹⁴⁷ Article 2 of the ACHR requires that "[t]he States Parties undertake to adopt, in accordance with their constitutional processes and the provisions of this Convention, such legislative or other measures as may be necessary to give effect to those rights or freedoms." (emphasis added)

¹⁴⁸ *Ximenes-Lopes*, 2006 Inter-Am. Ct. H.R. (ser. C) No. 149 (July 4, 2006), ¶¶ 89-90.

¹⁴⁹ Crow, *supra* note 29, at 240-45.

¹⁵⁰ See Ministry of Health Presentation, at Section 5.5.3, 18-19, available at <http://www.inca.gov.br/english/tobacco/globalaction.pdf>.

MONEY, MEET MOUTH: THE ERA OF REGULATION AND PRESCRIPTION DRUG IMPORTATION/REIMPORTATION

Aaron Jones Wong*

“The complexity of importation and reimportation of prescription drugs cannot be understated, as it is both a national and international issue involving economics, public policy, private industry, intellectual property, and criminal law.”

I. Introduction

Health care is an industry unlike any other. It is comprised of both goods and services like many other commercial industries, including the agriculture, airline, and housing industries. It is a necessity for survival in terms of preventative medicine, pharmaceutical drugs, or life-saving procedures, and a luxury for those who can afford often-expensive cosmetic procedures or medical devices. Like any other commercial industry in our free market society, it requires regulation and licensing to protect people from counterfeits, poor quality, and deliberate contamination. Why are we as a society so unwilling to devote the necessary resources to devise and implement quality control measures in an industry like health care, where quality services and pharmaceuticals are the only means of survival for millions of Americans?

The complexity of importation and reimportation of prescription drugs cannot be understated, as it is both a national and international issue involving economics, public policy, private industry, intellectual property, and criminal law. This paper explores why our country has failed to devote the necessary resources to health care, and in particular prescription drug importation and reimportation, in an economic and legal context. It analyzes the unique market characteristics of the pharmaceutical industry, the framework of pharmaceutical drug regulation including prescription drug importation, and the regulatory structure of importation in general. Part II provides background on the health care industry and prescription drug markets in the U.S. and abroad. Part III examines legislative proposals for drug importation and reimportation and the controversial congressional reaction to rising prescription drug prices in the U.S. Part IV addresses counterarguments primarily put forth by pharmaceutical companies and the U.S. Food and Drug Administration (FDA), against drug importation and reimportation. Part V discusses a variety of laws and regulations pertaining to the cross border flow

of goods, services, and people into the U.S. Part VI suggests methods of reform. Part VII concludes that, regardless of whether legalized importation is the answer, safety inadequacies in the regulation of imported drugs must be improved.

II. Health Care and Prescription Drugs: Rising Cost

A. The Current Landscape of Health Care Spending in the United States

According to a report published by economists and actuaries with the Office of the Actuary at the Centers for Medicare and Medicaid Services (CMS)¹, in 2008, health care spending in the United States (U.S.) was 16.6% of the Gross Domestic Product (GDP).² This report projects that by 2018, health care spending will amount to 20.3% of GDP — or \$4.4 trillion.³

We as a nation are approaching a crossroads. Growth in health care spending as a part of our national economy and increasing costs and lack of affordability are on a path towards each other at an alarming speed. Budget shortfalls and fiscal deficits are forcing states to redistribute funds to accommodate critical spending needs. Data suggest that the spike in personal health care spending is primarily attributable to rising medical care prices, along with the effects of the 2008-2009 recession, an increase in Medicaid enrollment, increasing numbers of uninsured Americans, and the decrease in GDP experienced in 2009,⁴ as contributing factors.⁵ The U.S. spends more than any other developing country on health care, both in terms of per capita spending and percentage of GDP.⁶ To highlight American spending priorities, health care spending is 4.3 times greater than the amount spent on national defense.⁷ While the recession has led to a deceleration in the growth of health care spending,⁸ it is also projected to cause up to thirteen million Americans to lose their health insurance before the end of 2010.⁹ That also means that thousands of Americans will not be able to pay for prescription drugs that they once could afford under their health insurance plan.

B. Prescription Drugs

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Payment for prescription drugs is one of the most controversial topics in the health care reform debate. In 2004, U.S. pharmacies filled “over 3.5 billion prescriptions.”¹⁰ In 2005, prescription drugs accounted for ten percent of health care dollars spent, double the 5 percent of health care dollars spent in 1985, the largest increase by far among health care spending categories.¹¹ Spending on prescription drugs in 2005 grew by eleven billion dollars, or 5.8%.¹² In total, in 2006, Americans spent over \$216 billion on prescription drugs.¹³

1. Demographics

In the next several years, the aging American population and the rise in the proportion of seniors to working adults will force Americans to reform regulation of the prescription drug market to decrease the price of prescription drugs, thereby making the drugs affordable. The need for prescription drugs continues to rise among people of all ages and use increases with age.¹⁴ Between 2001 and 2004, over eighty-seven percent of persons sixty-five and older were taking at least one medication and almost sixty percent of the elderly were taking three or more.¹⁵ Between 2000 and 2010, the population age sixty-five and over is expected to rise from 34,991,753 to 40,228,712, and between 2010 and 2020, from 40,228,712 to 54,804,470.¹⁶ With this demographic shift, and the connection between age and use of prescription medications, the need for prescription drugs is likely to rise.

Among those with health insurance, however, even those age eighteen to sixty-four have had prescription drug care delayed or have forgone purchasing prescription drugs because of their high cost.¹⁷ Nine percent of eighteen to sixty-four year olds delayed or forewent prescription drug treatment due to cost while only 5.1% of those over age sixty-five delayed treatment and 3.6% did not get treatment.¹⁸ As the working population reaches age sixty-five and requires more prescription medication, those percentages will likely rise as well.

2. Methods of Payment

The way Americans pay for prescription drugs has also changed over the past thirty-five years. In 1970, seventy percent of payments for prescription drugs were private, out-of-pocket expenditures.¹⁹ By 2006, those payments fell to twenty-five percent, while private insurance payments for prescription drugs rose to forty-seven percent.²⁰ This decrease resulted from expansion of benefits in both private health insurance plans and government programs, including the implementation of Medicare Part D in 2006.²¹ Despite the decrease in the share of health care expenditures

paid out-of-pocket, continuing growth in health care costs means that consumers may continue to have significant out-of-pocket expenditures for prescription drugs.²²

3. Price Increases

Statistics on prescription drug prices are relatively unreliable given the number of available drugs on the market. As of 2005, the FDA Orange Book²³ contained 11,706 approved prescription drugs.²⁴ Two studies in particular on prescription drugs most commonly prescribed to Medicare patients, one conducted by the government and another by the American Association of Retired Persons (AARP) Public Policy Institute, show that real prices of prescription drugs subject to the study rose significantly and outpaced consumer prices.²⁵

According to the study conducted in August 2005 by the Government Accountability Office (GAO) examining trends for prescription drugs prices reported in New York and Pennsylvania, the retail cost to an uninsured purchaser of a thirty day supply of the ninety-six drugs most commonly prescribed under a large federal-worker insurance program increased by almost twenty-five percent between January 2000 and December 2004.²⁶ The GAO updated the 2005 study in 2007 for a narrower group of prescription drugs to include data through January 2007, and found prices for brand-name drugs in that group “increased 48.6 percent, [or] 5.8 percent average annual rate of increase,” outpacing the Consumer Price Index (CPI) which experienced a “9.9 percent, [or] 2.6 percent average annual rate of increase.”²⁷ Tracking national drug price levels is difficult and unreliable, but the data show price increases in two of the largest prescription drug markets in the US over the last decade. Indeed, more comprehensive investigation of prescription drug prices is needed and has recently drawn support from Congress because of the effect on government programs.²⁸

4. Pharmaceutical Industry Analysis

The pharmaceutical industry was the third most profitable private industry in the U.S. in 2008 and 2009, with an almost twenty percent return of profit.²⁹ The ten most revenue producing prescription drugs in the U.S. in 2008 were all brand name drugs: Lipitor, Nexium, Plavix, Advair Diskus, Seroquel, Singulair, Enbrel, Actos, Prevacid, and Neulasta.³⁰ About seventy-five percent of FDA-approved prescription drugs have generic counterparts.³¹ While cheaper generics are available for brand name drugs that have

“While the U.S. government has a history of targeting direct and indirect subsidies towards particular industries, most notoriously agriculture, most economists agree that subsidies operate less in the interest of economic efficiency and more to protect domestic industries from foreign competition.”

lost exclusivity rights due to expiration of patents, generics are generally not available until patent rights expire.³²

Lucrative profits, favorable tax credits and provisions, and the potential monopoly created by exclusivity in patent rights are characteristic of the pharmaceutical industry's astronomical rise since the 1960s.³³ While the U.S. government has a history of targeting direct and indirect subsidies towards particular industries, most notoriously agriculture,³⁴ most economists agree that subsidies operate less in the interest of economic efficiency and more to protect domestic industries from foreign competition.³⁵ Subsidies can help stabilize markets and raise return to investment, but such benefits have not been proven.³⁶ Taxpayer and consumer dissatisfaction with the pharmaceutical industry can be traced to this mix of situational, private, and public factors that have contributed to the pharmaceutical industry's prominence in the economy.³⁷

a. A Public or Private Good?

The pharmaceutical industry is in a unique middle ground between public goods and private industry. Prescription drugs save and improve lives. Many Americans believe that health care is a public good. Millions of citizens in other countries already enjoy publicly provided health care, including publicly subsidized prescription drugs. A great number of Americans receive prescription drugs at a government-subsidized price through Medicare and Medicaid.

On the other hand, the prescription drug industry is, for the most part, a private industry funded by profits that are reinvested in research and development.³⁸ Funds for research and development costs are the industry's gift and curse. A lucrative new prescription drug can yield billions of dollars in revenue over the course of its lifetime as a brand name medication.³⁹ Yet for every successfully developed drug, most will fail in either research or development, taking with them a large amount of fixed costs.⁴⁰ According to the Pharmaceutical Research and Manufacturers of America (PhRMA), only one out of every 5000 drugs tested is eventually approved for use by the FDA, and it takes twelve to fifteen years to develop a new drug for market.⁴¹ The average cost of successful development of a new drug is \$800 million.⁴² PhRMA further estimates that only thirty percent of drugs approved for use generate enough revenue to recoup the average development cost.⁴³ These costs are a product of the complicated process of discovery or invention of new medicines, as well as FDA requirements for new drug approval, manufacture, and distribution.⁴⁴ The incentive to research and develop with hopes of profitability is tempered by the assumed fixed cost risk of failed research and development.⁴⁵

Conversely, pharmaceutical companies justify high prices, profits, and expenditures to the public by claiming that they develop a good that widely improves peoples' health. In 2009, Pfizer, the world's largest pharmaceutical manufacturer, stated its mission on the homepage of its company website:

At Pfizer, we're inspired by a single goal: your health. That's why we're dedicated to developing new, safe medicines to prevent and treat the world's most serious diseases. And why we are making them available to the people who need them most. We believe that from progress comes hope and the promise of a healthier world.⁴⁶

It is one thing to argue that the high cost of research and development will be redistributed from producers to consumers through high prices.

However, it is entirely different to create an environment, especially in a free-market economy, where producers generate limitless profits as a result of a government sanctioned system of approval, exclusivity, and subsidy, and consumers are given no alternative choices through restriction of competition and parallel trade.

Moreover, the Federal Trade Commission (FTC) has documented incidents of pharmaceutical companies attempting to distort further the market by compensating generic drug manufacturers for delaying the introduction of their lower cost products through patent infringement suit settlements, known as "reverse payment" agreements.⁴⁷ This conflict is separate from the controversial FDA drug review process, in which pharmaceutical companies under review by the FDA fund their own approval programs through drug application user fees.⁴⁸ In response to appellate court decisions upholding settlements between brand name and generic drug manufacturers, FTC investigators found that half of the settlements made in 2006 and 2007 included payments from the brand name company in exchange for a promise from the generic company to delay entry into the market.⁴⁹ The same was true for over two-thirds of the settlements between brand name and generic companies with exclusivity rights blocking other generic drug applicants.⁵⁰ The Preserve Access to Affordable Generics Act, introduced by Sen. Herb Kohl (D-WI) in February 2009, was proposed to prohibit such anti-competitive agreements.⁵¹ While the bill is one measure to protect the public from pharmaceutical companies' underhanded behavior, a legal and regulatory balance must still be struck between the public good and the private market.

b. Breaking Down Expenditures

Research and development expenditures in the pharmaceutical industry are high, and companies recoup those costs by passing them on to consumers.⁵² Evidence strongly suggests that, industry-wide, marketing expenditures for drugs equal or exceed research and development expenditures.⁵³ According to a study by two researchers from York University, in 2004 pharmaceutical companies spent \$57.5 billion on promotion and marketing.⁵⁴ According to a National Science Foundation (NSF) report for the same year, pharmaceutical companies spent \$31.5 billion (including public funds disbursed to the pharmaceutical industry) on domestic research and development.⁵⁵ The York University study concluded that, as a percentage of the \$235 billion in domestic prescription drug sales in 2004, promotion and marketing expenditures accounted for twenty-four percent of each sales dollar,⁵⁶ while research and development spending accounted for thirteen percent.⁵⁷

The NSF estimates may not take into account smaller firms that are not PhRMA members.⁵⁸ These smaller firms are privately funded and driven by research and development.⁵⁹ In the traditional model, biotechnology firms discover or develop a new drug then partner with a pharmaceutical manufacturer who markets and promotes the medication.⁶⁰ In 2003, pharmaceutical and biotechnology firms listed on the Standard and Poor Compustat database spent roughly sixty billion dollars on research and development expenditures.⁶¹ Taking this estimate into account, even at the most conservative level, including firms with high research and development expenditures and little to no marketing expenditures in the pharmaceutical industry, marketing and promotion costs equal or exceed research and development.

c. You Better Shop Around...But Can You?

The present regulatory environment surrounding U.S. pharmaceutical manufacturing allows American prescription drug prices to be the highest in the world. The U.S. “is the only major industrialized country in the world that does not currently regulate prescription drug prices.”⁶² In 2003, the Congressional Budget Office (CBO) estimated **that**, on average, foreign prices for prescription drugs were between forty-five percent and sixty-five percent lower than U.S. prices.⁶³

Brand name drug costs are the primary driving factor behind the movement to legalize drug importation from foreign countries. One notorious example of an expensive brand name drug is Lipitor. A 20 mg tablet of Lipitor, the top revenue producing prescription medication in the U.S. in 2008,⁶⁴ sold for four to five dollars in 2009 at CVS, the largest pharmacy chain in the U.S.⁶⁵ In several other countries, including the United Kingdom, Israel, Canada, and New Zealand, the same prescription dosage of Lipitor sold for anywhere from \$1.32 to \$2.90.⁶⁶ Even where U.S. consumers try to take advantage of lower prescription drug prices abroad, stringent regulation of prescription drug importation for personal use prevents them from doing so.

III. Drug Importation and Reimportation

Drug importation and reimportation policies have been proposed to address high drug prices in the U.S. Drug importation refers to the practice of importing prescription drugs manufactured outside of U.S. borders into the country.⁶⁷ Drug reimportation refers to the practice of importing prescription drugs originally manufactured in the U.S. and then exported elsewhere back into the U.S.⁶⁸ The terms are often used interchangeably, but under their precise legal definitions, mean different things.⁶⁹

The Food, Drug, and Cosmetic Act⁷⁰ of 1938 (FD&C Act) was passed to “prevent the adulteration, misbranding, and false advertising of food, drugs, devices, and cosmetics in interstate, foreign, and other commerce subject to the jurisdiction of the U.S., for the purposes of safeguarding public health and preventing deceit upon the purchasing public.”⁷¹ The FD&C Act is primarily concerned with ensuring that drugs in interstate commerce, including those that are imported or reimported, meet the FDA’s approval process.⁷² In 1984, to stimulate drug development and innovation, Congress passed the Drug Price Competition and Patent Term Restoration Act⁷³ (popularly known as the Hatch-Waxman Act).⁷⁴ The Act provided up to five years of additional patent protection for prescription drug manufacturers to compensate for time spent in clinical trials and awaiting FDA approval.⁷⁵ The Act also allowed generic drug manufacturers to complete an abbreviated new drug application and forego testing requirements if the generic drug met certain equivalence standards.⁷⁶

In 2000, Congress passed the Medicine Equity and Drug Safety Act⁷⁷ amending the FD&C Act, to allow drug importation in an effort to reduce medication prices.⁷⁸ The statute contained an importation provision which then Secretary of the Department of Health and Human Services (HHS), Donna Shalala, had the authority to decertify if she determined that implementing the provision would “pose no additional risk to the public’s health and safety.”⁷⁹ Secretary Shalala did in fact decertify the importation provision.⁸⁰

The Pharmaceutical Market Access Act,⁸¹ first introduced in 2003 in the House by Rep. Gil Gutknecht, was designed to amend the FD&C Act and:

- (1) Give all Americans immediate relief from the outrageously high cost of pharmaceuticals;
- (2) Reverse the perverse economics of the American pharmaceutical markets;
- (3) Allow the importation of drugs only if the drugs and the facilities where they are manufactured are approved by the Food and Drug Administration, and to exclude pharmaceutical narcotics; and
- (4) Require that imported prescription drugs be packaged and shipped using counterfeit-resistant technologies approved by the Bureau of Engraving and Printing (technologies similar to those used to secure United States currency).⁸²

The Act would authorize the Secretary of HHS to promulgate regulations for the importation of prescription drugs.⁸³ Congressional findings in support of the Act stated that:

- (1) Americans unjustly pay up to 1000 percent more to fill their prescriptions than consumers in other countries
- (2) The United States is the world’s largest market for pharmaceuticals yet consumers still pay the world’s highest prices.
- (3) An unaffordable drug is neither safe nor effective. Allowing and structuring the importation of prescription drugs ensures access to affordable drugs, thus providing a level of safety to American consumers they do not currently enjoy.
- (4) According to the Congressional Budget Office, American seniors alone will spend \$1.8 trillion dollars on pharmaceuticals over the next ten years.
- (5) Allowing open pharmaceutical markets could save American consumers at least \$635 billion of their own money each year.⁸⁴

The Act passed in the House but failed in the Senate.⁸⁵

Sen. Byron Dorgan (D-ND) introduced the latest bill in the string of congressional efforts to open U.S. borders to drug importation, the Pharmaceutical Market Access and Drug Safety Act of 2005.⁸⁶ Amendments in the 2005 bill to Section 804 of the FD&C Act would require the Secretary of HHS to promulgate regulations allowing “qualifying individuals” to import prescription drug products covered under the legislation, but the bill was never passed.⁸⁷

Conversely, also in 2005, Rep. Gregory Meeks (D-NY) independently introduced a concurrent resolution opposing legalizing personal drug importation.⁸⁸ While the resolution was never adopted, it reiterated many of the arguments against prescription drug importation and reimportation, including foreign price controls, the December 2004 HHS study on importation, the implications importation would have on the pharmacist/patient relationship, and the lack of savings U.S. consumers would experience if importation were legal.⁸⁹ However, the final finding stated that “[w]hereas despite significant efforts, including joint efforts with United States Customs and Border Protection and import alerts or bulletins, the Food and Drug Administration currently does not have sufficient resources to ensure adequate inspection of *current* levels and categories of personal shipments of prescription drugs entering the United States.”⁹⁰

In an effort to include the legislation as an amendment to the current federal health care reform bill and capitalize on political momentum surrounding

the effort to increase access to health care and lower costs, Sen. Dorgan proposed his bill again in December 2009.⁹¹ According to Dorgan's proposal, CBO estimated the bill would cut federal government costs by \$19.4 billion by 2020, and save consumers one hundred billion dollars in the same span.⁹² Once again, the bill failed a floor vote,⁹³ which was preceded by arguments from FDA Commissioner Margaret Hamburg to the Senate in opposition because, "as currently written," the bill would be "logistically challenging to implement and resource intensive" and presents significant safety risks.⁹⁴

Rep. Meeks' resolution did not address current inadequacies in the regulatory system. Only two statements on the price issue related to large-scale changes. The first, placing the responsibility to lower prices on the industry, stated that "the pharmaceutical industry and the health care community should work to ensure that all citizens have access to prescription drugs with the same level of safety and efficacy guaranteed under the *current* system of regulation"⁹⁵ (emphasis added). The second called for deregulation of foreign price controls to encourage the flow and sale of cheaper drugs into the U.S. for American consumers.⁹⁶ Commissioner Hamburg's two-page letter provided no solutions to the system's inadequacies. Prescription drug importation and reimportation remain illegal in the U.S.⁹⁷ A satisfactory version of the bill has yet to be enacted. More importantly for the purposes of this article, as displayed by its emphasis on the dangers of current and potential importation, the federal government has not taken sufficient action to address the difficulties in safely regulating illegal importation.

