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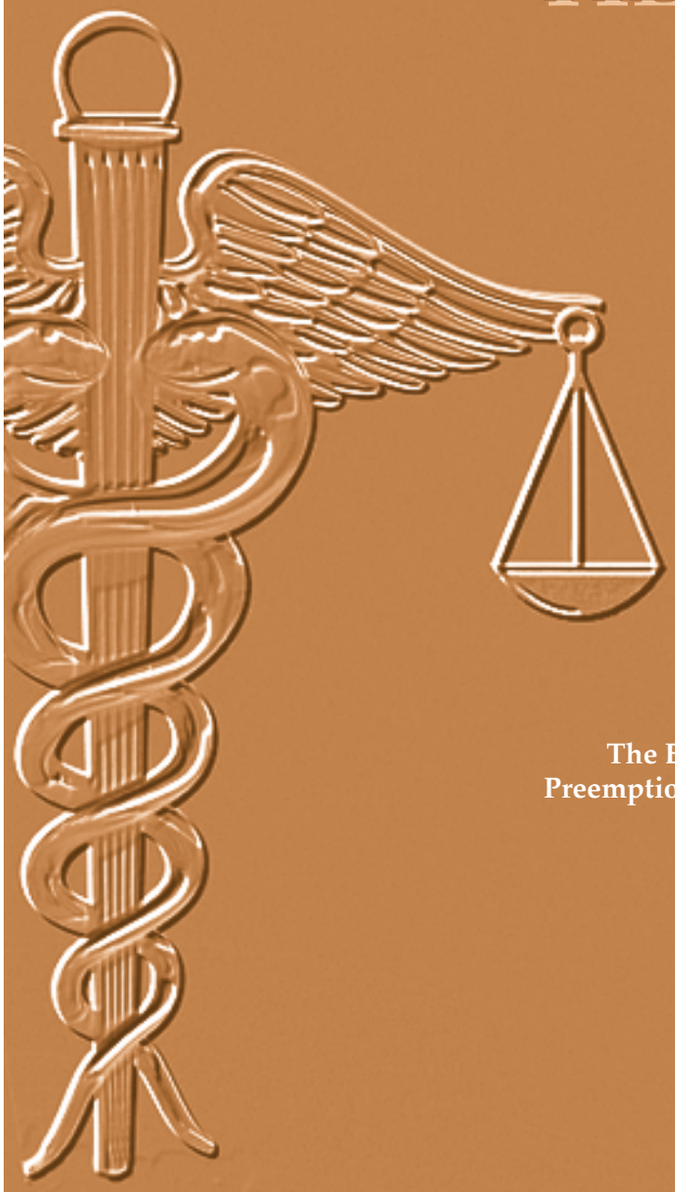

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AMERICAN UNIVERSITY

Health Law & Policy

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Letter from the Editors

Dear *Health Law & Policy* Reader:

On behalf of the Editorial Board, it is with great enthusiasm that we present our second issue of *Health Law & Policy*. The articles in this issue reflect a fresh and highly responsive perspective to new developments in the ever-changing field of health care law. Since health care is a major issue in the current presidential candidate debate, and an important topic of concern in everyday discourse, we strived to create a publication that would inform individuals and illustrate the myriad of ways in which these topics influence our lives.

This issue consists of an impressive range of innovative practitioner and student articles. It includes a focus on international law through an article exploring medical neutrality and the struggles of the 'Benghazi Six,' medical workers who were sentenced to death for allegedly infecting Libyan children with the HIV virus. Concerns about the role of medical workers conveyed in this article parallel domestic discussions about the role of medical personnel that students, professors, and practitioners frequently address through academia and in the practice of law. For instance, a well-renowned United States physician recently faced public outcry for performing medical procedures that attenuated the growth of a nine-year-old girl at her parents' request. Finally, one of the most salient issues today is the debate over a universal health care system; accordingly, we feature an article that profiles universal health care programs around the globe and queries whether universal health care is the best solution to the medical problems in the United States.