IV. FDA/PHARMA Arguments against Importation/Reimportation

A. Pharmaceutical Companies: Decrease in Profits Leading to Loss of Incentive for Research and Development

The general argument justifying why brand name prescription drug costs are highest in the U.S. is that there are extremely high fixed costs for research and development that must be recouped in revenue to provide an incentive for investment in future drugs.⁹⁸ The fact that the industry spends an equal or greater amount on marketing and promotions than on research and development seriously undermines the argument that drug companies must protect their profits from being swallowed by the importation of drugs from countries with lower prices at the risk of losing the incentive to spend on the future development of new drugs.⁹⁹ Pharmaceutical companies benefit from several important characteristics of the domestic market and domestic government regulation. As previously mentioned, unlike nearly every other industrialized nation with a pharmaceutical market, there are no price controls on prescription drugs in the U.S.¹⁰⁰ Second, public funds are used for private pharmaceutical company research and development.¹⁰¹ Third, the pharmaceutical industry lobby is one of the largest in the country. Finally, exclusivity through patent rights allows pharmaceutical manufacturers to sell their products without competition.¹⁰² Given our country's treatment of prescription medication as a mixed public/private good, these protections are unparalleled in any other industry.

B. Food and Drug Administration Safety Concerns: Counterfeit, Poor Quality, or Contaminated Drugs

The FDA and pharmaceutical companies also argue that legalized importation would threaten to circumvent FDA standards for drug safety.¹⁰³

The FDA's statutory responsibility is to "assure the American public that the drug supply is safe, secure, and reliable."¹⁰⁴ Of primary concern to the FDA is that the "safety and effectiveness" of drugs from outside the closed legal and regulatory system in the U.S. cannot be ensured.¹⁰⁵ Though there are no reliable data on the quantity or scale of counterfeit drug operations attempting to penetrate the U.S. border, the FDA claims that its number of counterfeit drug investigations have quadrupled since the late 1990s.¹⁰⁶ More recently, the rise in internet prescription drug sales and overseas counterfeiters with sophisticated technologies and criminal backed bankrolls have challenged the FDA to augment its efforts in securing the closed U.S. pharmaceutical distribution system.¹⁰⁷

In 2006, the FDA published a consumer bulletin warning against purchasing prescription drugs from RxNorth, a company operating several websites based in Canada.¹⁰⁸ The investigation is ongoing. Also in 2006, several defendants from Atlanta, Georgia, were indicted by a federal grand jury relating to a scheme to distribute unapproved versions of Ambien, Valium, Xanax, Cialis, Lipitor, Vioxx, and other drugs over the internet.¹⁰⁹ The defendants opened a facility in Belize, manufactured over twenty-four different prescription drugs, and conspired to market the drugs through e-mail advertisements claiming the drugs were Canadian generics.¹¹⁰ In 2005, a group of businesses and individuals were indicted in the Western District of Missouri for involvement in a forty-two million dollar conspiracy to distribute counterfeit Lipitor manufactured at a facility in Central America and genuine Lipitor purchased in Central America.¹¹¹ The increase of large scale sophisticated counterfeiting operations, smuggling, and internet sales reveal the greater issue — that more resources must be expended in the regulation of prescription drugs across U.S. borders.

Information on the safety of illegally imported prescription drugs is "very limited" — no agency of the federal government systematically collects data on the volume of prescription drug imports.¹¹² According to an HHS report in December 2004, approximately ten million packages containing prescription drugs enter the U.S. annually from all over the world.¹¹³ However, the GAO has condemned the findings as based on extrapolation of limited data, and thus unreliable.¹¹⁴

The FDA is extremely under-funded, but is "doing its best to use its limited international authorities to stop the increasing flow of violative drugs into this country" because "the sheer volume [of illegally imported prescription drugs] has grown to exceed the capability of FDA field personnel to properly process."¹¹⁵ To address this growing health risk, the FDA has responded to the threats imposed by importation by "employing a risk-based enforcement strategy to target [their] existing enforcement resources effectively in the face of multiple priorities, including homeland security, food safety, and counterfeit drugs."¹¹⁶ The current system "is already overwhelmed by the number of incoming packages, and this presents a significant ongoing challenge for the Agency."¹¹⁷ The volume of imported prescription drugs expected to rise suggests that the current strategy must be significantly revamped or abandoned.

V. U.S. Regulation of Importation/Reimportation

The most influential actor in the prescription drug industry is the federal government. Legal and regulatory protections allowing the prescription drug market to continue operating in a closed system and generating increased profits must be re-examined. This section will delve into the responsibilities

and resources of federal agencies that regulate the importation of goods into U.S. borders and compare their magnitude and effectiveness.

The FDA “coordinates with other governmental bodies and meets regularly with other federal agencies and state officials to share information and identify opportunities for partnering in enforcement actions.”¹¹⁸ U.S. Customs and Border Protection (CBP), U.S. Drug Enforcement Administration (DEA), U.S. Immigration and Customs Enforcement (ICE) are among the FDA’s federal agency partners.¹¹⁹ The FDA maintains these relationships, among other reasons, to “leverage resources and best protect American consumers.”¹²⁰ These federal agencies all share a congressionally delegated duty to protect our borders from harmful threats.

A. FDA Regulation of Importation

The FD&C Act authorizes the FDA to oversee the production of drugs that meet approved standards, whether manufactured in the U.S. or abroad.¹²¹ Legally imported drugs are introduced to the U.S. market only through FDA-approved manufacturing facilities and methods.¹²² The FD&C Act outlines a list of prohibited acts that include introducing any adulterated or misbranded food or drug into interstate commerce and causing a drug to be a counterfeit drug, selling, dispensing, or holding for sale or dispensing a counterfeit drug.¹²³ Violation can result in a court ordered injunction, or civil or criminal liability for all those who caused, aided or abetted, or conspired in one of the prohibited acts.¹²⁴ According to the FDA, by failing to legalize prescription drug importation, Congress has concluded “that the safety and effectiveness of imported drugs is best assured by carefully limiting how prescription drugs can be imported in the U.S. as part of a closed drug distribution system.”¹²⁵

1. Personal Importation at Points of Entry

Under limited circumstances, an individual entering or returning to the U.S. may personally import new prescription drugs, even those that are unapproved, if their situation meets certain exigency standards and documentation required by the FDA.¹²⁶ According to a statement on its website in 1998, the FDA, on its own initiative, developed guidance on personal importation in its Regulation Procedures Manual (RPM) entitled “Coverage of Personal Importations”.¹²⁷ The purpose of the guidelines is to provide guidance on allowing personal-use quantities of FDA-approved imported products in baggage and mail and “to gain the greatest degree of public protection with allocated resources.”¹²⁸ The importation policy states that “because the amount of merchandise imported into the [U.S.] in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified.”¹²⁹ The FDA has focused its enforcement priorities on commercially shipped products, including small mail-order solicitations, which are not subject to these RPM guidelines. They have focused “less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.”¹³⁰

The guidelines themselves allow for significant discretion in accepting a personal importation of an unapproved drug into the U.S. “when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.”¹³¹ Stressing that RPM guidelines “are intended only to provide operating guidance for FDA personnel and are not

intended to create or confer any rights, privileges, or benefits on or for any private person,” the statement goes on to describe situations where personal importation may be allowed at FDA agents’ discretion.¹³² Examples given in the guidelines include a person who has started treatment with an unapproved drug in a foreign country, has an “ethnic background” and prefers products from his or her homeland or labels in their native language, or suffers from a condition for which there is no FDA-approved drug.¹³³

In two cases, FDA personnel may act permissively in deciding whether to allow the personal importation. In the first case, when an agent identifies the drug’s intended use as appropriate, for example for treatment of a non-serious condition, and “the product is not known to represent a significant health risk,” the agent may exercise wide discretion.¹³⁴ In the second case, wide discretion may be exercised where:

- a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient’s own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.¹³⁵

Should the agent have questions about any situation, the guidelines advise him or her to hold the drug and “consult with the appropriate headquarters office.”¹³⁶

FDA personnel are instructed “not to examine personal baggage.”¹³⁷ CBP officers are responsible for examining baggage and will notify their local FDA office when they have identified an FDA-regulated drug intended for commercial distribution or an FDA-regulated drug that may represent a risk to public health.¹³⁸ FDA agents are responsible for regulating mail importations, but only after CBP sets them aside following an initial determination that they may be in violation of the FD&C Act.¹³⁹

2. Importation at Mail Facilities

According to the 2004 HHS report, CBP and FDA officials at certain mail facilities used different practices and procedures to inspect packages containing prescription drugs.¹⁴⁰ The basis upon which packages were targeted varied based on several subjective and objective factors, such as the inspector’s intuition and experience, whether packages came from suspect countries or companies, and whether shipments were to individuals.¹⁴¹ While some illicit packages were inspected and seized, many others either were not inspected and released immediately or were released after being held for inspection.¹⁴² Because they were unable to process the volume of packages, FDA officials released tens of thousands of packages containing prescription drug products that could have posed a health risk to American consumers.¹⁴³

In response to the observational study on mail facilities, the FDA issued new nationwide procedures outlining how FDA agents are to prioritize packages for inspection, inspect the packages, and determine whether FDA-regulated

pharmaceuticals should be allowed into the U.S. by mail.¹⁴⁴ CBP personnel are required to forward any mail from FDA's national list of targeted countries that appear to contain prescription drugs to FDA agents.¹⁴⁵ CBP inspectors must request and have FDA management approve a deviation from this requirement.¹⁴⁶ Still, related testimony before Congress revealed that "[w]hile the new procedures should encourage processing uniformity across facilities, many packages that contain prescription drugs are still released," because all packages CBP forwards to the FDA that FDA inspectors do not process at the end of each day are returned to the U.S. Postal Service (USPS) for delivery.¹⁴⁷

Perhaps the most important fact in the HHS report was the finding that there was only the equivalent of seventeen full time FDA employees whose responsibility it was to inspect all of the international mail facilities in the U.S. for counterfeit drugs.¹⁴⁸ When twenty to thirty million packages enter our borders through USPS each year,¹⁴⁹ this level of taxpayer resources devoted to drug regulation in the interest of public health and safety is completely unacceptable. Shockingly, these measures are being practiced with the importation ban still in effect. It is estimated that more than 3.5 to 350 million U.S. prescriptions could be affected by counterfeit or substandard drugs each year.¹⁵⁰ As the number of prescriptions filled in the U.S. continues to climb, a significant increase in resources allocated to regulating importation is even more justified today than when the FDA developed its RPM guidelines. While it may be true that implementing an anti-counterfeit system as outlined in the Pharmaceutical Market Access Act would not be justified in terms of a decrease in prices for American consumers, available resources should be put towards strengthening our nation's current regulation of drug importation.

3. Budget Allocations

Dollar amounts and manpower allocated to the regulation of drug importation are also telling. In the 2009 fiscal year, the FDA requested from Congress a total budget of \$2.4 billion, which includes \$1.77 billion in budget authority and \$628 million in industry user fees.¹⁵¹ This amount is \$129.7 million more than in fiscal year 2008 budget, a 5.7% increase.¹⁵² The proposal included "strategic increases to strengthen food protection, modernize drug safety, speed approval of generic drugs, and improve the safety and review of medical devices."¹⁵³ Between October 2008 and September 2009, the FDA was projected to experience a full-time equivalent staff increase of 526 employees.¹⁵⁴ The FY 2010 budget includes a request for the largest increase in FDA funding history, calling for a total budget of \$3.2 billion.¹⁵⁵ This represents a nineteen percent increase from 2009,¹⁵⁶ and for comparison, almost four times the percentage increase from 2008 to 2009.

The FDA Human Drugs Program (HDP) is authorized to ensure that prescription, generic, and over-the-counter (OTC) drug products are adequately available to the public and are safe and effective.¹⁵⁷ The HDP is responsible for monitoring drug products for unexpected health risks and for enforcing the quality of drug products.¹⁵⁸ The HDP received roughly \$777 million for its total budget in 2009 and requested \$908 million in 2010.¹⁵⁹ The HDP operates with assistance from the FDA Office of Regulatory Affairs (ORA), which provides leadership on import and inspection policies.¹⁶⁰ In 2009, the ORA received \$725 million for its total budget, a roughly twelve percent increase over 2008.¹⁶¹ Through its field offices,

ORA supports the HDP by conducting domestic and foreign inspections of drug manufacturers to assess their compliance with manufacturing standards and investigating incidents of product tampering that may affect FDA-regulated goods.¹⁶²

Where criminal activity is involved, ORA's Office of Criminal Investigations (OCI) complements the ORA Field Drug Program (FDP).¹⁶³ Both appropriations and user fees fund the FDP.¹⁶⁴ The amount allocated to the FDP in the 2010 budget request is just under \$145 million and supports 763 full time employees, an increase of roughly twenty-seven million dollars and sixty-four employees over 2009.¹⁶⁵

The 2009 allocation to the FDP included funding for an initiative targeting post-manufacture prescription drug safety by monitoring imported prescription drugs.¹⁶⁶ Designed to combat an FDA estimated twelve percent increase in the volume of imported pharmaceutical drugs in 2009, the funding increase was designed to allow the FDP to "support three new agents to investigate criminal drug import violations."¹⁶⁷ Thus, of the expected increase of 526 new full time FDA staff, only three will have the responsibility of investigating criminal importation.

Fortunately, in both criminal and civilian drug importation cases, ORA coordinates import activities with CBP. However, the FDA explicitly acknowledges in its budget documents that security concerns and the increase in the number of imports make the task of regulation difficult with the current amount of resources the FDA receives.¹⁶⁸ In fiscal year 2010, the FDA projects a total of 20.5 million import lines, two percent (or 410,000) of which will be human drugs and biologic products.¹⁶⁹ That is hardly an acceptable workload for so few personnel. Such a meager increase, combined with the assignment of three new field agents, is an unreasonable response to a problem the FDA acknowledges is growing exponentially. Notably, the budget includes five million dollars for "the FDA to develop policies to allow Americans to buy drugs approved in other countries."¹⁷⁰ While this is a step in the direction of acknowledging importation as a possible solution, the budget makes no explicit mention of a related full time employee increase, and within the budget justification there is only one explanation of what development will take place.¹⁷¹ In 2010, of the five million dollars dedicated to developing import policies generally, only one million dollars is allocated to the FDP,¹⁷² a disappointing number considering the historic increase and the need to improve effectiveness of any effort to strengthen current importation enforcement policy.¹⁷³

B. U.S. Customs and Border Protection Regulation

The FDA and the CBP work together on several fronts to examine products entering U.S. borders, protect the American public from foreign health risks, and enforce the laws of the U.S. against illegal activity and international threats.¹⁷⁴ On March 1, 2003, all immigration inspectors, agricultural border inspectors, and the border patrol merged with U.S. Customs to form the U.S. Customs and Border Protection agency within DHS.¹⁷⁵ There are now four agencies within DHS charged with securing U.S. borders: CBP, the Bureau of Immigration and Customs Enforcement (ICE), the U.S. Coast Guard, and the Transportation Security Administration (TSA).¹⁷⁶ The merger was part of both Title VI of the Customs Modernization Act (also known as the Mod Act),¹⁷⁷ enacted as part of NAFTA implementing legislation in 1993, and the Homeland Security Act of 2002.¹⁷⁸ With the creation of CBP, all arms of the federal government with significant border

enforcement responsibilities were unified into one agency for the first time in U.S. history.¹⁷⁹

1. CBP by the Numbers

In 2008, there were over 19,726 U.S. Customs inspectors and canine enforcement officers.¹⁸⁰ In fiscal year 2008, CBP inspectors logged more than thirty million entries of commercial imports.¹⁸¹ To fund its growing operations, CBP's budget request for fiscal year 2009 represented an increase of \$1.66 billion, or 17.9% over 2008, and totals \$10.94 billion — \$1.45 billion of which was to be collected through user fees.¹⁸² In contrast, the 2008 budget request represented a nine percent increase over fiscal year 2007.¹⁸³ The only highlight in the CBP 2008 fiscal year in review statement relating to consumer import safety states that CBP “established a dedicated import safety branch and worked closely with other federal agencies to protect the American public from unsafe . . . imported products. CBP collocated [sic] Consumer Product Safety Commission personnel at several of our ports of entry to improve targeting and information sharing between the agencies.”¹⁸⁴

2. Proposed CBP Policies

In a 2005 report to Congress, the GAO made several recommendations to the various agencies responsible for regulating prescription drug imports.¹⁸⁵ The overarching idea was to require a CBP task force involving ICE, FDA, USPS, DEA, and the Office of National Drug Control Policy to develop a strategic framework to help formulate policy reforms.¹⁸⁶ First, the GAO recommended that the task force establish an approach for estimating the scope of the prescription drug problem, particularly the volume of drugs entering the country through mail and carrier facilities.¹⁸⁷ Second, to estimate the scope of the problem, the task force would gauge results by establishing objectives, milestones, and performance measures and a methodology to gauge results.¹⁸⁸ Third, the task force would determine the resources needed to address the flow of illegally imported prescription drugs and where those resources should be targeted.¹⁸⁹ Fourth, the task force would evaluate progress, identify barriers to achieving goals, and suggest modifications to the current regulatory system.¹⁹⁰ As a final and unrelated suggestion, the GAO recommended that the Secretary of HHS re-examine and provide a report on removing or modifying the requirement that the FDA must allow personal importers the opportunity to provide documentation that their prescription drugs are legitimate.¹⁹¹

Implementation of these recommendations is ongoing, but has yet to be fully achieved. For example, in response to the second recommendation, CBP claimed it had developed a document that contains a mission statement, outlines the responsibilities of the various agencies, and presents objectives, milestones, and performance measures.¹⁹² According to the GAO, however, the CBP document does not: establish concrete milestones including target dates by which tasks should be completed, outline performance measures that CBP and other agencies can use to gauge performance and results, or show what resources are needed to address the problem and where resources should be targeted.¹⁹³ While the recommendations did not give detailed instructions, four years is not an unreasonable time to allow a federal agency to work in conjunction with other agencies and develop documents to address an increasing problem. Because the FDA claims it faces a higher incidence of unapproved drugs entering U.S. borders with no additional funding, there must be both a greater sense of urgency

and a policy response not only from government agencies but also from legislators and the President to reform drug regulation.

One positive example of CBP and FDA joint operations shows that increased coordination between the agencies in terms of both manpower and technology can be fruitful. Pursuant to an agreement between CBP and the FDA, the FDA is allowed to commission CBP officers to assist the FDA with examination and investigation of food imports when importers provide prior notice of importation as part of the Bioterrorism Act.¹⁹⁴ The agreement also requires that the FDA provide appropriate training to commissioned CBP inspectors, provide twenty-four hour assistance to CBP, reimburse CBP for costs associated with examination and investigation, share information, and jointly develop additional agreements to implement the agreement's purpose.¹⁹⁵ In addition to providing FDA with manpower, CBP is required to collect samples for analysis, or analyze samples themselves, to detect illegitimate food imports.¹⁹⁶

Again, data are difficult to collect on the effectiveness of measures involving import interdiction. Training border personnel in multiple areas of regulation is one cost-effective method of increasing the federal government's ability to regulate imports. By having agents who are independently capable of examining, investigating, and detaining goods that they determine may be illicit, counterfeit, or a health risk, the FDA will better be able to make use of limited resources. Placing more efficient FDA or CBP personnel on the frontlines could lower costs in the long run and create high-skilled jobs.

C. TSA Regulation of Commercial Air Travel

Congress created the TSA in response to the September 11, 2001 terrorist attacks and charged the DHS agency with protecting U.S. air and ground transportation to ensure freedom of movement for people and goods.¹⁹⁷ Under authority of the Aviation and Transportation Security Act, the TSA established a baggage screener workforce and took over the responsibility of screening domestic commercial air passengers and bags from commercial air carriers.¹⁹⁸ CBP remains responsible for screening international commercial air travelers.

The TSA's budget request for fiscal year 2009 was \$7.1 billion, a total increase of \$286 million over the fiscal year 2008.¹⁹⁹ Of the total amount requested, \$5.3 billion went toward aviation security.²⁰⁰ Beginning as a relatively small agency, the TSA now employs over 50,000 people.²⁰¹ The TSA provides a valuable example of effective hiring and training measures for inspections agents to increase manpower. In building its workforce essentially from the bottom up, TSA began by hiring and training the first federal screeners, known as Transportation Security Officers (TSOs) in airports and charged them with stopping simple prohibited items including razors and firearms.²⁰² TSOs are now “highly-trained, multi-skilled” agents that perform physical and behavioral screening using sophisticated screening equipment throughout airports nationwide.²⁰³

In 2006, TSA screened 708,400,522 people through airport security, 535,020,271 individual pieces of checked luggage, and opened and examined 85,571,710 bags for prohibited items.²⁰⁴ The TSA attributes its effectiveness in training and retaining TSOs to a number of initiatives, including: career development, attrition reduction, and workplace safety measures.²⁰⁵ In particular, to address inadequacies in field offices, TSA requires field offices to maintain a Model Workplace Program to improve

their employees' work environment. This has reduced full-time attrition from 13.6% in 2004 to 11.6% in 2007 and part-time attrition from 57.8% in 2004 to 37.2% in 2007.²⁰⁶ The TSA also changed its centralized hiring process to the local airport level, reducing hiring cost per TSO by over thirty-six percent from 2004 to 2007.²⁰⁷

VI. Reforms

Drug importation and reimportation may be an adequate solution to the problem of escalating and unaffordable prescription drug prices. Regardless of whether importation is the answer, there are existing issues within the FDA that must be addressed to solve current inadequacies in drug regulation.

In theory, government funding is a finite resource which must be appropriated to agencies and programs in a manner commensurate with their importance to and effectiveness at addressing problems. Looking at the resources the government applies to certain government measures in relation to others should provide the American people, both with an idea of what problems the government currently finds most pressing and how pressing those problems are as determined by the amount of funding they receive. Furthermore, with the current rate at which the government is spending on economic stimulus,²⁰⁸ there are plenty of funds available if the government deems a problem to be urgent enough for the well-being of the nation.

A safe supply of prescription drugs is a legitimate government interest, as are safe commercial air travel and the safety of all imported products. In the absence of accurate data on the incidence of unsafe or counterfeit goods,²⁰⁹ determining how many resources should be funneled is largely a subjective exercise. To the American people, prescription drugs, which accounted for over \$216 billion in sales in 2008,²¹⁰ are an incredibly important and growing expense as the population continues to age.²¹¹

Breaches in border safety are incredibly difficult to measure because there are no methods to gauge how many illicit goods go undetected.²¹² Gauging the magnitude of the prescription drug problem is difficult because drugs can be imported through the mail or carried across the border.²¹³ As the GAO recommended to the CBP, creating a network or database to accurately determine how many illicit prescription drugs enter U.S. borders should be the first step.²¹⁴

The FDA is inhibited by three factors in the battle against unapproved, unsafe, or counterfeit prescription drugs: lack of adequate funding, lack of adequate manpower, and inefficient processes.²¹⁵ There are several lessons the government can take from other measures used in regulation of people and products at our borders. While DHS, CBP, and TSA are not perfect, each presents a valuable method the FDA could adopt in increasing its abilities to combat safety issues in prescription drug importation.

1. Funding

Lack of funding is at the top of the list of FDA deficiencies. The FY 2009 FDA budget request was a 5.7% increase over fiscal year 2008 budget,²¹⁶ a relatively small increase in comparison to the 2009 CBP request, which jumped 17.9% over 2008.²¹⁷ The TSA's budget request for fiscal year 2009 was \$7.1 billion, a total increase of \$286 million over fiscal year 2008 that more closely resembles the FDA's relative increase from 2008.²¹⁸ Of the

total amount requested, seventy-five percent went toward Aviation Security, one program within the TSA.²¹⁹

Although it is difficult to compare funding measures of these three agencies because of differences in the number of incidences of total examinations and inspections — up to fifty million for the FDA, eighty-five million for the TSA, and thirty million for CBP²²⁰ — there have almost certainly been more incidences of illegal importation of goods, including prescription drugs, than there have been terrorist threats on aircrafts in the U.S. since 2008.²²¹ This is not an argument that the TSA should receive less funding, but there must be a more proportionate amount of funding to the level and magnitude of the risk at issue. The one million dollar budget allocation to the FDP for development of a drug importation user fee is especially disappointing.²²² If FDA concerns for drug safety are so pressing, more funding must be allocated. While the 2010 funding increase is a landmark step,²²³ it remains to be seen how far that step will go toward actually increasing enforcement of drug safety.

2. Manpower

FDA manpower and efficient use of that manpower must also be increased. While the FDA has greatly expanded its hiring of scientists, doctors and statisticians since 2007,²²⁴ field agents must become a priority. Physical examination is the only current method available to seize unsafe prescription drugs at import points of entry.²²⁵ Between October 2008 and September 2009, the FDA was to experience a full-time equivalent staff increase of 526 and of those, only three new agents were to be hired to investigate criminal drug import violations as part of the FDA's FDP (there was no mention of an increase in the number of agents responsible for investigating personal importation).²²⁶

This issue provides a chance for the government to create highly skilled jobs in a time when many government agencies, especially those dedicated to security, are understaffed. Agreements like the one between CBP and the FDA on commissioning and training agents in multiple disciplines are a good starting point in addressing the lack of personnel available to process the massive amount of imports.²²⁷ The problem must be addressed at different levels. Implementing new hiring practices at the local level in individual mail facilities and improving retention to eliminate hiring costs, as the TSA has done,²²⁸ would be an excellent starting point to cut administrative costs while creating jobs.

Job creation must be part of the equation to solve the problem of inadequate manpower. For example, the number of full time FDA personnel examining all drug imports at international mail facilities around the country must be increased from seventeen.²²⁹ Such a number is completely unacceptable. The result, that at one facility roughly 10,000 packages a week are returned to USPS for delivery, is equally unacceptable.²³⁰ At least some FDA personnel should be positioned onsite, rather than stationed in the field office and called to the mail facility when a USPS or CBP agent determines a package should be held.²³¹

3. Processes

To ensure that adequate funding and sufficient manpower are put to productive use, the FDA and other agencies involved must formulate a plan to address the importation dilemma that includes more efficient processes. First, the GAO recommendations to CBP must be completed.²³² Since 2005,

none of the four recommendations the GAO proposed have been adequately met.²³³ Five years is far too long to fail to achieve a basic framework for developing new policies. Congress, especially those proponents of personal prescription drug importation, must push these agencies to complete the task.

On the enforcement level, the FDA and CBP must put in place more effective procedures for inspection of personal drug importation. The FDA has focused its enforcement efforts on commercial rather than personal shipments because the value and size of those imports do not justify a more complete inspection process.²³⁴ This argument is entirely resource-based and shifts the focus away from the FDA's concern about consumer product safety. As mentioned above, the system is in need of restructuring or abandonment²³⁵ combined with an increase in available agents to inspect both commercial and personal shipments at adequate levels. When this article was submitted for publication, FDA Commissioner Hamburg announced that in 2010, the FDA would begin using an improved risk-based database, the PREDICT system, to replace its current import documentation database.²³⁶ Implementation of the PREDICT system shows that the FDA has sought methods to improve the inspection process. It will be interesting to see how PREDICT improves FDA's ability to detect illicit imported prescription drugs.²³⁷

In practice, a determination for importation is a judgment that must be made quickly. Risk-based database tracking, due to the varying nature of regulation of international mail,²³⁸ cannot target the continuing problem of lack of resources allocated to international mail facilities. The FDA has yet to propose a solution to this problem (perhaps there is no systematic solution), but the lack of sufficient manpower is evident.²³⁹ As for personal importation policy, in the interest of pragmatism, allowing agents a significant amount of discretion in the RPM guidelines is good policy because of the subjective nature of the inquiry.²⁴⁰ Though "we cannot inspect our way to safety,"²⁴¹ agencies can improve methods and augment the ability to meet the increasing numbers of illicit imported prescription drugs.

VII. Conclusion

Why are we as a society so unwilling to devote the necessary resources to devise and implement quality control measures in an industry like health care, where quality services and pharmaceuticals are the only means of survival for millions of Americans? We as a nation are at a crossroads. The depth of the current economic recession increases the likelihood that the American people will demand health care reform at a greater pace than governments are currently undertaking. Though the FDA claims safety cannot be assured if personal importation is legal, it cannot effectively regulate the current in flow of prescription drugs through international mail, commercial shipment, or consumer importation at border points of entry. The FDA and CBP must establish a method to gauge the magnitude of the problem. They have failed in this regard. No measures for improvement will be possible or effective until the degree of the problem can be understood. Funding, manpower, and processes must be reformed to address the current inadequacies in prescription drug regulation. Increased funding, job creation, multi-disciplinary training, and on-site personnel are possible answers to the problems.

The amount of prescription drugs entering the U.S. has increased substantially in the past twenty years and will undoubtedly continue to increase in the foreseeable future.²⁴² Market forces will force America to fundamentally change how we regulate the pharmaceutical industry, prescription drug prices, and the safety of imported drugs. Drug importation and reimportation may very well be an adequate solution to the problem of escalating and unaffordable prescription drug prices. Regardless of whether importation is the answer, we must put our money where our mouth is and address existing issues to solve current inadequacies in imported drug regulation.

¹ Andrea Sisko, et al., *HEALTH SPENDING PROJECTIONS THROUGH 2018: RECESSION EFFECTS ADD UNCERTAINTY TO THE OUTLOOK*, 28 no. 2 *HEALTH AFF.*, w346, Feb. 24, 2009, <http://content.healthaffairs.org/cgi/content/full/hlthaff.28.2.w346/DC1> [hereinafter *Health Spending Projections*] (Feb. 27, 2010).

² Steven Reinberg, *Recession Scrambling Health Spending in U.S.*, *U.S. NEWS & WORLD REP.*, Feb. 24, 2009, <http://health.usnews.com/articles/health/healthday/2009/02/24/recession-scrambling-health-spending-in-us.html> (Feb. 25, 2009).

³ *Id.*

⁴ See Council of Economic Advisors, *Joint Economic Comm.*, 111th Cong., Economic Indicators December 2009 (Comm. Print 2009), http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=economic_indicators&docid=f:00de09.txt.pdf (showing both nominal and real GDP decreases in 2009 from 2008 levels).

⁵ *Health Spending Projections*, *supra* note 1, at w346-48, w351, w356.

⁶ Cal. Health Care Found., *Snapshot: Health Care Costs 101*, 5 (2007), <http://www.chcf.org/topics/healthinsurance/index.cfm?itemID=132421> [hereinafter *Snapshot*]. As a means of comparison, health care spending in Switzerland is 11.6% of GDP, yet its per capita health care spending is roughly 33% lower than in the U.S. *Id.*

⁷ Nat'l Coal. on Health Care, *Health Care Facts: Costs 1(2009)*, <http://nchc.org/sites/default/files/resources/Fact%20Sheet%20-%20Cost.pdf> [hereinafter *NCHC, Facts About Health Care*].

⁸ See *Health Spending Projections*, *supra* note 1, at w346-48 (explaining that recession will contribute to deceleration of growth in national health care spending though growth in private spending is projected to decrease as growth in public spending is projected to increase).

⁹ See *id.* (noting these figures combine two projected estimates of 7 million and 6 million Americans losing their health insurance coverage as a result of the recession. The second projection conditions the loss on national unemployment reaching 10 percent. Official Bureau of Labor statistics for January 2010 declare a 9.7 percent unemployment rate (though it should be noted that this rate does not include the 3.6 million Americans who want to work but have not looked because they have either given up looking or believe no jobs are available)); Economic News Release, United States Department of Labor, Bureau of Labor Statistics, *Employment Situation Summary* (Feb. 5, 2010), available at <http://www.bls.gov/news.release/empsit.nr0.htm> (last visited Feb. 27, 2010).

¹⁰ Dr. Bryan A. Liang, *Fade to Black: Importation and Counterfeit Drugs*, 32 *AM. J. L. & MED.* 279, 279 (2006).

¹¹ See *Snapshot*, *supra* note 6, at 6-7. For reference, the categories include: (1) Hospital Care; (2) Physician and Clinical Services; (3) Dental/Other Professional; (4) Nursing Home Care; (5) Home Health Care; (6) Prescription Drugs; (7) Other Medical Products; (8) Administration; (9) Government Public Health Activities; and (10) Investment. *Id.*

¹² *Id.* at 18.

¹³ *Id.* at 56. See NAT'L CTR. FOR HEALTH STATISTICS, *HEALTH, UNITED STATES 2008: WITH A SPECIAL FEATURE ON THE HEALTH OF YOUNG ADULTS 129* (2009), <http://www.cdc.gov/nchs/hsus.htm> [hereinafter *NCHS Health 2008*] ("Prescription drug spending increased by 9% in 2006, partly as a result of the implementation of Medicare Part D, a Medicare expansion that partially finances prescription drugs for the elderly and disabled").

¹⁴ *Id.* at 369.