Each year, more students at the Washington College of Law (WCL) are discovering that the health care field makes for an exciting academic and professional career. *Health Law & Policy* continues to serve as a testament to the ever-increasing appreciation of the health law field. As health care opportunities and interests continue to expand at WCL, we look forward to ushering in a new generation of law students to move *Health Law & Policy* into the future.

We extend our genuine gratitude and thanks to our advisor, Professor Corrine Parver, and to our dedicated staff members for their efforts in making this issue a success. We sincerely hope you enjoy this issue as much as we enjoyed putting it together.

Sincerely,

Georgiana Avramidis
Editor-in-Chief

Jennifer Cadena
Editor-in-Chief

Gabrielle A. Mulnick
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The Health Care Crisis in America: Is Universal Health Care the Solution to Our Problems?

*By Charisse Y. Gates**

I. Background

Despite the United States' commanding economy, leading technology, and superior medical programs, it ranks 32nd in life expectancy, 37th in adult mortality, and fifth in infant mortality among World Health Organization (WHO) member states.[1] In 2005, the United States' total health care expenditures were $2 trillion, representing 16 percent of its Gross Domestic Product (GDP) compared to 10.9 percent of the GDP in Switzerland, 10.7 percent in Germany, 9.7 percent in Canada, and 9.5 percent in France.[2] Yet, our country's poor health status is largely due to its inequitable distribution of medical resources. For the wealthy minority, access to heath care is virtually unlimited. But the majority of Americans face economic, social, and political barriers to the quality health care services and cutting edge technologies available in the United States.

> "[O]ur country's poor health status is largely due to its inequitable distribution of medical resources."

Studies show that enrollment in a health insurance program promotes positive health outcomes by encouraging healthy behavior.[3] Insured individuals tend to seek medical attention early when conditions are easier and less costly to treat.[4] Individuals without insurance are more likely to postpone or forego care, thereby increasing their risk of developing preventable health problems, disability, and premature death.[5] In a recent study, 28 percent of uninsured participants reported that they did not seek necessary medical services within the last year because they could not afford them.[6] This figure was three times higher than the percentage of persons with health insurance who chose to forego treatment.[7] Additionally, mortality during hospitalization is higher among uninsured patients.[8] The Institute of Medicine (IOM) estimates that lack of insurance is associated with 18,000 unnecessary deaths every year among adults between the ages of 25-64.[9]

Presently, the United States is the only industrialized nation that lacks a universal health care system guaranteeing all citizens access to quality medical care.[10] Recent attempts at health care reform in the United States have been ineffective at reducing the number of uninsured individuals. The U.S. Census Bureau reported that 46.6 million Americans, of which 8.3 million were children, did not have health insurance in 2005 – an increase from 45.3 million in 2004.[11] Even when individuals have insurance, their coverage may be insufficient. In 2003, 16 million Americans were underinsured, meaning that they had health insurance, but their plans were inadequate. This status could result from employers not providing health care. Individuals may also have limited insurance plans that do not cover family members, or plans with unreasonably high deductibles or co-insurance.[12]

In the United States, the financial burden on uninsured families is inversely proportional to family income. Most people are uninsured because they cannot afford coverage.[13] More than half of the uninsured are in low-income families and about half are ethnic or racial minorities.[14] Seventy percent of insured individuals are in families with one or more full-time workers who do not receive employer-provided coverage, or are unable to afford corresponding insurance premiums.[15] The majority of uninsured Americans are between the ages of 19-64 years, of whom twenty percent are children.[16] Thirty-six percent of the American population falls below the federal poverty level, but only 25 percent of the population receives public assistance through Medicare or Medicaid.[17] While almost half of non-citizens are uninsured, American citizens still comprise 79 percent of the uninsured population.[18]

According to the Kaiser Family Foundation and the Health Research and Educational Trust, employer health insurance premiums increased by 9.2 percent in 2005, nearly three times the rate of inflation and five times the average increase in workers' salaries.[19] The annual premium for an employer health plan for a single person is $4,000 and for a family of four, premiums average $11,000.[20] Based on current trends, premiums are expected to rise. Experts predict that prices will reach $2.9 trillion in 2010 and $4 trillion in 2015 (20 percent of the GDP in the United States).[21]