- ¹⁵ *Id.*
- ¹⁶ ADMIN. ON AGING, PROJECTIONS OF FUTURE GROWTH OF OLDER POPULATIONS 2 (2009), http://www.aoa.gov/AoARoot/Aging_Statistics/future_growth/docs/By_Age_Total_Population.xls (Feb. 28, 2010) [hereinafter *Future Growth of Older Populations*].
- ¹⁷ NCHS Health 2008, *supra* note 13, at 5. Respective percentages for those uninsured are roughly 22 percent. *Id.* at 332.
- ¹⁸ *Id.* at 331.
- ¹⁹ Snapshot, *supra* note 6, at 19.
- ²⁰ *Id.*
- ²¹ NCHS Health 2008, *supra* note 13, at 56.
- ²² *Id.*
- ²³ The Orange Book, published by the FDA and “named for its orange cover . . . contains a list of all the drugs approved for marketing in the United States.” Michael A. Carrier, *Unsettling Drug Patent Settlements: A Framework for Presumptive Illegality*, 108 MICH. L. REV. 37, 46 (2009).
- ²⁴ Joseph Goldfarb, Ph.D, et al., *Network Analysis of FDA Approved Drugs and Their Targets*, 74 MT. SINAI J. MED. 27, 28 (2007).
- ²⁵ U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-05-779, PRESCRIPTION DRUG PRICE TRENDS 6 (2005) [hereinafter *GAO-05-779*]; U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-07-1201R, PRESCRIPTION DRUG PRICE TRENDS 3 (2007) [hereinafter *GAO-07-1201R*]; David J. Gross, Leigh Purvis, & Stephen W. Schondelmeyer, *Rx Watchdog Report*, Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Medicare Beneficiaries 2002 to 2007 18 (2008).
- ²⁶ *GAO-05-779*, *supra* note 25, at 6. The GAO disclaims that the study was limited and these figures cannot be extrapolated to describe national price trends. They relate only to figures reported to “two large state programs that assist low-income Medicare beneficiaries in purchasing prescription drugs: Pennsylvania’s Pharmaceutical Assistance Contract for the Elderly (PACE) program from January 2000 through December 2004, and New York’s Elderly Pharmaceutical Insurance Coverage (EPIC) program from August 2000 through December 2004.”
- ²⁷ *Id.* at 3.
- ²⁸ See Duff Wilson, Rising Prices of Drugs Lead to Call for Inquiry, N.Y. TIMES, Nov. 19, 2009, at B1, available at <http://www.nytimes.com/2009/11/19/health/policy/19drugs.html> (last visited Feb. 28, 2010) (reporting Congressional requests for investigation into drug industry price increases in the midst of current health care reform efforts).
- ²⁹ FORTUNE 500, *Annual Ranking of America’s Largest Corporations*, May 2009, <http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits/> (Feb. 28, 2010).
- ³⁰ Ed Lamb, *Top 200 Prescription Drugs of 2008*, PHARMACY TIMES, May 2009, <http://www.pharmacytimes.com/issue/pharmacy/2009/2009-05/RxFocusTop200Drugs-0509> (last visited Feb. 27, 2010).
- ³¹ Kaiser Family Found., Prescription Drug Trends, 2 (May 2007).
- ³² See Wansheng Jerry Liu, Balancing Accessibility and Sustainability: How to Achieve the Dual Objectives of the Hatch-Waxman Act While Resolving Antitrust Issues in Pharmaceutical Patent Settlement Cases, 18 ALB. L.J. SCI. & TECH. 441, 443, 447-48 (2008) (discussing procedure under the Hatch-Waxman Act by which generic prescription drugs may seek FDA approval for availability on the market prior to, or after, patent expiration of the brand name drug).
- ³³ See Jonathan L. Mezrich, *International Tax Issues of the U.S. Pharmaceutical Industry*, 10 AKRON TAX J. 127, 127-29 (1993) (describing history of the U.S. pharmaceutical from the 1930’s to the early 1990’s).
- ³⁴ Daniel A. Sumner, *Agricultural Subsidy Programs*, in *The Concise Encyclopedia of Economics* 1-2 (David R. Henderson ed., 2008), available at <http://www.econlib.org/library/Enc/AgriculturalSubsidyPrograms.html> (last visited Feb. 28, 2010).
- ³⁵ *Id.*
- ³⁶ *Id.*
- ³⁷ See Congressional Budget Office, Research and Development in the Pharmaceutical Industry 11 (2006) [hereinafter *R&D*] (describing “public dialogue” regarding the relationship between rising drug prices, rising research and development spending, slowing innovation, and government investment in research and development).
- ³⁸ Joseph H. Golec & John A. Vernon, Essay, *What’s at Stake in Pharmaceutical Reimportation: The Costs in Terms of Life Years, Lives, and Dollars*, 16 U. FLA. J. L. & PUB. POL’Y 135, 136 (2005).
- ³⁹ See Lamb, *supra* note 30, at 3 (noting each of the top 20 revenue producing brand name drugs in 2008 topped \$2 billion in revenue in that year alone).
- ⁴⁰ Golec, *supra* note 38, at 139.
- ⁴¹ Todd A. Rosenfeld, Comment, *The Counterfeit Drug Invasion: How Drug Re-Importation Unjustifiably Poses a Threat to the Health of the U.S. Public*, 25 U. PA. J. INT’L ECON. L. 1047, 1049-50 (2004).
- ⁴² *Id.* at 1050.
- ⁴³ *Id.*
- ⁴⁴ *Id.*
- ⁴⁵ Golec, *supra* note 38, at 137.
- ⁴⁶ Pfizer Home Page (2009), <http://www.pfizer.com/> (last visited Mar. 2009).
- ⁴⁷ S. Rep. No. 111-123, at 2 (2009).
- ⁴⁸ Liang, *supra* note 10, at 302.
- ⁴⁹ S. Rep. No. 111-123, at 4; see FTC, Agreements Filed with the FTC under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Summary of Agreements Filed in FY 2007 3 (May 2008), <http://www.ftc.gov/os/2008/05/mmaact.pdf> (last visited Feb. 27, 2010) (showing in Figure II that of the 25 agreements restricting generic entry 14 involved payment to the generic manufacturer and of those 14 agreements 11 involved first filer generic companies who are eligible for 180 days of market exclusivity for their product under the Hatch Waxman Act); Carrier, *supra* note 23, at 38-51. For background and more information on the Hatch Waxman Act provisions governing generic versus brand name manufacturer patent litigation and reverse payment agreements.
- ⁵⁰ *Id.*
- ⁵¹ Liang, *supra* note 10, at 302.
- ⁵² Golec, *supra* note 38, at 136.
- ⁵³ Marc-Andre Gagnon & Joel Lexchin, *The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States*, 5 PUB. LIBR. OF SCI. MED. 29, 32 (2008).
- ⁵⁴ *Id.* at 31.
- ⁵⁵ *Id.*
- ⁵⁶ *Id.* at 32.
- ⁵⁷ *Id.*
- ⁵⁸ See Golec, *supra* note 38, at 144 (analyzing PhRMA industry profile for 2004 and stating that PhRMA estimates of research and development spending [around \$33.2 billion, roughly that of the National Science Foundation estimate] are conservative because they only include PhRMA members and not small, research and development focused firms).
- ⁵⁹ *Id.*
- ⁶⁰ Deborah Hopewell, *Biotech v. Pharma: Once Different, Now Collaborative Entities*, SAN JOSE BUS. J., (2003), <http://sanjose.bizjournals.com/sanjose/stories/2003/06/23/focus3.html> (Feb. 28, 2010).
- ⁶¹ Golec, *supra* note 38, at 144.
- ⁶² Joseph Golec, W. Keener Huguen, & John A. Vernon, *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J.L. & MED. 175, 176 (2006).
- ⁶³ Cong. Budget Office, Cost Estimate: H.R. 2427: The Pharmaceutical Market Access Act of 2003, 3 (2003).
- ⁶⁴ Lamb, *supra* note 30, at 3.
- ⁶⁵ Search run on PharmacyChecker.com for 20mg per tablet cost of Lipitor (Apr. 10, 2009).
- ⁶⁶ *Id.*
- ⁶⁷ See Liang, *supra* note 10, at 280 (describing the movement of prescription drugs in and out of countries through both legal and illegal means).
- ⁶⁸ See 21 U.S.C. § 381(d)(1). The provision prohibits any drug that was manufactured in the US and then exported from being imported back into the U.S. by any person but the drug manufacturer.
- ⁶⁹ Indeed even Congress has conflated the two in practice. The Pharmaceutical Market Access Act, H.R. 2427, 108th Cong. (2003), states that it pertains to reimportation, but its provisions relate only to importation.
- ⁷⁰ Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938) (current version at 21 U.S.C. § 301 (2000)).

- ⁷¹ H.R. REP. NO. 75-2139, at 1.
- ⁷² See 21 U.S.C. § 381(a). The imports provision requires the Secretary of Health and Human Services to “furnish to the Secretary of the Treasury a list of establishments” properly registered with the Department of Health and Human Services and refuse admission into interstate commerce any drugs that, after examination and opportunity for the owner to have a hearing, do not conform with the requirements of the Act.
- ⁷³ 35 U.S.C. § 156 (2000).
- ⁷⁴ Carrier, *supra* note 23, at 41.
- ⁷⁵ *Id.* at 44.
- ⁷⁶ *Id.* at 43.
- ⁷⁷ 21 U.S.C. § 284 (2000).
- ⁷⁸ Liang, *supra* note 10, at 298, n.125.
- ⁷⁹ 21 U.S.C. § 384(1)(1) (2000); Liang, *supra* note 10, at 298, n.125.
- ⁸⁰ *Id.*
- ⁸¹ H.R. 2427, 108th Cong. (2003).
- ⁸² *Id.*
- ⁸³ *Id.*
- ⁸⁴ *Id.*
- ⁸⁵ See THOMAS, H.R. 2427 Summary & Status, <http://thomas.loc.gov/cgi-bin/bdquery/z?d108:h.r.02427>: (last visited Feb. 27, 2010) (showing no further Congressional action after July 2003 referral to Senate Committee on Health, Education, Labor, and Pensions).
- ⁸⁶ H.R. 700, 109th Cong. (2005).
- ⁸⁷ *Id.*
- ⁸⁸ H. Con. Res. 75, 109th Cong. (2005).
- ⁸⁹ *Id.*
- ⁹⁰ *Id.*
- ⁹¹ Press Release, Byron L. Dorgan — United States Senator, North Dakota, Senate to Vote on Dorgan Amendment to Lower Prescription Drug Prices (Dec. 9, 2009), available at <http://Dorgan.senate.gov/newsroom/record.cfm?id=320522> (last visited Dec. 28, 2009).
- ⁹² *Id.*
- ⁹³ Julie Rovner, *Senate Inches Toward Final Vote on Health Bill*, NPR, Dec. 2009, <http://www.npr.org/templates/story/story.php?storyId=121497843> (last visited Dec. 28, 2009).
- ⁹⁴ Letter from Margaret Hamburg, Comm’r, Food and Drug Admin., to Tom Carper, United States Senator, Del. (Dec. 8, 2009) (on file with author).
- ⁹⁵ *Id.*
- ⁹⁶ *Id.*
- ⁹⁷ Liang, *supra* note 10, at 298, n.125.
- ⁹⁸ Golec, *supra* note 62, at 182.
- ⁹⁹ See *Policy Implications of Importing Drugs into the United States: Hearing Before the Subcomm. on Interstate Commerce, Trade, and Tourism of the S. Comm. on Commerce, Sci., and Transp.*, 112th Cong. (2007) [hereinafter *Lutter Statement*] (statement of Randall W. Lutter, Ph.D., Acting Deputy Commissioner for Policy, Food and Drug Administration) (stating a key finding identified from the Department of Health and Human Services Task Force examining drug importation that “legalized importation of now-unapproved drugs will likely adversely affect the future development of new drugs for American consumers”).
- ¹⁰⁰ Golec, *supra* note 62, at 176.
- ¹⁰¹ See *R&D*, *supra* note 37, at 1.
- ¹⁰² See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL’Y L. & ETHICS 193, 201 (2005) (quoting U.S. Constitution art. I, § 8, cl. 8 language regarding intellectual property and arguing that pharmaceutical patents on “blockbuster drugs” may lead to a monopoly and the creation of market power under antitrust analysis).
- ¹⁰³ See Lutter Statement, *supra* note 99 (discussing findings from DHHS Task Force Report on Prescription Drug Importation and concluding that where the foreign source of drugs is unknown “the FDA cannot assure the safety or effectiveness of [the] drugs.”); Press Release, PhRMA, PhRMA Statement on Prescription Drug Importation (Mar. 4, 2009) <http://www.phrma.org/node/914> (last visited Feb. 28, 2010) (quoting statement from Senior Vice President Ken Johnson that “[w]e should not pursue policies that could expose Americans to substandard drug products and potentially weaken the [FDA] by crippling the Agency’s ability to fulfill its mission in protecting public health and safety.”).
- ¹⁰⁴ See Lutter Statement, *supra* note 99.
- ¹⁰⁵ *Id.*
- ¹⁰⁶ *Importation of Prescription Drugs: Hearing Before the Permanent Subcomm. on Investigations of the Comm. on Gov. Affairs*, 109th Cong. 2 (2004) [hereinafter *Taylor Statement I*] (statement of John M. Taylor, III, Associate Commissioner for Regulatory Affairs, Food and Drug Administration).
- ¹⁰⁷ Lutter Statement, *supra* note 99. The FDA uncovered one particular tactic of website counterfeiters known as “Bait and Switch” in 2005. FDA intercepted drugs sold over the Internet and imported from India, Israel, Costa Rica, and Vanuatu. “Nearly half” of those drugs were purported to have been shipped from Canadian pharmacies when in fact, eighty-five percent of them originated in 27 different countries.
- ¹⁰⁸ *Id.* at Appendix A.
- ¹⁰⁹ *Id.*
- ¹¹⁰ *Id.*
- ¹¹¹ *Id.*; Press Release, Food & Drug Admin., Federal Authorities Cease Sale and Distribution of Counterfeit Lipitor (Aug. 31, 2005), available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2005/ucm108483.htm>.
- ¹¹² *Prescription Drugs: Enhanced Efforts and Better Agency Coordination Needed to Address Illegal Importation: Testimony Before the H. Subcomm. on Oversight and Investigations, Comm. on Energy and Commerce*, 108th Congress 4 (2005) [hereinafter *Stana Statement*] (Statement of Richard M. Stana, Director of Homeland Security and Justice Issues, United States Government Accountability Office).
- ¹¹³ *Id.*
- ¹¹⁴ *Id.*
- ¹¹⁵ *Taylor Statement I*, *supra* note 106, at 3.
- ¹¹⁶ *Id.* at 3.
- ¹¹⁷ *Id.* at 3.
- ¹¹⁸ Lutter Statement, *supra* note 99.
- ¹¹⁹ *Id.*
- ¹²⁰ *Id.*
- ¹²¹ *Id.*
- ¹²² *Id.*
- ¹²³ 21 U.S.C. §§ 331(a), (i)(3) (2000).
- ¹²⁴ 21 U.S.C. §§ 332-33, 8 (2000).
- ¹²⁵ *Id.*
- ¹²⁶ Food & Drug Admin., *Regulatory Procedures Manual*, Chpt. 9: Import Procedures and Actions 9-2 (2009) [hereinafter *Import Procedures*].
- ¹²⁷ *Id.* at 9-12.
- ¹²⁸ *Id.*
- ¹²⁹ *Id.*
- ¹³⁰ *Id.*
- ¹³¹ *Id.* at 9-13.
- ¹³² Division of Import Operations and Policy, Food and Drug Admin., *Information on Importation of Drugs* (1998) available at <http://www.fda.gov/ForIndustry/ImportProgram/ImportPolicyandInformationbyProduct/default.htm> (last visited Feb. 28, 2010).
- ¹³³ *Id.*; *Import Procedures*, *supra* note 126.
- ¹³⁴ *Id.* at 9-14.
- ¹³⁵ *Id.*
- ¹³⁶ *Id.*
- ¹³⁷ *Id.* at 9-12.
- ¹³⁸ *Id.*
- ¹³⁹ *Id.*
- ¹⁴⁰ *Stana Statement*, *supra* note 112, at 20.
- ¹⁴¹ *Id.*
- ¹⁴² *Id.*
- ¹⁴³ *Id.*
- ¹⁴⁴ *Id.* at 20-21.
- ¹⁴⁵ *Id.*
- ¹⁴⁶ *Id.*
- ¹⁴⁷ *Id.*
- ¹⁴⁸ See Liang, *supra* note 10, at 282 (finding that because the FDA personnel did not remain on site, their presence was measured in hours worked).
- ¹⁴⁹ *Id.*
- ¹⁵⁰ *Id.*

- ¹⁵¹ Press Release, Food & Drug Admin., President's FY 2009 Budget Advances Food and Medical Product Safety, and the Safety of FDA-Regulated Imports (February, 2008) [hereinafter *FY 2009 Budget Press Release*].
- ¹⁵² *Id.*
- ¹⁵³ *Id.*
- ¹⁵⁴ *Id.*
- ¹⁵⁵ Food & Drug Admin., Summary of the FDA's 2010 Budget (2009).
- ¹⁵⁶ *Id.*
- ¹⁵⁷ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Human Drugs, Fiscal Year 2009 10 (2009) [hereinafter *Human Drugs 2009*].
- ¹⁵⁸ *Id.*
- ¹⁵⁹ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Human Drugs, Fiscal Year 2010 (2009) [hereinafter *Human Drugs 2010*].
- ¹⁶⁰ *Id.*
- ¹⁶¹ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Field Activities—Office of Regulatory Affairs, Fiscal Year 2010 1 (2009) [hereinafter *FDA ORA FY 2010*].
- ¹⁶² *Id.*
- ¹⁶³ *Id.*
- ¹⁶⁴ *Id.*
- ¹⁶⁵ *Human Drugs 2010*, *supra* note 159.
- ¹⁶⁶ *Human Drugs 2009*, *supra* note 157, at 10.
- ¹⁶⁷ *Id.*
- ¹⁶⁸ *FDA ORA FY 2010*, *supra* note 161, at 3.
- ¹⁶⁹ *Id.*
- ¹⁷⁰ Office of Mgmt. & Budget, Food and Drug Admin., Congressional Justification, Summary of Changes, Fiscal Year 2010 (2009).
- ¹⁷¹ *Human Drugs 2010*, *supra* note 159; *FDA ORA FY 2010*, *supra* note 161.
- ¹⁷² *FDA ORA FY 2010*, *supra* note 161, at 9.
- ¹⁷³ *Id.* The funding, according to the budget will “be used to begin to develop a Drug Importation User Fee for FDA.”
- ¹⁷⁴ See, e.g. *Stana Statement*, *supra* note 112, at 10-14 (describing FDA and CBP statutory authority under the FD&C Act and the Controlled Substances Import and Export Act as well as coordination efforts in connection with importation regulation); *Growing Trade, Growing Vigilance: Import Safety Today and Tomorrow: Statement Before the S. Finance Committee*, 110th Congress 1, 3 (2007) (Statement of Daniel Baldwin, Assistant Commissioner, Office of International Trade, U.S. Customs and Border Protection, Department of Homeland Security explaining CBP coordination with FDA on bioterrorism preparedness in connection with food imports).
- ¹⁷⁵ Robert C. Bonner, Remarks of Commissioner Robert C. Bonner (Apr. 1, 2003), available at http://www.cbp.gov/xp/cgov/newsroom/commissioner/speeches_statements/archives/2003/apr01003.xml (last visited Feb. 28, 2010).
- ¹⁷⁶ Blas Nunez-Neto, Congressional Research Service, Border Security: Key Agencies and Their Missions 1 (2005).
- ¹⁷⁷ H.R. 3450, 103rd Cong. (1993).
- ¹⁷⁸ H.R. 5005, 107th Cong. (2002).
- ¹⁷⁹ *Id.*
- ¹⁸⁰ U.S. Customs & Border Prot., Securing America's Borders—CBP 2008 Fiscal Year in Review (Nov. 5, 2008) available at http://www.cbp.gov/xp/cgov/newsroom/highlights/08year_review.xml [hereinafter *CBP 2008*].
- ¹⁸¹ *Id.*
- ¹⁸² U.S. Customs & Border Prot., Budget Request for CBP Totals Just Under \$11 Billion (Feb. 5, 2008), http://www.cbp.gov/xp/cgov/newsroom/fact_sheets/cbp_overview/bdget_11bil_factsheet.xml (last visited Feb. 28, 2010) [hereinafter *CBP Budget Request 2008*].
- ¹⁸³ Written Testimony Before the H. Subcomm. on Homeland Security of the Appropriations Comm., 110th Cong. 12 (2007) (statement of W. Ralph Basham, Commissioner, U.S. Customs and Border Protection).
- ¹⁸⁴ *CBP 2008*, *supra* note 180.
- ¹⁸⁵ U.S. Gov't Accountability Office, GAO-05-372, Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation 43-44 (2005) [hereinafter *Strategic Framework*].
- ¹⁸⁶ *Id.*
- ¹⁸⁷ *Id.*
- ¹⁸⁸ *Id.*
- ¹⁸⁹ *Id.*
- ¹⁹⁰ *Id.*
- ¹⁹¹ *Id.*
- ¹⁹² U.S. Gov't Accountability Office, GAO-05-372, Prescription Drugs: Strategic Framework Would Promote Accountability and Enhance Efforts to Enforce the Prohibitions on Personal Importation Recommendations for Executive Action (2005) available at <http://www.gao.gov/products/GAO-05-372#recommendations> (last visited Apr. 2009) (updating online post tracking CBP progress in meeting GAO recommendations for a strategic framework) under GAO-05-372) [hereinafter *Recommendations for Executive Action*].
- ¹⁹³ See *id.* (showing GAO comments in response to CBP's submissions in regard to GAO's recommendations).
- ¹⁹⁴ Memorandum of Agreement Between Customs & Border Prot. & the Food & Drug Admin. 1 (Dec. 3, 2003) available at <http://www.fda.gov/AboutFDA/Partnerships/Collaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucml15145.htm> (last visited Feb. 28, 2010) [hereinafter *MOU*].
- ¹⁹⁵ *Id.*
- ¹⁹⁶ *Id.*
- ¹⁹⁷ Nunez-Neto, *supra* note 176, at 5.
- ¹⁹⁸ *Id.*
- ¹⁹⁹ Written Testimony Before the S. Comm. on Commerce, Sci., and Transportation, 110th Cong. 1 (2008) [hereinafter *Hawley Statement*] (statement of Kip Hawley, Assistant Secretary, U.S. Department of Homeland Security).
- ²⁰⁰ *Id.*
- ²⁰¹ Written Testimony Before the H. Subcommittee on Homeland Sec. of the Comm. on Appropriations, 111th Cong. 1 (2009) [hereinafter *Rossides Statement*] (statement of Gale D. Rossides, Acting Administrator, U.S. Department of Homeland Security).
- ²⁰² *Id.* at 2.
- ²⁰³ *Id.*
- ²⁰⁴ Transp. Sec. Admin., Screening Statistics: Facts and Figures for 2006 (2006) http://www.tsa.gov/research/screening_statistics.shtm [hereinafter *Screening Statistics*].
- ²⁰⁵ *Hawley Statement*, *supra* note 199, at 2.
- ²⁰⁶ *Id.*
- ²⁰⁷ *Id.*
- ²⁰⁸ See Michael A. Fletcher, Obama Leaves DC to Sign Stimulus Bill, Wash. Post, February 18, 2009, available at <http://www.washingtonpost.com/wp-dyn/content/article/2009/02/17/AR2009021700221.html?sid=ST2009021702300> (last visited Feb. 28, 2010).
- ²⁰⁹ *Taylor Statement I*, *supra* note 106.
- ²¹⁰ *NCHS Health 2008*, *supra* note 13.
- ²¹¹ *Future Growth of Older Populations*, *supra* note 16.
- ²¹² *Taylor Statement I*, *supra* note 106.
- ²¹³ See *infra*, Part V.A.1 (describing arguments in support of the difficulty of calculating accurate statistics on illicit importation through these channels and exploring their nature).
- ²¹⁴ *Strategic Framework*, *supra* note 186, at 43-44.
- ²¹⁵ See *infra*, Part V.A (discussing FDA budget figures, programs, and full time employment statistics).
- ²¹⁶ *FY 2009 Budget Press Release*, *supra* note 162.
- ²¹⁷ *CBP Budget Request 2008*, *supra* note 183.
- ²¹⁸ *Hawley Statement*, *supra* note 200, at 2.
- ²¹⁹ *Id.* at 1.
- ²²⁰ *FDA ORA FY 2010*, *supra* note 162; Liang, *supra* note 10, at 282; *Screening Statistics*, *supra* note 205; *CBP 2008*, *supra* note 181.
- ²²¹ Terrorism statistics are difficult to ascertain as most do not include foiled attempts. However, looking at fatality rates from terrorist attacks on commercial airplanes in the U.S., since 2000, roughly one of every 25 million passengers was killed in an attack. Nate Silver, *Crunching the Risk Numbers*, WALL ST. J., Jan. 8, 2010, available at <http://online.wsj.com/article/SB10001424052748703481004574646963713065116.html>.
- ²²² *FDA ORA FY 2010*, *supra* note 162, at 9.
- ²²³ Summary of the FDA's 2010 Budget, *supra* note 156.

²²⁴ Press Release, Food & Drug Admin., FDA Embarks on Major Hiring Initiative for its Public Health Mission (Apr. 2008).

²²⁵ Dr. Margaret Hamburg, Commissioner of Food and Drugs, Remarks at the Center for Strategic and International Studies (Feb. 4, 2010) *available at* <http://www.fda.gov/NewsEvents/Speeches/ucm199926.htm> [hereinafter *Hamburg Remarks*].

²²⁶ *FY 2009 Budget Press Release*, *supra* note 152; Human Drugs 2009, *supra* note 158, at 10.

²²⁷ *MOU*, *supra* note 195.

²²⁸ *Hawley Statement*, *supra* note 200, at 2.

²²⁹ Liang, *supra* note 10, at 282.

²³⁰ *See Stana Statement*, *supra* note 113, at 22 (stating that at one international mail facility in the U.S. 9,000 to 10,000 packages referred to the FDA by CBP were returned uninspected).

²³¹ *Strategic Framework*, *supra* note 186, at 26.

²³² *Id.* at 43-44.

²³³ *Recommendations for Executive Action*, *supra* note 193.

²³⁴ *Import Procedures*, *supra* note 126, at 9-12.

²³⁵ *See infra* Part IV.B.

²³⁶ *Hamburg Remarks*, *supra* note 225.

²³⁷ It should be noted that PREDICT is used for checking import shipments at border points, and seems not to apply to international mail facilities. *Id.*

²³⁸ *Import Procedures*, *supra* note 126, at 9-12.

²³⁹ *See infra* Part V.A (discussing FDA budget figures, programs, and full time employment statistics).

²⁴⁰ *Import Procedures*, *supra* note 126, at 9-13.

²⁴¹ *Hamburg Remarks*, *supra* note 225.

²⁴² *See infra* Part IV.B (describing trends in the price of prescription drugs, rise in health care costs and other contributing factors).

AT&T v. HULTEEN: THE GHOST OF THE SUPREME COURT ON PREGNANCY DISCRIMINATION AND PAY EQUALITY FOR WOMEN'S PENSION BENEFITS IN AMERICA

Walakewon Blegay*

I. Introduction

Title VII of the Civil Rights Act of 1964 (Civil Rights Act) was enacted to eliminate discriminatory employment practices on the basis of race, color, religion, sex or national origin.¹ In 1978, Congress elaborated on Title VII by enacting the Pregnancy Discrimination Act (PDA), requiring that employers treat pregnant employees the same as employees who were not pregnant.² In *AT&T v. Hulteen*, the Supreme Court ruled on whether it is permissible to penalize retiring women by lowering their retirement pension benefits for taking pregnancy-related disability leave before the enactment of the PDA.³

Consider this scenario: In 1976, Company H had a policy that distinguished disability leave based on whether it was pregnancy-related. Employees who took pregnancy-related disability leave only received pension benefits credit for thirty days of leave. Employees taking non-pregnancy-related disability leave received unlimited credit for their pension benefits.⁴ After the enactment of the PDA, Company H allowed the same credit for both pregnancy and non-pregnancy-related disability leave. However, it refused to adjust its credit system for the employees who took pregnancy-related disability leave before the PDA.⁵ Lilly, an employee of Company H, took pregnancy-related disability leave in 1976, before the Act, and received smaller pension benefits than her colleagues who took non-pregnancy-related disability leave.⁶ Under the holding of *AT&T v. Hulteen*, Lilly is not entitled to recover this discrepancy because Company H's pension benefits calculation is facially neutral. The PDA would have to be retroactive to find this action discriminatory.⁷

Historically, discrimination against women concerning childbirth and pregnancy was legally sanctioned and resulted in fewer advantages for women in the workforce.⁸ Pregnancy was treated less favorably than other physical conditions that affected an employee's performance in the workplace.⁹ Most employers discharged a woman as soon as she became noticeably pregnant, and if she returned, she was considered a new, rather than a returning employee.¹⁰

Before 1978, many employers would give female employees a maximum of thirty days of credited pregnancy-related disability leave, while non-pregnant employees would receive unlimited credit for disability leave.¹¹ Laws such as Title VII and the PDA were enacted to protect pregnant women from this practice.¹² These laws forced many employers to change their policies to allow unlimited credit for pregnancy-related disability leave.¹³ However, PDA women who took pregnancy-related disability leave prior to the Act, were unable to receive full credit for leave lasting longer than thirty days.¹⁴ Consequently, these women not only received smaller pension benefits, but also were ineligible for new early retirement programs.¹⁵

In *AT&T v. Hulteen*, the Supreme Court considered whether limiting the pregnancy-related benefits credit where leave was taken before the PDA, was a Title VII violation of the PDA.¹⁶ The Court held that employer AT&T did not violate Title VII when it limited pension benefits based on this criteria.¹⁷ The Court ruled that AT&T's actions were facially neutral and qualified for the bona fide seniority system exception.¹⁸ To create a Title VII violation, the Court concluded that the PDA would have to apply retroactively.¹⁹

This Note argues that the reasoning in *Hulteen* was flawed because AT&T's pension benefits calculation was intentionally discriminatory. Furthermore, the PDA does not have to be retroactive for AT&T's pension benefits calculation to be a Title VII violation.²⁰ Part II examines the congressional intent behind the PDA, the tests for determining a discriminatory action under Title VII, and the background of *Hulteen*.²¹ Part III argues that AT&T's pension benefits calculation was intentionally discriminatory and a current Title VII

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violation. The Court should have given the Equal Employment Opportunity Commission's position deference.²² Part IV proposes that, in response to *Hulteen*, Congress should amend the Lilly Ledbetter Fair Pay Act to decrease the employee's burden of proof in fringe benefit discrimination claims.²³ Part V concludes that *Hulteen* penalizes women that are protected by law for taking pregnancy-related disability leave and the law must be changed to provide relief to these women.²⁴

II. Background

A. The Civil Rights Act's Protection of Pregnant Women in the Workplace and the Supreme Court's Deference to the Equal Employment Opportunity Commission

The Civil Rights Act requires employers to provide equal opportunities to all employees.²⁵ Title VII of the Civil Rights Act prohibits discriminatory employment practices on the basis of race, color, religion, sex or national origin.²⁶ To meet this end, Title VII created the Equal Employment Opportunity Commission (EEOC) and delegated to it the primary responsibility of preventing and eliminating unlawful employment practices.²⁷ Employment discrimination based on pregnancy continued after the passage of the Civil Rights Act. In 1973, the EEOC responded by developing guidelines that prohibited employment policies that discriminated against pregnant employees.²⁸

The Supreme Court has given deference to the EEOC interpretation guidelines. The Court gives deference to an agency's interpretation of an ambiguous statute, if the agency has the authority to promulgate rules on that statute.²⁹ Congress gave the EEOC the power to issue regulations on Title VII and provided in Section 713(b) of Title VII that a reliance on the EEOC interpretations would absolve an employer from liability.³⁰ The Court gave the EEOC guidelines "great deference" in *Phillips v. Martin Marietta Corp.* because the EEOC was charged with administering Title VII.³¹ The Supreme Court also gave the EEOC guidelines "great deference" in *Griggs v. Duke Power Co.*, because the Civil Rights Act itself and the legislative history supported the EEOC interpretation.³² The Court has given the EEOC interpretations great deference, because the EEOC has been given authority by Congress to administer the principles of Title VII.³³

B. The Development of the PDA

Congress enacted the PDA in response to *General Electric Company v. Gilbert*, where the Court held that the exclusion of pregnancy-related disabilities from a company's comprehensive disability program did not constitute sex discrimination under Title VII.³⁴ Congress

elaborated on the purpose of Title VII by enacting the Pregnancy Discrimination Act that prohibited discrimination based on pregnancy, childbirth, or any related medical conditions.³⁵ Congress disagreed with the *Gilbert* decision and concluded that the company's employment practice was sex discrimination because men in the comprehensive disability program did not get the same treatment as women for involuntary or voluntary medical procedures.³⁶

The PDA requires that pregnant employees receive equal treatment as other employees with respect to their benefits, and their ability to work.³⁷ The plain language of the PDA defines discrimination "because of sex" or "on the basis of sex" to include discrimination based on pregnancy, childbirth, or pregnancy-related medical condition.³⁸ The statute also directly covers the receipt of benefits under a fringe benefit program.³⁹

At the time Congress enacted the PDA, over eighty million women were working to support their children. The employment practice upheld in *Gilbert* would have had a devastating effect on families.⁴⁰ Therefore, Congress enacted the PDA to repudiate the *Gilbert* decision, and prohibit employment decisions on the basis of pregnancy.⁴¹

C. The Bona Fide Seniority System Exception Under Title VII Section 703(h)

Congress exempted bona fide seniority systems from Title VII and the PDA if the discriminatory effect is facially neutral.⁴² A bona fide seniority system determines an employee's compensation, conditions or privileges of employment by the quantity or quality of production without intentionally discriminating based on race, color, religion, sex, or national origin.⁴³ Under Section 703(h) of Title VII, a seniority system is facially neutral if it unintentionally affects a protected group.⁴⁴ Employers seeking exemption must also show that their policies are implemented in good faith.⁴⁵

The Court has interpreted Section 703(h) to protect employers that have unintentionally extended the effect of past discrimination.⁴⁶ In *International Brotherhood of Teamsters v. United States*, Black and Hispanic employees brought a cause of action against their employer. Servicemen and city drivers, who were predominately Black and Hispanic, were paid less than line drivers, who were predominately White.⁴⁷ The city drivers or servicemen who transferred to line driver jobs started at the bottom of all line drivers, forfeited all of their competitive seniority.⁴⁸ The Court ruled that this seniority system was bona fide and exempt from Title VII under Section 703(h) because the system applied equally to all races.⁴⁹ Most of the city drivers and servicemen who were discouraged

Congress enacted the PDA in response to *General Electric Company v. Gilbert*, where the Court held that the exclusion of pregnancy-related disabilities from a company's comprehensive disability program did not constitute sex discrimination under Title VII.

from transferring to line driver jobs were White.⁵⁰ Therefore, the seniority system was not a violation of Title VII, because there was no discriminatory intent.⁵¹

D. When a Violation Occurs Under Title VII

The Civil Rights Act of 1991, states that a Title VII violation occurs when a discriminatory seniority system actually deprives an employee of benefits.⁵² In addition, President Obama signed recently signed the Lilly Ledbetter Fair Pay Act that states that an employer violates Title VII if its employee receives benefits that are based on discriminatory intent.⁵³ The Civil Rights Act of 1991, states that a Title VII violation occurs when a discriminatory seniority system actually deprives an employee of benefits.⁵⁴ The Lilly Ledbetter Fair Pay Act was a response to the *Ledbetter v. Goodyear Tire & Rubber Co. Inc.*⁵⁵ decision that ruled that an unlawful employment practice occurs each time an individual is paid or receives benefits that are subject to a discriminatory compensation decision.⁵⁶ Therefore, an employer violates Title VII when their employee receives benefits that are affected by a discriminatory decision.⁵⁷

E. Title VII Disparate-Impact Claims

The Supreme Court uses three tests to determine the legality of employment practices under Title VII.⁵⁸

1. The Similarly Situated Rule: Any Benefit that Delivers Less to a Similarly Situated Employee Is a Violation of Title VII

The Court developed the similarly situated rule in *Bazemore v. Friday*. According to this rule, a Title VII violation occurs every time an employee's compensation is affected by discrimination, regardless of whether the pattern began prior to the effective date of Title VII.⁵⁹ A Title VII violation occurs when similarly situated employees receive different pay. Liability may be imposed to the extent that the discrimination was perpetuated after the enactment of Title VII.⁶⁰

The Ninth Circuit applied the *Bazemore* rule in *Pallas v. Pacific Bell*, holding that Pacific Bell's pension benefits calculation violated Title VII.⁶¹ In 1987, the aggrieved party was deemed ineligible for her company's early retirement program, because she took pregnancy leave in 1972.⁶² The retirement program was facially discriminatory because it denied early retirement to women on the sole basis that they took pregnancy-related leave prior to the PDA.⁶³ The EEOC uses the fact pattern from *Pallas* as an example of an unlawful employment practice under Title VII.⁶⁴

2. The Present Violation Rule: A Seniority System Is Facially Neutral When It Gives Present Effect to Past Discrimination

The Supreme Court also evaluates Title VII disparate-impact claims using the present violation rule derived from *United Airlines v. Evans*.⁶⁵ This rule ensures that employers are not found liable under Title VII for facially neutral actions that are merely present effects of past discrimination.⁶⁶ In *Evans*, the Court held that the discriminatory effects of United Airlines' seniority system were solely the result of past discrimination, therefore no present violation existed.⁶⁷ The complaining party, worked as a flight attendant for United Airlines, which had a policy that flight attendants had to be unmarried females.⁶⁸ The airline forced her to resign in 1968 after she got married, then rehired her in 1972 without giving her any credit for her prior service.⁶⁹

The Court ruled that United Airlines' policy was non-discriminatory for two reasons. First, the claim was based on present effects of past discrimination, because the claim was brought in 1977, based on discrimination that occurred in 1968 and was corrected in 1972. Second, the policy applied to employees equally.⁷⁰ For these reasons, no Title VII violation had occurred.⁷¹

3. The Ledbetter Rule: Title VII Disparate-Impact Claims Must Show Unlawful Employment Practice and Discriminatory Intent.