Currently, a combination of federal and state taxes, property taxes, and tax subsidies finance 64 percent of the cost of the American health care system. Individual out-of-pocket payments, such as co-pays, deductibles, and fee-for-service payments collected when service is rendered, account for approximately 17 percent of total heath care costs. Employers only pay 19 percent of health care costs.[22]

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Access to health care is not just a problem for the uninsured – it is a problem for the entire nation. The increasing uninsured population has wide-reaching effects across communities, such as a higher morbidity rate and decreased workplace productivity. Higher rates of sick days reduce productivity and incoming revenue within an organization, forcing employers to terminate jobs, lay off employees, or decrease salaries to compensate for this loss. In addition, uninsured individuals are less likely to be immunized, which increases the possibility of outbreaks of communicable diseases creating risks for greater morbidity and premature mortality.

This article describes various strategies to increase access to health care, and examines single and multi-payer health insurance systems, including universal health care, in other countries and states. Both the advantages and disadvantages of each system are discussed.

II. Discussion: Strategies to Increase Access to Health Care

A. Single Payer Health Insurance Systems

Advocates of universal health care have proposed replacing our current system, which has multiple payers, plans, and options, with a single payer system in which either the federal government or a subcontracting entity will cover the cost of health care for the entire population. Proposed legislation "would prohibit private insurance companies from duplicating coverage for services already covered by the public insurance program."[23]

Opponents of a single payer health system criticize its effectiveness by categorizing it as a form of "socialized medicine" in which the government owns and operates all health care facilities. Contrary to socialized medicine schemes, however, a single payer system is a financing, not a governing, mechanism. The government collects and allocates money for health care but has little involvement in the actual delivery of services. Although public funds pay the costs, care is provided privately at not-for-profit hospitals and clinics where individuals can choose their own providers. Physicians are compensated either on a fee-for-service basis or paid salaries by hospitals or nonprofit health maintenance organizations.[24]

Contrary to the current system in the United States, services in the single payer system would be delivered based on need rather than on an ability to pay; co-payment and deductibles would be eliminated. Single payer universal health care systems closely resemble the United States' government-funded Medicare and Medicaid programs.[25] Overall, these changes would result in decreased consumer costs.[26]

i. Examples of Single Payer Universal Health Care Systems in Other Countries

a) Canada

Canada has operated under a single payer universal health care framework since 1947.[27] Canada's estimated annual total health expenditure is only 9.9 percent of its GDP, approximately $2,669 per person. Its infant mortality rate is just five per 1,000 live births, while life expectancy is 78 years for men and 83 years for women.[28]

The federal government in Canada administers the national health insurance plan (Medicare). The Canadian Medicare program receives funds from general tax revenues that account for 72 percent of health expenditures.[29] In addition, most Canadians have private insurance plans that extend their access to supplemental services, such as dental care, rehabilitation, prescription drugs, and private nursing care. This private sector component, along with out-of-pocket payments, accounts for 28 percent of health expenditures.[30] Most physicians in Canada are in private practice and accept fee-for-service Medicare payments as set by the government. Hospitals are mainly not-for-profit and operate under regional or institution-specific budgets.[31]

While every Canadian citizen has health insurance, and health care expenditures represent a reasonable percent of the nation's economy (compared to United States), the Canadian health care system has been described as a system of rationing where "everything is free but nothing is readily available."[32] Cost-control problems are evident by long waiting lists, dilapidated equipment, and outdated technology. A study conducted by the Fraser Institute found that median waiting times were "consistently and significantly longer than physicians feel is clinically reasonable."[33] For example, in 2005, the total average waiting time for surgery was 17.7 weeks from 12.3 weeks for an MRI scan, 5.5 weeks for a CT-scan, and 3.4 weeks for an ultrasound.[34]

b) Australia

Australia's estimated annual total health expenditure is only 9.6 percent of its GDP, which is approximately $3,123 per person. Its infant mortality rate is six deaths per 1,000 live births and life expectancy is 71 years for men and 74 years for women.[35]

In Australia, national health insurance is funded by a mixture of general tax revenue, a 1.5 percent levy on taxable income, state revenue, and patient fees. The government funds 68 percent of health expenditures (45 percent federal and 23 percent state) and governs

> Access to health care is not just a problem for the uninsured – it is a problem for the entire nation.