In *Ledbetter v. Goodyear Tire & Rubber Co. Inc.* the Court introduced another rule to use when evaluating Title VII disparate impact claims. The *Ledbetter* Rule requires that a disparate-impact claim consist of an unlawful employment practice and discriminatory intent.⁷² In *Ledbetter*, the aggrieved party claimed that employer evaluated her poorly because of her gender, which resulted in lower pay than her male colleagues.⁷³ The Supreme Court reasoned that a fresh violation takes place when an unlawful employment practice is committed with intentions to discriminate.⁷⁴ A Title VII disparate-impact claim must include an unlawful employment practice and intentional discrimination.⁷⁵

F. AT&T v. Hulteen

The *Hulteen* Court evaluated whether AT&T's pension benefits calculation policy violated Title VII.⁷⁶ The policy denied full pension benefits to employees who took pregnancy-related disability leave prior to the PDA. However, the policy gave full pension benefits to employees that took other temporary non-pregnancy-related disability leave.⁷⁷ The Court held that AT&T's pension benefits calculation was a bona fide seniority system that was facially neutral and exempt from liability under Section 703(h).⁷⁸ The PDA would have to be retroactive to find AT&T's pension benefits calculation discriminatory.⁷⁹

1. Facts

The AT&T pension plan was inherited from its predecessor Pacific Telephone and Telegraph's (PT&T).⁸⁰ The PT&T pension plan was based on a net credit system, which calculated benefits based on an employee's period of service at the company minus his or her unaccredited leave.⁸¹ Employees who took pregnancy leave received the maximum service credit for six weeks of leave, while those on disability leave earned full service credit for their entire periods of absence.⁸² PT&T adopted an Anticipated Disability Plan (ADP) that granted service credit for pregnancy-related disability leave on the same basis as leave taken for other temporary disabilities.⁸³ When PT&T transferred its ownership to AT&T, AT&T retained its predecessor's policy and made no adjustments to the ADP for the credit lost by employees that took pregnancy-related disability leave prior to the PDA.⁸⁴

The aggrieved parties in this case took pregnancy-related disability leave before the PDA and did not receive credit for the leave taken over thirty days.⁸⁵ The parties filed a complaint with the EEOC between 1994 and 2002, and the EEOC issued a Letter of Determination finding reasonable cause to believe that AT&T discriminated against the respondents.⁸⁶

2. En Banc Review

On *en banc* review, the Ninth Circuit held that based on the similarly situated rule in *Bazemore* and *Pallas*, AT&T's pension benefits calculation

violated Title VII because it distinguished between similarly situated employees based on pregnancy.⁸⁷ AT&T violated Title VII because it excluded from the pension benefits calculation pregnancy-related disability leave lasting more than thirty days and taken prior to the PDA.⁸⁸ Holding that AT&T's policy was discriminatory was aligned with the Congressional intent behind the PDA.⁸⁹

The court reasoned that the present violation rule in *Evans* did not apply because AT&T's pension benefits calculation was neither a past violation with present effect nor facially neutral.⁹⁰ In fact, the Ninth Circuit held that the respondents' claim was a present violation of the PDA.⁹¹ Under the Civil Rights Act of 1991, the complaining parties were harmed when their pregnancy-related disability leave taken prior to the PDA was excluded from the pension benefits policy.⁹² AT&T's pension benefits calculation was intentionally discriminatory and a present Title VII violation.⁹³

3. The Supreme Court's Decision

On May 18, 2009, the Supreme Court overturned the Ninth Circuit's decision by ruling that AT&T's pension benefits calculation was facially neutral and not a violation of Title VII.⁹⁴ The Court held that the pension benefits in question were the current effects of AT&T's net credit system, which was considered lawful prior to the enactment of the PDA.⁹⁵ The similarly situated rule in *Bazemore* did not apply to this case.⁹⁶ The Court distinguished *Bazemore* because *Bazemore* did not involve a seniority system and that discriminatory action occurred prior to enactment of the .⁹⁷

The Supreme Court concluded that AT&T had a bona fide seniority system that is protected under Section 703(h), because it was not internationally discriminatory.⁹⁸ The only way to conclude that Section 703(h) does not protect AT&T's seniority system is to apply the PDA retroactively, which was not a clear Congressional intent.⁹⁹

In a dissenting opinion, Justice Ginsberg agreed with the Ninth Circuit's decision that AT&T's pension benefits calculation was intentionally discriminatory because it distinguished between the respondents and other similarly situated employees based on pregnancy.¹⁰⁰ Justice Ginsberg reasoned that while the PDA does not require redress for past discrimination, it was enacted to end sex-based discrimination from and after 1978.¹⁰¹

III. Analysis

A. The Supreme Court Erred in Ruling that AT&T's Pension Benefits Calculation Was Facially Neutral and Exempt from Liability Under the Bona Fide Seniority System Exception

The Supreme Court wrongly held that AT&T's pension benefits policy was exempt from liability under the bona fide seniority system exception. The policy violated Title VII because AT&T's benefits calculation was intentionally discriminatory according to the plain text and Congressional intent of the PDA, as well as judicial precedent.¹⁰²

1. AT&T's Pension Benefits Policy Is Intentionally Discriminatory According to the Plain Reading of the Pregnancy Discrimination Act, and Thus Violates Title VII.

The Court incorrectly held that AT&T's pension benefits calculation was facially neutral. AT&T's pension benefit calculation is intentionally discriminatory according to the plain text of the PDA.¹⁰³ Because the effect of the pension calculation was to reduce benefits based on sex, the plain text of the policy was intentionally discriminatory.¹⁰⁴ The PDA requires that the respondents be treated the same as other employees in their pension benefits, regardless of whether pregnancy-related disability leave was applied before the PDA.¹⁰⁵ The act of calculating the respondents' pension benefits is "based on" or "because of" sex because AT&T deliberately chose to use the credit application of the pregnancy-related disability leave from prior to the enactment of the PDA to calculate the complaining parties' pension benefits.¹⁰⁶

AT&T's pension benefits calculation was intentionally discriminatory because it violated the core principles of the PDA that require that employers treat "women affected by pregnancy" the same for all employment-related purposes.¹⁰⁷ The complaining parties were pregnant women affected by AT&T's pension benefits calculation because they were treated differently than other similarly situated employees who did not take pregnancy-related disability leave.¹⁰⁸ AT&T's pension benefits calculation awarded lesser pension benefits to the individuals who took pregnancy-related disability leave before the PDA was enacted than it awarded to other similarly situated employees that took non-pregnancy-related disability leave.¹⁰⁹ Therefore, the Court incorrectly held that AT&T's pension benefits calculation was facially neutral because the calculation was intentionally discriminatory according to the plain text of the PDA.¹¹⁰

“AT&T's pension benefits calculation was intentionally discriminatory because it violated the core principles of the PDA that require that employers treat “women affected by pregnancy” the same for all employment-related purposes.”

“AT&T’s intent to discriminate was further evinced when it agreed to award full credit to one female employee that took pregnancy-related disability leave before the PDA, without changing the net credited system for all affected employees.”

2. AT&T’s Pension Benefits Policy Is Intentionally Discriminatory According to the Congressional Intent of the Pregnancy Discrimination Act, and Thus Violates Title VII.

Additionally, the Court incorrectly held that AT&T’s pension benefits calculation was facially neutral because the calculation is intentionally discriminatory according to the congressional intent of the PDA.¹¹¹ Congress intended for the PDA to prohibit companies from reducing employees’ pension benefits because of pregnancy.¹¹²

Congress enacted the PDA to reestablish the principle of Title VII as it had been understood prior to the *Gilbert* decision.¹¹³ *Gilbert* upheld principles contrary to the EEOC interpretation guidelines on Title VII, which protected pregnant women from unjust employment discrimination.¹¹⁴ The legislative history of the PDA endorsed EEOC’s 1972 guidelines, that prohibited AT&T from reducing employees’ pension benefits based on pregnancy.¹¹⁵ The EEOC guidelines require an employer to calculate pension benefits and disability credit on the same terms for all employees.¹¹⁶

The PDA clarified that discrimination based on pregnancy and childbirth was sex discrimination and prohibited under Title VII.¹¹⁷ After the PDA, employment practices such as General Electric’s disability program, at issue in *Gilbert*, and AT&T’s pension benefits calculation are considered sex discrimination under Title VII.¹¹⁸ Therefore, the Supreme Court incorrectly held that AT&T’s pension benefits calculation was facially neutral because Congress intended for the PDA to require that pension benefits calculations provide the same benefits to all employees whether pregnant or not.¹¹⁹

3. AT&T’s Pension Benefits Calculation Is Intentionally Discriminatory According to the Bazemore Rule and Ledbetter Requirements, And Therefore Violates Title VII

Under *Bazemore*’s similarly situated rule, the Court incorrectly held that AT&T’s pension benefits calculation was facially neutral. Similar to the seniority system in *Bazemore*, where Black employees were paid less than White employees for the same position, AT&T granted full pension benefits for retiring employees who took non-pregnancy related disability leave and only granted partial credit to employees who took pregnancy-related leave.¹²⁰ AT&T’s intent to discriminate was further evinced when it agreed to award full credit to one female employee that took pregnancy-related disability leave before the PDA, without changing the net credited system for all affected employees.¹²¹ Following

Bazemore, courts have held, as in *Pallas* and *Hulteen*, that seniority systems awarding pensions disparately based on pregnancy are Title VII violations.¹²² AT&T’s pension benefits calculation is similar to the system in *Pallas*.¹²³ In *Pallas*, Pacific Bell’s new retirement program disqualified female employees because of pregnancy leave. Likewise, AT&T made no adjustments to PT&T’s net credit system causing employees that took pregnancy-related disability leave before the enactment of the PDA to suffer smaller pensions.¹²⁴ The previous analysis demonstrating that AT&T’s employment practice violated the *Bazemore* rule also demonstrates that the practice violates the Ledbetter standard for disparate-impact claims.¹²⁵ The Court wrongly held that AT&T’s pension benefits calculation was facially neutral because AT&T’s pension benefits calculation is intentionally discriminatory according to *Bazemore*’s similarly situated rule and *Ledbetter*’s disparate-impact claim requirements.¹²⁶

4. AT&T’s Pension Benefits Calculation Does Not Qualify for the Bona Fide Seniority System Exception in Teamster and Section 703(h), and Thus Violates Title VII.

The Court erred in applying *Teamsters* and the Section 703(h) exemption to AT&T’s pension benefits calculation.¹²⁷ Unlike the seniority system in *Teamsters* that applied to all races equally, AT&T’s seniority system did not apply to all employees equally.¹²⁸ Here, the complaining parties had sufficient evidence that the differential treatment resulting from AT&T’s pension benefits calculation was rooted in discriminatory intent.¹²⁹ The Supreme Court erred in applying *Teamsters* and the Section 703(h) exemption, and therefore AT&T violated Title VII.¹³⁰

B. The Court Erred in Holding that the PDA Would Have to Be Retroactive For It To Apply to AT&T’s Pension Benefits Calculation

The PDA would not require a retroactive effect for it to apply to the AT&T case for two reasons.¹³¹ First, the *Evans* present violation rule does not apply to this case. Second, AT&T’s pension benefits calculation is a present violation according to the Civil Rights Act of 1991 and the Lilly Ledbetter Fair Pay Act.

1. Evans’ Present Violation Rule Does Not Apply to AT&T’s Pension Benefits Calculation Because the Calculation Is a Present Title VII Violation

AT&T’s discriminatory act is different from the United Airlines’ seniority system in *Evans*.¹³² Unlike *Evans*, AT&T’s discriminatory act was a new Title VII violation because it distinguished between similarly situated employees.¹³³ *Evans*’ present violation

rule does not apply to this case because the AT&T employees were affected by both a decision to apply only thirty days of credit for their pregnancy-related disability leave, and the calculations of their pension benefits.¹³⁴

This case is not a present violation because AT&T's policy was not a violation continuing from prior to the enactment of the PDA. Each pension benefits calculation for each aggrieved party was a discriminatory compensation decision and a separate Title VII violation.¹³⁵ Therefore, the PDA would not have to be applied retroactively for AT&T's pension benefits calculation to constitute a present Title VII violation.¹³⁶

2. AT&T's Pension Benefits Calculation Is a Present Violation According to the Civil Rights Act of 1991 and the Lilly Ledbetter Fair Pay Act Because the Employees Were Harmed When They Received Smaller Pension Benefits Based on Pregnancy Discrimination.

According to the Civil Rights Act of 1991 and the Lilly Ledbetter Fair Pay Act, the PDA would not have to be applied retroactively for a Title VII violation because employees were harmed by the deprivation of benefits when they received smaller pension benefits based on pregnancy discrimination.¹³⁷ Both statutes allowed the complaining party to file a claim with the EEOC within 180 days of AT&T awarding reduced benefits based on pregnancy.¹³⁸

Under the Civil Rights Act of 1991 and the Lilly Ledbetter Fair Pay Act, the employees were harmed because they received reduced benefits.¹³⁹ Therefore, the respondents had the right under Title VII to file a charge with the EEOC each time they received a pension benefit based on pregnancy status.¹⁴⁰ In conclusion, the Supreme Court erred in holding that the PDA would have to be retroactive for the respondents to recover.¹⁴¹

C. The Court Should Have Given Deference to the Equal Employment Opportunity Commission's Endorsement of the Pallas Decision

The EEOC's endorsement of the *Pallas* decision was entitled to deference by the Court.¹⁴² If the Court had heeded the EEOC interpretation, it would have held that AT&T must allow women who were on pregnancy-related disability leave to accrue seniority in the same way as those who were on leave for reasons unrelated to pregnancy.¹⁴³ The EEOC deserved "great deference" in this case, similar to the level of deference in *Phillips* and *Griggs*.¹⁴⁴

EEOC is charged with administering Title VII.¹⁴⁵ Section 713(a) of Title VII grants the EEOC the power to issue regulations on Title VII.¹⁴⁶ Furthermore, Congress gave the EEOC authority to issue regulations defining unlawful employment practices under Title VII. Therefore, the Court should have given deference to any reasonable interpretation of the Title VII by the EEOC.¹⁴⁷

The Court should have given the EEOC guidelines "great deference" in determining a Title VII violation as it did in *Griggs*, because the EEOC's endorsement of the *Pallas* decision supports the principles of the Civil Rights Act and contains valid reasoning.¹⁴⁸ The factual similarities between *Hulteen* and *Pallas* make the EEOC's endorsement well-reasoned.¹⁴⁹

The EEOC's endorsement of the *Pallas* decision supports the principles of the Civil Rights Act because it required that women that are affected by pregnancy are treated the same as their colleagues who are not or cannot become pregnant.¹⁵⁰ Furthermore, the *Pallas* decision followed the principles of the PDA in clarifying that discrimination based on pregnancy and childbirth was sex discrimination and prohibited under Title VII.¹⁵¹ Therefore, the Supreme Court should have given the EEOC great deference.¹⁵²

IV. Policy Recommendation

A. Congress Should Decrease Employees' Burden of Proof of Intent to Discriminate in Fringe Benefit Discrimination Cases

The Court's decision in *AT&T v. Hulteen* is a setback in the fight for women's equality and will result in smaller pension and retirement benefits for women.¹⁵³ Congress must respond to the Court's decision, as it did in *Gilbert*, to protect these women from discriminatory employment practices.¹⁵⁴ Congress should amend the Lilly Ledbetter Fair Pay Act by decreasing the burden on employees to prove an employer's intent to discriminate.¹⁵⁵

While the Lilly Ledbetter Fair Pay Act made it easier for employees to win Title VII disparate-impact claims, employees still have a hefty burden of proof.¹⁵⁶ It is very difficult for an employee to prove the employer's intent to discriminate, especially when the practice originated years ago.¹⁵⁷ Congress should include clarifying language that an employee can prove a "discriminatory compensation decision" by showing that she is a member of the protected class and was treated differently than a similarly situated person.¹⁵⁸

“According to the Civil Rights Act of 1991 and the Lilly Ledbetter Fair Pay Act, the PDA would not have to be applied retroactively for a Title VII violation because employees were harmed by the deprivation of benefits when they received smaller pension benefits based on pregnancy discrimination.”

V. Conclusion

The Court holding in *AT&T v. Hulteen* was erroneous because AT&T's pension benefits calculation was intentionally discriminatory, a present Title VII violation, and failed to give the EEOC deference.¹⁵⁹ AT&T's pension benefits calculation should not have been allowed to prevail as a bona fide seniority system.¹⁶⁰ This decision penalizes women for taking pregnancy-related disability leave in their earlier careers, and creates another obstacle in work place equality.¹⁶¹

Congress should respond to this decision by amending the Lilly Ledbetter Fair Pay Act to decrease the burden on employees proving employer's intent to discriminate in fringe benefit discrimination.¹⁶² Congress' response will prevent unfair treatment of retirement mothers.¹⁶³

¹ See Pub. L. No. 88-352, § 703, 78 Stat. 241, 255 (1964) (codified as amended at 42 U.S.C. § 2000e-2 *et seq.* (2006)) (defining unlawful employment practices under the Civil Rights Act).

² See Pub. L. No. 95-555, 952 Stat. 2076 (1978) (codified as amended at 42 U.S.C. § 2000e(k)(2006)) (prohibiting employers' policies that discriminate against women based on pregnancy).

³ 129 S. Ct. 1962, 1971 (2009) (determining that PDA would have to be retroactive for retiring women to recover their pension benefits).

⁴ See *id.* at 1967 (noting that AT&T's policy for pregnancy-related disability leave only permitted six weeks of credited personal leave for female employees).

⁵ See *id.* (recognizing that after the enactment of PDA, AT&T adopted a leave policy that applied identically to both pregnant and non-pregnant employees).

⁶ See *id.* (mentioning that aggrieved employees received smaller pensions because of the pregnancy-related disability leave taken prior to the enactment of PDA).

⁷ See *id.* at 1973 (holding that AT&T's pension benefits calculation was a bona fide seniority system that was facially neutral and exempt from liability under Title VII).

⁸ See *id.* at 1974 (Ginsburg, J., dissenting) (acknowledging that societal attitudes about pregnancy and motherhood have severely impeded women's employment opportunities).

⁹ See CONGRESSIONAL RESEARCH SERVICE, JUDICIAL AND LEGISLATIVE TREATMENT OF PREGNANCY: A REVIEW OF DEVELOPMENTS FROM UNPROTECTED STATUS TO ANTI-DISCRIMINATION-EQUAL TREATMENT DEVELOPMENTS AND SPECIAL TREATMENT 4 (Library of Congress) (1987) (providing examples of state laws that prohibit pregnant women from working or receiving benefits, under the rationale that pregnant women and healthy babies need protection).

¹⁰ See S. COMM. ON LABOR AND HUMAN RESOURCES, 96TH CONG., *LEGISLATIVE HISTORY OF THE PREGNANCY DISCRIMINATION ACT OF 1978*, Pub. L. No. 95-555, at 25 (Comm. Print 1980) [hereinafter *LABOR AND HUMAN RESOURCES*] (establishing that women in this situation lose comprehensive pension benefits due to this policy).

¹¹ See Shannon Barrows Bjorklund, *The Impact of Pregnancy Discrimination on Retirement Benefits: A Present Violation of Title VII or Claim Belonging to History*, 75 U. CHI. L. REV. 1191, 1192 (2008) (asserting that this dilemma has affected a large number of women by causing a loss of retirement benefits).

¹² See Pub. L. No. 88-352, 78 Stat. 241 (1964) (codified as amended at 42 U.S.C. § 2000e *et seq.* (2006)) (prohibiting unlawful employment practices against female employees); see Pub. L. No. 95-555, 952 Stat. 2076 (1978) (codified as amended at 42 U.S.C. § 2000e(k)(2006)) (protecting women that have been affected by pregnancy from discriminatory employment practices).

¹³ See *LABOR AND HUMAN RESOURCES*, *supra* note 10, at 12 (explaining that PDA and Title VII require that all employers provide the same leave and benefit policies to all employees).

¹⁴ See Bjorklund, *supra* note 11, at 1192 (highlighting employers such as Bell Companies that refused to grant full credit for pregnancy-related disability leave taken over thirty days).

¹⁵ See *Hulteen*, 129 S. Ct. at 1966; *Leffman v. Sprint Corp.*, 481 F.3d 428, 432 (6th Cir. 2007); *Ameritech Benefit Plan Comm. v. Comm'n Workers of Am.*, 220 F.3d 814, 823 (7th Cir. 2000); *Pallas v. Pac. Bell*, 940 F.2d 1324, 1327 (9th Cir. 1991) (adjudicating claims against employers that refuse to adjust the credit of female employees that took pregnancy-related disability leave prior to the enactment of PDA).

¹⁶ See 129 S. Ct. 1962; Bjorklund, *supra* note 11, at 1192 (explaining how Section 703(h) exempts seniority systems that limit pension benefits based on pregnancy from liability if they are facially neutral).

¹⁷ See *Hulteen*, 129 S. Ct. at 1970 (holding that the actual credit application was a past action that was lawful prior to the enactment of PDA).

¹⁸ See *id.* (reasoning that AT&T's pension benefit calculation was not intentionally discriminatory because AT&T changed its policy to apply to all employees equally after the enactment of PDA).

¹⁹ See *id.* at 1971 (recognizing that there is no congressional intent showing that PDA is retroactive).

²⁰ See *id.* at 1980 (Ginsburg, J., dissenting) (arguing that AT&T's pension benefits calculation is intentionally discriminatory according to congressional intent and the Supreme Court's precedent).

²¹ See *infra* Part II (explaining the evolution in jurisprudence for the calculation of pregnancy-related disability leave taken prior to the enactment of PDA under Title VII).

²² See *infra* Part III (concluding that AT&T's pension benefits calculation does not qualify for the bona fide seniority system exception in Section 703(h)).

²³ See *infra* Part IV (addressing the implications of this policy and its impact on women).

²⁴ See *infra* Part V (recognizing that *AT&T v. Hulteen* leaves an obstacle in the workplace).

²⁵ See H.R. REP. NO. 95-948, at 2 (1978), *reprinted in* 1978 U.S.C.C.A.N. 4717, 4751 (prohibiting discrimination against an employee because of his or her race, color, religion, sex, or national origin).

²⁶ See *LABOR AND HUMAN RESOURCES*, *supra* note 10, at 12 (enacting the Civil Rights Act to protect all individuals from unjust employment discrimination, including pregnant women).

²⁷ See H.R. REP. NO. 86-187, at 151 (1964), *as reprinted in* 1964 U.S.C.C.A.N. 2183, 2355 (assigning the task of upholding the principles of Title VII to the EEOC).

²⁸ See 29 C.F.R. § 1604.10 (1973) (providing that all employment practices, such as the duration of leave, accrual of seniority benefits, privileges, and payment under any health or temporary disability insurance or sick leave plan, shall be applied to disability due to pregnancy or childbirth on the same terms and conditions as they are applied to other disabilities).

²⁹ See *Chevron U.S.A. Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984) (holding that an agency interpretation of an ambiguous statute is entitled to agency deference where the grant of authority was ambiguous and the interpretation was reasonable or permissible).

³⁰ See John S. Moot, *An Analysis of Judicial Deference to EEOC Interpretation Guidelines*, 1 ADMIN. L.J. 213, 223 (1987) (recognizing that the EEOC has the authority to issue interpretations of Title VII); 42 U.S.C. § 2000e-12(a) (2006) (giving the EEOC the authority to issue procedural regulations in administering the provisions of Title VII).

³¹ 400 U.S. 542, 545 (1971) (following the interpretation of the EEOC for defining Title VII's exception for employment decisions based on a bona fide occupational qualification).

³² 401 U.S. 434 (1971) (holding that the EEOC interpretation precludes that use of employment testing procedures unless they are substantially job related).

³³ See Moot, *supra* note 30, at 224 (proving the Supreme Court's willingness to share the responsibility with the EEOC to construe Title VII).

³⁴ See 429 U.S. 125, 136 (1976) (reasoning that this exclusion does not discriminate against women because not all women are pregnant).

³⁵ See *LABOR AND HUMAN RESOURCES*, *supra* note 10, at 1 (describing the *Gilbert* decision as a serious setback to women's rights and the development of Title VII).

³⁶ See *id.* at 17 (considering that many male disabilities such as vasectomies, circumcisions, prostatectomies and sports injuries were covered, while pregnancy was the only disability excluded).

³⁷ See *id.* at 25 (rejecting the view that employers may treat pregnancy

and its incidents with disregard to its functional comparability to other conditions).

³⁸ See 42 U.S.C. § 2000e(k) (2006) (prohibiting employment practices that are based on anything relating to sex and nothing in the statute can be interpreted otherwise).

³⁹ See *id.* (clarifying that PDA applies to all employment-related purposes).

⁴⁰ See LABOR AND HUMAN RESOURCES, *supra* note 10, at 3 (acknowledging that decisions such as *Gilbert* will have the detrimental effect of keeping women at the lowest rung of the job ladder).

⁴¹ See *Hulteen*, 129 S. Ct. at 1976 (Ginsburg, J., dissenting) (arguing that PDA also prohibits pension payments that treat women affected by pregnancy disadvantageously).

⁴² See 42 U.S.C. § 2000e-2(h) (2006) (indicating that it is not discriminatory for a bona fide seniority system to distinguish between similarly situated employees based on sex).

⁴³ See *id.*

⁴⁴ See *id.* (stating that a seniority system that intentionally discriminates based on sex is not exempt under Title VII).

⁴⁵ See Bjorklund, *supra* note 11, at 1194 (explaining that the seniority system exception is provided even if a system has a negative disparate-impact on protected groups).

⁴⁶ See *Int'l Brotherhood of Teamsters v. United States*, 431 U.S. 324, 353 (1977) (emphasizing that the seniority system perpetuates the effects of pre-Act discrimination).

⁴⁷ See *id.* at 329 (showing the disparate-impact on the minority community).

⁴⁸ See *id.* at 344 (recognizing that the seniority system locks Black and Hispanic Americans in non-line driver job because of the loss of seniority).

⁴⁹ See *id.* at 356 (arguing that an overwhelming majority of workers that are discouraged from transferring to line driver jobs are White).

⁵⁰ See *id.* (noting that the practice of placing different jobs in separate bargaining units is in accord with industry practice and consistent with the National Labor Relation Board).

⁵¹ See *id.* (determining that the disparate-impact on the minority employees was just the present effects of past discrimination).

⁵² See Civil Rights Act of 1991, Pub. L. No. 102-166, § 112, 105 Stat. 1071, 1079 (1991) (codified as amended at U.S.C. § 2000e-5(e)(2) (2006)) (applying to seniority systems that have been adopted for an intentionally discriminatory purpose).

⁵³ See Lilly Ledbetter Fair Pay Act of 2009, Pub. L. No. 111-2, 123 Stat. 5 (2009) (codified as amended at 42 U.S.C. § 2000e-5(e) (2006)) (clarifying that an employee is harmed by the deprivation of benefits every time they receive a paycheck that is subject to discriminatory intent).

⁵⁴ See Civil Rights Act of 1991, Pub. L. No. 102-166, § 112, 105 Stat. 1071, 1079 (1991) (codified as amended at U.S.C. § 2000e-5(e)(2) (2006)) (applying to seniority systems that have been adopted for an intentionally discriminatory purpose).

⁵⁵ 550 U.S. 618, 621 (2007)

⁵⁶ See Lilly Ledbetter Fair Pay Act of 2009, Pub. L. No. 111-2, 123 Stat. 5 (2009) (codified as amended at 42 U.S.C. § 2000e-5(e) (2006)) (allowing the aggrieved person to obtain relief, including recovery of back pay from their employer).

⁵⁷ See Bjorklund, *supra* note 11, at 1196 (analyzing congressional intent to bar all challenges to present day application of discriminatory practices that were in existence when Title VII became law).

⁵⁸ See *id.* (acknowledging that the Supreme Court had to specifically resolve what constituted a present violation of Title VII in the use of pay scales and seniority systems that have continued their patterns from before the enactment of Title VII).

⁵⁹ See *Bazemore v. Friday*, 478 U.S. 385, 396 (1986) (indicating that it is the duty of the employer to eliminate pre-Act discriminatory practices).

⁶⁰ See *id.* (ensuring that employees of all races are protected from unlawful employment practices).

⁶¹ See *Pallas*, 940 F.2d at 1327 (discussing the perpetuation of the discrimination that occurred prior to the enactment of PDA).

⁶² See *id.* at 1326 (observing that the respondent was three to four days short of the necessary amount of service credit).

⁶³ See *id.* (reasoning that this was not an attempt to litigate the discriminatory impact of a program initiated before the enactment of PDA).

⁶⁴ See EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, *EMPLOYEE BENEFITS*,

EEOC COMP. MAN. § 3-VIII(B)(Oct. 3, 2000).

⁶⁵ 431 U.S. 553, 558 (1977) (defining present or past violations under Title VII).

⁶⁶ *Id.* at 558.

⁶⁷ See *id.* at 556 (indicating that the emphasis should not be on a continuing violation that began prior to the enactment of Title VII but proving that a present violation exists).

⁶⁸ See *id.* at 554.

⁶⁹ See *id.* at 555 (mentioning that United Airlines entered a new collective bargaining agreement which ended the “no marriage” rule” but the respondent was not covered under that agreement).

⁷⁰ See *id.* at 557 (arguing that United Airlines had a bona fide seniority system because the policies applied to all employees equally).

⁷¹ See *id.* (concluding that unlike the no-marriage policy, having less seniority is not the consequence of sex discrimination).

⁷² See *Ledbetter v. Goodyear Tire & Rubber Co. Inc.*, 550 U.S. 618, 621 (2007) (explaining that the EEOC charging period is triggered when a discrete unlawful practice takes place).

⁷³ See *id.* at 621 (mentioning that the petitioner submitted a questionnaire to the EEOC alleging certain sex discrimination).

⁷⁴ See *id.* at 628 (defining “employment practice” as a discrete act or single occurrence).

⁷⁵ See *id.* at 634 (characterizing the similarly situated violation in *Bazemore* as an obvious discriminatory act).

⁷⁶ See *Hulteen*, 129 S. Ct. at 1966 (determining whether AT&T’s pension benefits calculation was set under a bona fide seniority system).

⁷⁷ See *id.* (determining whether AT&T’s pension benefits calculation was set under a bona fide seniority system).

⁷⁸ See *id.* at 1971 (recognizing that AT&T’s alleged discriminatory action was lawful under *Gilbert*).

⁷⁹ See *id.*

⁸⁰ See *Hulteen v. AT&T Corp.*, 2003 WL 25777891, at *3 (N.D. Cal. Aug. 11, 2003), *rev’d*, 441 F.3d 653 (9th Cir. 2006), *rev’d en banc*, 498 F.3d 1001 (9th Cir. 2007) (suggesting the transfer would have been an ideal time for AT&T to apply full credit for the female employees that took pregnancy-related disability leave prior to the enactment of PDA).

⁸¹ See *Hulteen*, 2003 WL 25777891, at *1 (explaining that this calculation is the basis for determining early retirement, qualification for certain voluntary termination packages, job bidding and shift preference).

⁸² See *id.* at *3 (observing that before 1977, AT&T had a “forced leave” policy that required pregnant women to take personal leave before they were rendered disabled).

⁸³ See *id.* at *2 (noting that the ADP superseded the Pregnancy Payment Plan, where the employee could begin pregnancy-related disability leave at any time but could only be eligible for disability benefits for up to thirty days).

⁸⁴ See *id.* (explaining that the lack of adjustment in service credit resulted in loss of eligibility for early retirement and smaller pension benefits).

⁸⁵ See *id.* at *1 (discussing their argument that AT&T had a fiduciary duty to treat all employees equally).

⁸⁶ See *Hulteen*, 498 F.3d at 1004 (acknowledging that the Communications Workers of America also filed a charge of discrimination with the EEOC).

⁸⁷ See *id.* at 1015 (reasoning that liability was imposed on AT&T perpetuating pre-Pregnancy Discrimination Act discrimination in their pension benefits calculation).

⁸⁸ See *id.* at 1011 (holding that AT&T’s pension benefits calculation was obviously discriminatory and too apparent to warrant discussion).

⁸⁹ See *id.* at 1010 (asserting the importance of interpreting according to the ordinary meaning of the statute).

⁹⁰ See *id.* at 1006 (distinguishing the seniority system in *Evans* from the systems in *Pallas* and *Hulteen* that developed early retirement programs using intentionally discriminatory pension benefits calculations).

⁹¹ See *id.* at 1011 (dismissing AT&T’s argument that PDA is being applied retroactively).

⁹² See *Hulteen*, 498 F.3d at 1011. (establishing that it was well within AT&T’s control to add the pregnancy-related disability leave taken prior to the enactment of PDA in the pension benefits calculation).

⁹³ See *id.* (indicating that the plain reading of Title VII supports this holding).

⁹⁴ See *Hulteen*, 129 S. Ct. at 1969 (recognizing that seniority systems receive special treatment under Title VII).

⁹⁵ See *id.* at 1966 (concluding that AT&T's net credit system was consistent with the rule of *Gilbert*).

⁹⁶ See *Bazemore v. Friday*, 478 U.S. 385, 396 (1986) (holding that a Title VII violation occurs every time an employee's compensation delivers less to a similarly situated employee because of discriminatory intent).

⁹⁷ See *id.* (acknowledging that the discriminatory action in *Bazemore* began before the enactment of Title VII and continued after Title VII was enacted).

⁹⁸ See *Hulteen*, 129 S. Ct. at 1970 (indicating that AT&T's pension benefits calculation was not considered gender discrimination).

⁹⁹ See *id.* at 1971 (concluding that Congress intended that PDA take effect on the day of its enactment, except in its application to certain benefits programs, as to which effectiveness was retroactive 180 days).

¹⁰⁰ See *id.* at 1976 (Ginsburg, J., dissenting) (confirming that the repetition of pregnancy-based disadvantageous treatment is prohibited under Title VII).

¹⁰¹ See *id.* at 1974 (Ginsburg, R., dissenting) (pointing out the history of discrimination against women concerning childbirth and pregnancy that was legally sanctioned and resulted in fewer advantages for women in the workforce).

¹⁰² See *Hulteen*, 498 F.3d at 1015 (reasoning that liability was imposed on AT&T because of AT&T's intent to discriminate).

¹⁰³ See *id.* at 1010 (supporting the legal conclusion that the plain reading of Title VII prohibits AT&T's pension benefits calculation for the respondents).

¹⁰⁴ See *id.* at 1011 (recognizing that AT&T deliberately lowered the respondents' pension benefits because they were pregnant).

¹⁰⁵ See *Hulteen*, 129 S. Ct. at 1980 (Ginsburg, J., dissenting) (declaring that PDA is to be understood as establishing that no woman's pension benefits are to be diminished based on pregnancy).

¹⁰⁶ See *Hulteen*, 498 F.3d at 1011 (recognizing that it was well within AT&T's control to account for the full pregnancy-related disability leave from prior to the enactment of PDA in the pension benefits calculation).

¹⁰⁷ See 42 U.S.C. § 2000e(k) (2006) (including that employers are required to provide the same benefits to all of their employees for employment purposes).

¹⁰⁸ See *Hulteen*, 498 F.3d at 1010 (adopting the dictionary definition which defines "affect" as acted upon, influenced, or changed).

¹⁰⁹ See *id.* at 1011 (arguing that the respondents were affected by AT&T's actions during two separate events: the credit application and the pension benefits calculation).

¹¹⁰ See *id.* at 1010 (concluding that AT&T continued its systematic discrimination, which was illegal under PDA).

¹¹¹ See *Hulteen*, 129 S. Ct. at 1980 (Ginsburg, J., dissenting) (confirming that Congress repudiated employment practices similar to AT&T's pension benefits calculation by enacting PDA).

¹¹² See H.R. REP. NO. 95-948, at 2 (1978), as reprinted in 1978 U.S.C.A.N. 4717, 4750 (prohibiting discrimination based on pregnancy, childbirth and related medical conditions).

¹¹³ See *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 675-76 (1983) (mentioning that when Congress amended Title VII, it unambiguously expressed its disapproval of both the holding and reasoning of the Supreme Court in the *Gilbert* decision).

¹¹⁴ See LABOR AND HUMAN RESOURCES, *supra* note 10, at 12 (asserting that *Gilbert* destroyed the hard work of the EEOC in eliminating pregnancy discrimination).

¹¹⁵ See H.R. REP. NO. 94, at 2 (confirming that the guidelines rightly implemented Title VII by prohibiting employment practices based on pregnancy or pregnancy-related medical conditions).

¹¹⁶ See 29 C.F.R. § 1604.10 (1973) (requiring that seniority benefits that affect disability leave should also be applied to all employees equally).

¹¹⁷ See LABOR AND HUMAN RESOURCES, *supra* note 10, at 12 (amending Title VII so that there can be no doubt of congressional intent to prohibit pregnancy discrimination).

¹¹⁸ See *id.* at 39 (recognizing that the core principle under Title VII would consider a classification involving pregnancy as strongly "sex related"); See *Hulteen*, 129 S. Ct. at 1970 (comparing AT&T's seniority system to the system in *Gilbert*).

¹¹⁹ See *Hulteen*, 129 S. Ct. at 1975-76 (arguing that the Supreme Court erroneously upheld *Gilbert* as law today, after Congress clearly stated *Gilbert*

was wrongly decided).

¹²⁰ See *Hulteen*, 498 F.3d at 1004 (recognizing that the limitation of the credit for the respondents resulted in reduced pension benefits).

¹²¹ See *id.* at 1011-12 (referencing a letter that the employee received from AT&T voluntarily offering to credit thirty days of pregnancy-related disability leave taken in 1974 to her pension benefits).

¹²² See *id.* at 1007 (establishing that liability is imposed each time similarly situated employees are treated differently based on pregnancy).

¹²³ See *id.* at 1015 (denying AT&T's claim that *Pallas* should be overruled).

¹²⁴ See *id.* at 1003 (implying that the respondents would have had more favorable retirement benefits if they had taken non-pregnancy-related disability leave).

¹²⁵ See *Ledbetter*, 550 U.S. at 633 (recognizing the employment practice in *Bazemore* as obviously unlawful according to Title VII).

¹²⁶ See *Hulteen v. AT&T*, 498 F.3d 1001, 1006-07 (9th Cir. 2007) (en banc) (concluding that an employer who adopts and retains a pay structure such as the one in *Bazemore* is intentionally discriminating against its employees).

¹²⁷ See *AT&T Corp. v. Hulteen*, 129 S. Ct. 1962, 1977 (2009) (Ginsburg, J., dissenting) (implying that it would be difficult to conclude that AT&T's scheme was neutral on its face and discriminated against women only in effect).

¹²⁸ See *id.* (describing the seniority system in *Hulteen* as unequal in its application); see also *Teamsters v. United States*, 431 U.S. 324, 356 (1977) (arguing that the workers that are discouraged from transferring to line driver jobs are White, Black and Hispanic).

¹²⁹ Cf. *Teamsters*, 431 U.S. at 358 (reasoning that the petitioners were unable to provide sufficient evidence of discriminatory intent).

¹³⁰ See *id.* at 1980 (concluding that Congress did not intend the reduction of women's pension benefits attributable to their placement on pregnancy-related disability leave to result from employer's discriminatory practices).

¹³¹ See *Hulteen v. AT&T*, 498 F.3d 1001, 1006-07 (9th Cir. 2007) (en banc) (affirming that each paycheck that violates *Bazemore*'s similarly situated rule is a separate Title VII violation).

¹³² See *Evans*, 431 U.S. at 557 (recognizing that the *Evans* claim was brought in 1972, which is four years after United Airlines' discriminatory act).

¹³³ See *Ledbetter v. Goodyear Tire & Rubber Co.*, 550 U.S. 618, 631 (2007) (confirming that a new Title VII violation occurs when an unlawful employment practice and discriminatory intent is proven).

¹³⁴ See *id.* at 1010 (arguing that the respondents were affected by an employment decision made on the basis of pregnancy which is prohibited by PDA).

¹³⁵ See *Bazemore*, 478 U.S. at 398 (reasoning that a violation occurs every time an unlawful Title VII employment practice is applied).

¹³⁶ See *Ledbetter v. Goodyear Tire & Rubber Co.*, 550 U.S. 618, 630-31631 (2007) (noting that a new EEOC charging period commences when a new Title VII violation occurs).

¹³⁷ See *Hulteen*, 498 F.3d at 1011 (ruling that the respondents were injured by the deprivation of benefits by AT&T in 1994).

¹³⁸ See Civil Rights Act of 1991, Pub. L. No. 102-166, § 112, 105 Stat.

1071, 1079 (1991) (codified as amended at 42 U.S.C. § 2000e-5(e)(2) (2006)) (clarifying that the injury occurs at the time the seniority system is applied to the aggrieved party); see also *Lilly Ledbetter Fair Pay Act of 2009*, Pub. L. No. 111-2, 123 Stat. 5 (2009) (codified as amended at 42 U.S.C. § 2000e-5(e) (2006)) (stating that an unlawful employment practice occurs when an individual is subject to a discriminatory compensation decision).

¹³⁹ See *Bazemore*, 478 U.S. at 395398 (holding that liability may be imposed on an employer for perpetuating pre-Title VII discriminatory employment decisions in the present day).

¹⁴⁰ See *Ledbetter*, 550 U.S. at 636 (reasoning that the existence of past discriminatory acts does not bar employees from filing charges about related discrete acts so long as the acts are independently discriminatory).

¹⁴¹ See *Hulteen*, 498 F.3d at 1011 (concluding that AT&T's pension benefits calculation violated PDA).

¹⁴² See *Pallas v. Pac. Bell*, 940 F.2d 1324, 1327 (9th Cir. 1991) (holding that Pacific Bell's early retirement program was facially discriminatory because it treated employees differently based on pregnancy).

¹⁴³ See EQUAL EMPLOYMENT OPPORTUNITY COMMISSION, *EMPLOYEE BENEFITS*, EEOC COMP. MAN. § 3-V.III(B)(Oct. 3, 2000) (requiring that employers

treat pregnancy-related disability leave the same as other medical leave in calculating the years of service that will be credited in evaluating an employee's eligibility for a pension or for early retirement).

¹⁴⁴ See Moot, *supra* note 30, at 224 (noting that the EEOC's main authority is to investigate charges and file lawsuits relating to the Title VII).

¹⁴⁵ See *id.* at 223 (explaining that Justice Marshall's deference to the EEOC in *Phillips* supports a broader principle of deferring to the EEOC interpretation where reasonable).

¹⁴⁶ See 42 U.S.C. § 2000e-12(a) (2006) (giving the EEOC the authority to issue procedural regulations in administering the provisions of Title VII).

¹⁴⁷ See H.R. REP. NO. 86-187, at 151 (1964), *as reprinted in* 1964 U.S.C.C.A.N. 2183, 2355 (assigning the task of upholding the principles of Title VII to the EEOC).

¹⁴⁸ See *Griggs v. Duke Power Co.*, 401 U.S. 424 (1971) (characterizing the EEOC as the "enforcing agency" for Title VII).

¹⁴⁹ *Contra* Bjorklund, *supra* note 11, at 1207 (arguing that EEOC's position lacks consistency and persuasiveness).

¹⁵⁰ See *Pallas v. Pac. Bell*, 940 F.2d 1324, 1326-27 (9th Cir. 1991) (emphasizing the purpose of the Civil Right Act in protecting pregnant employees from employment discrimination based on sex).

¹⁵¹ See *id.* at 12 (establishing that Title VII was intended to prohibit pregnancy discrimination).

¹⁵² *Contra* Bjorklund, *supra* note 11, at 1207 (arguing that the EEOC is not entitled to the *Chevron* deference but can be a persuasive authority).

¹⁵³ See *AT&T Corp. v. Hulteen*, 129 S. Ct. 1962, 1978 (2009) (Ginsburg, J., dissenting) (explaining the historical perception of women as mothers and not workers).

¹⁵⁴ See Bjorklund, *supra* note 11, at 1192 (determining that the Ninth Circuit decision in *Pallas* affected over 37,000 women).

¹⁵⁵ See *id.* (emphasizing the Supreme Court's high regard for employees demonstrating the existence of an "intentionally" discriminatory decision).

¹⁵⁶ See Mark H. Meyerhoff & Elizabeth A. Avedikian, *The Impact of AT&T v. Hulteen*, LAW 360, June 10, 2009, at 4, *available at* http://www.lcwlegal.com/newspublications/Articles/Law360_0611_AvedikianMeyerhoff.pdf (concluding that *Hulteen* will toll the length of time within which employees may bring pay discrimination charges).

¹⁵⁷ See *id.*, at 4 (noting that even with the accomplishments of the Lilly Ledbetter Fair Pay Act, it will be very difficult for an employee to prove that an employer intentionally discriminated against them for years).

¹⁵⁸ See *Bazemore v. Friday*, 478 U.S. 385, 395 (1986) (establishing that the employees were protected under Title VII and proved that their employer treated them differently than other similarly situated employees based on race).

¹⁵⁹ See *AT&T Corp. v. Hulteen*, 129 S. Ct. 1962, 1970 (2009) (holding that AT&T's pension benefits calculation was not intentionally discriminatory and is a bona fide seniority system).

¹⁶⁰ See *id.* (holding that AT&T's pension benefits calculation was facially neutral).

¹⁶¹ See *id.* at 1976 (Ginsburg, J., dissenting) (stressing that this decision confirms societal attitudes about pregnancy and motherhood).

¹⁶² See Meyerhoff & Avedikian, *supra* note 157, at 4 (indicating that decreasing the employee's burden in proving intent to discrimination will satisfy the necessity of demonstrating the existence of an "intentionally" discriminatory decision).

¹⁶³ See *Hulteen*, 129 S. Ct. at 1980 (Ginsburg, J., dissenting) (recognizing that the respondents will continue to experience the impact of a "*Gilbert-blessed-plan*" for the rest of their lives).

SALIENT ISSUES AFFECTED BY THE 2010 HEALTH REFORM LAW

Curbing Medicaid Fraud

Ernest Johnson, 2L

Since the formation of the Medicaid program, Medicaid fraud has persisted. Cases involving fraud, waste, and abuse have included unscrupulous doctors and nurses abusing the program by issuing faulty bills, overcharging for services, or offering payments in exchange for an individual's Medicaid number. The victims are often patients of a lower socioeconomic status with very few options for redress.

The new health care reform law provides opportunities designed to strengthen the current Medicaid safeguards. Under the new law, there is a substantial \$250 million dollar increase over the next ten years in funding for the Health Care Fraud and Abuse Control Fund, which is overseen by the Health Care Fraud and Abuse Control Program (HCFAC). The HCFAC was designed to harmonize local, state and federal law enforcement activities in their efforts to combat health care fraud and abuse.

With this increased funding, Medicaid will be able to strengthen its Medicaid Fraud Control Units (MFCU). These units were established by Congress in 1977 to investigate cases revealing intent to defraud the Medicaid Program. MFCUs also scrutinize situations involving the neglect or abuse of patients, such as those in nursing homes. To assist in this effort, the National Association of Medicaid Fraud Control Units will continue to aid in the interstate communication between MFCUs.

Abortion and Healthcare Reform

Kristen Barry, 2L

During the last year of the health care reform debate, abortion has been at the forefront of controversy leading up to the passage of the Patient Protection and Affordable Care Act. In fact, President Obama's Executive Order to

ensure the enforcement and implementation of abortion restrictions has been seen as the key to obtaining the necessary votes to pass health care reform legislation in the House of Representatives. The Executive Order essentially maintains the Hyde Amendment, which has banned the use of federal funds for abortion since 1976 with exceptions for rape, incest and danger to the mother's life.

Prior to the Executive Order, there were some concerns by pro life activists that the new law left a grey area where federal funds might be used for abortions under the new insurance exchange and in federally run community health clinics.

To address the first concern, the bill added language imposing a surcharge that would be paid by individuals electing a health insurance policy with abortion coverage. The funds obtained from the surcharge would be kept separate from taxpayer money. In addition, no health plan is required to offer coverage for abortion services and states are given the option to ban abortion coverage in health plans offered through the exchange.

President Obama's Executive Order addressed the second concern by stating that federal law under the Hyde Amendment prohibits use of federal funds for abortion services in federally funded Community Health Centers. Again, the language stressed that the Hyde Amendment abortion protections remained intact and applied to the health care reform bill.

The Scope of the New Health Insurance Coverage

Natassia M. Rozario, 1L

On March 23, 2010, President Obama made health care reform the law of the land and declared, "[w]e have just now enshrined the core principle that everybody should have some basic security when it comes to their health." The new law provides health insurance

to thirty-two million currently uninsured people by 2014, but it still leaves more than twenty-three million people uninsured.

Who's in?

- The existing poor and uninsured make up a bulk of the thirty two million people to receive coverage. By lowering the Medicaid eligibility requirements, the law expands Medicaid coverage to individuals making less than \$14,400 and families of four making less than \$29,000. For everyone above the new eligibility requirements, the law offers income-based subsidies through a state insurance market exchange system.
- Young adults, up to age twenty-six, will receive insurance under their parents plan.
- A greater number of small business employees will obtain health insurance coverage from their employers under the federal mandates.

Who's out?

- Unauthorized immigrants comprise eight million of the twenty-three million who will not obtain coverage. With immigration reform, however, these numbers may change.
- The twenty-three million remaining uninsured also include those persons who will be eligible for Medicaid but who will not sign up for it, those who will be exempt because of religious or affordability reasons, and those who prefer to pay the individual penalty rather than comply with the mandates.

Reforming the Costs of Care

Natassia M. Rozario, IL

The rising cost of health care in the United States is a grave concern. In 2007, the country spent sixteen percent of its GDP on healthcare costs, which was higher than any other country in the world. National spending on health care has also been increasing by more than six percent a year, according to the annual National Health Expenditure estimate. Despite the billions of dollars spent, the U.S. lags behind other countries in quality of care. According to one World Health Report, the U.S. ranked 37th out of 191 countries.

The health care reform legislation, although criticized by some for not being aggressive enough, makes serious attempts to bend the cost curve. While the legislation will cost a hefty amount, some \$950 billion over the ten years, the Congressional Budget Office estimates that the legislation will reduce the federal deficit by \$142 billion over the next ten years. To hold costs down, the health insurance expansion will not start until 2014. In the interim, the amount of revenue generated from taxes and the amount saved from Medicaid and Medicare cuts will pay for the legislation.

Further, the new legislation outlines a myriad of cost-cutting mechanisms. As discussed in a recent *New England Journal of Medicine* article by Chernew et al., these mechanisms include: 1) reducing excessive Medicare payments, 2) taxing generous insurance plans, 3) empowering an independent Medicare advisory board, 4) addressing and reducing fraud and abuse within the Medicare program, 5) enacting malpractice reform, 6) investing in information technology and comparative-effectiveness research, and 8) investing in prevention.

Of course, how effective the legislation will be in reducing costs depends on its implementation.

HEALTH LAW & POLICY INSTITUTE

Program Dates:
June 21—July 1, 2010

Courses:

- *Health Law “Boot Camp”*
- *Medicine for Lawyers*
- *International Health and Human Rights*
- *Comparative Health Systems*
- *Legal Issues in Health Care Fraud, Abuse & Compliance*
- *Introduction to Genetics*
- *Introduction to Bioethics*
- *Intersection of Intellectual Property & Health Care*
- *Pharmaceuticals & the Law*
- *Health Care Business Transactions*

Program Fees:

Academic Credit

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Student Activity Fee: \$50

Certificate of Attendance/ CLE

1 course: \$1,200

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3 courses: \$2,500

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SUMMER SESSION

HEALTH LAW AND POLICY INSTITUTE

June 21 - July 1, 2010

WEEK ONE

International Health and Human Rights

Introduces students to the substance and theory of human rights law through a focus on public health. Exploring the linkage between human rights, international public health policy, and international law, the course examines the right to health vis-à-vis other human rights, as framed by international treaties and covenants.

Monday and Tuesday (June 21-22)

8:30am-5:00pm

Comparative Health Systems

This course examines health systems from a comparative perspective. Like the U.S., many countries are struggling with economic, social and legal issues facing their respective health care systems and are being overwhelmed by escalating costs. In the process, many countries are confronting tensions between improving quality, ensuring adequate access, and controlling costs. This course will begin by defining “health systems” and exploring what they do and how they have evolved. We will then look at the configuration of health systems, examining different frameworks for healthcare delivery, financing, coverage, and allocation of resources. Next, we will focus on select health care systems around the globe and review the structure and functioning of their health systems. We will explore country-level debates on issues such as funding and will note how a country’s history has influenced the development of its health system. The teaching strategies for this class include readings, lectures, group discussions, and experienced guest speakers.

Monday through Thursday (June 21-24)

9:30am-1:00pm

Health Care Business Transactions

This course is designed to introduce students to the business and legal issues that arise in health care transactions and the regulatory environment surrounding such transactions. This course will cover health care contracts and joint ventures, with a particular emphasis on hospital-physician business relationships. This course will also delve into the nuts and bolts of health care merger and acquisition transactions. The goal of this course is to provide students with practical knowledge and an opportunity to participate in contract drafting, issue spotting and negotiation exercises.

Wednesday and Thursday (June 23-24)

8:30am-5:00pm

Bioethics

Considers legal, ethical, and public policy problems posed by developments in health care financing, allocation, and delivery. Topics include bioethics, federal reform of health policy, health care dispute resolution, health care transactions, managed care, medical liability, health law legislative and regulatory process, and public health law.

Thursday and Friday (June 24-June 25)

8:30am-5:00pm

Health Law Fundamentals and Health Care Reform (“Boot Camp”)

Addresses the unique issues attorneys face in counseling health industry clients, including: coding, coverage, reimbursement, billing, compliance and other regulatory matters. Includes Congressional and state legislative initiatives, health care reform and recent Federal government regulatory actions.

Monday through Thursday evenings (June 21-June 24)

6:00pm-9:00pm and Friday morning (June 25): 9:00am-noon

WEEK TWO

Legal Issues in Health Care Fraud and Abuse

Examines fraud and abuse in the delivery of health care through discussions of the criminal and civil laws and regulations that combat various forms of health care fraud. Course includes a False Claims “Boot Camp”, as well as Stark and Anti-kickback statute issues; health care anti-fraud enforcement efforts; sanctions; and compliance. Monday and Tuesday (June 28-29)

8:00am-6:00pm

Introduction to Genetics

Genetics and the Law is intended to introduce students to the many ways in which the legal system, construed broadly, is influenced by and influences the science of genetics. This course also aims to introduce students to the ethical and societal concerns raised by new genetic technologies and how the law addresses these issues or may do so in the future

Monday and Tuesday (June 28-29)

8:30am-5:00pm

Intellectual Property and Health Care

Provides significant exposure to the many relationships between U.S. patent, trademark and copyright laws and health care, including: Introduction to trademark law; Issues concerning trademarks and pharmaceuticals; Introduction to patent law; Introduction to Hatch-Waxman; Drug development pipeline and IP counseling; Reverse Payments and Health Care Reform; Patenting Life Forms; Introduction to copyright law; Copyright and medical coding- who owns CPT?; Copyright issues and medical imaging; Copyright and medical technology - databases, software; Introduction to the international IP protection schemes; IP issues concerning medical devices; and The interplay in health care between privacy and IP-- data privacy, genetics, and biotechnology.

Wednesday and Thursday (June 30-July 1)

8:30am-5:00pm

Pharmaceuticals and the Law

As government increasingly determines the environment for how drugs are developed and delivered to patients, it is critical for biopharmaceutical manufacturers to engage in the policy realm to promote patient access to appropriate care and to preserve medical innovation. This course will provide an introduction to the range of legal and policy issues relevant to the pharmaceutical industry, including:

- The regulatory regime governing drug development, approval, and promotion.
- The laws and regulations governing access to biopharmaceuticals and other types of care under large government healthcare programs.
- Fraud and abuse laws and regulations and “transparency” policy trends, including disclosure of and restrictions on interactions with healthcare providers.
- “Healthcare reform” policy trends, including cost containment, expanding coverage for the uninsured, and improving the quality of healthcare.
- Intellectual property protections for biopharmaceuticals, including patents and data exclusivity.
- Product liability and biopharmaceuticals.

Wednesday and Thursday (June 30-July 1)

8:30am-5:00pm

Introduction to Medicine for Lawyers

Teaches up-to-date information in an introduction to basic medical principles and practices, and reviews medical negligence law for those students interested in medical liability issues.

Monday through Thursday evenings (June 28-July 1)

6:00pm-9:00pm

Health Law and Policy

PROGRAM ON LAW AND GOVERNMENT



Bringing together lawyers from across the country and other nations, the Health Law and Policy Program utilizes lectures, group exercises, and practical simulations in the education of its students. WCL distinguishes itself with a pragmatic approach to health law, offering a distinctive, well-designed curriculum focused on providing students the skills needed for future practice, taught by expert faculty.

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Students may select their courses from several educational tracks during their studies at WCL. The tracks follow growing health law specializations with focus on potential career paths. Students also have the option to create their own program based upon their interests.

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Current Trends in American Health Policy
Health Care Legislative and Regulatory Process
Food and Drug Law
Administrative Law
Advanced Problems in Administrative Law and Regulatory Policy
AIDS and the Law
Bioethics
Disability Law and Disability Rights Clinic
Elder Law: Policies and Practice
Federal Regulatory Process
Genetics
Health Law
Lobbying and the Legislative Process
Public Health
Psychiatry and the Law
Regulatory Law and Policy
Reproductive Rights

HEALTH CARE AND BUSINESS LAW

Health Law
Legal Issues in Health Care Fraud and Abuse
Advanced Corporate Law
Antitrust
Biotechnology
Business Associations and Corporate Law
Corporate Bankruptcy
ERISA/Pensions, Employment and Labor law
Federal Corporate Income Tax Law
Insurance Law
Intellectual Property, Patent Law and Access to Medicines
Medical Malpractice/Liability
Medicine for Lawyers
Mergers and Acquisitions
U.S. Patent Law

INTERNATIONAL HEALTH AND HUMAN RIGHTS

Economic, Social and Cultural Human Rights
Health Law
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Intellectual Property, Human Rights and Development
International Business Transactions
International Health and Human Rights
International Health Care Organizations
International Humanitarian Law
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