"The Massachusetts program is designed to give consumers a choice of plans, ensure true coverage portability, and allow continuing federal tax-breaks for employer group health insurance."

hospital benefits, pharmaceuticals, and medical services.[36] States are responsible for operating public hospitals, regulating nursing homes, and community-based general service clinics. Australians also have access to several not-for-profit private insurers that offer plans to cover gaps between Medicare benefits and fees assessed for inpatient services. These private insurance plans cover a third of the population and account for 11 percent of health expenditures.[37]

Physicians in this system are generally reimbursed fee-for-service. The government sets the fee schedules, but physicians are free to charge above the scheduled fee or may directly bill the government when there is not a patient charge. Out-of-pocket payments account for 19 percent of health expenditures. Similar to Canada, patients are free to choose their general practitioner, an individual who serves as a managed care gatekeeper.[38]

c) Denmark

Denmark's estimated annual total health expenditure is only 8.6 percent of its GDP, approximately $2,780 per person**.** Its infant mortality rate is five deaths per 1,000 live births and life expectancy is 76 years for men and 80 years for women.[39]

Progressive income taxes fund the publicly-administered Danish health care system. Each patient chooses a general practitioner who makes referrals to specialists. There are no co-payments for physician or hospital visits, but patients do pay co-payments for prescription drugs. Together, 14 counties and the city of Copenhagen run the country's hospitals.

Physicians who work with hospitals receive salaries which are negotiated between the government and doctors' unions. General practitioners are compensated 40 percent per capita and 60 percent fee-for-service, whereas specialists are mostly fee-for-service.[40]

ii. First Step, First State: Single Payer Universal Health Care in the United States—Massachusetts Health Care Reform Act

The Massachusetts Health Reform Act (MHRA), enacted on April 12, 2006, is the first successful legislation creating a single payer health care system in the United States.[41] Health benefits are administered by a newly created state agency, the Connector. The Connector serves as an intermediary between citizens and private insurance plans and funds all services. The Massachusetts program is designed to give consumers a choice of plans, ensure true coverage portability, and allow continuing federal tax-breaks for employer group health insurance.[42] Under the program, workers will be able to switch plans during an annual open season and retain the same coverage as they change jobs.[43]

The MHRA increases enrollment in Massachusetts' current Medicaid program and includes all adults whose income is less than 100 percent of the Federal Poverty Level (FPL).[44] Medicaid eligibility also extends to all children in households at 300 percent at or below the FPL.[45] The MHRA then creates a single payer system based on both individual and employer responsibility.

The individual mandate of MHRA required all Massachusetts residents to obtain health insurance by July 1, 2007. Residents must show proof of this coverage on their annual tax returns. Failure to do so results in the loss of personal deductions. Continued failure to comply will subject individuals to financial penalties up to 50 percent of the cost of an insurance plan.[46] People with incomes greater than 100 percent, but less than 300 percent of the FPL, will be eligible for government-funded sliding scale subsidies for the purchase of necessary coverage plans.[47] To help make insurance affordable for the remaining population, the MHRA allows citizens to use pre-tax dollars to purchase plans.

MHRA's "employer mandate" requires that all employers with more than ten employees provide "some degree" of health benefits.[48] The government requires employers who do not offer such benefits to pay their "fair share" of health care expenditures for the uninsured up to $295 annually per full-time employee.[49] In order not to burden small businesses, the Connector offers new specially-priced plans that were previously not available to small businesses because insurers could now pool the risk of the small businesses and insure themselves a profit previously unavailable.[50] Each worker may choose the most suitable health plan from those offered.[51]

Any Massachusetts resident may buy coverage directly through the Connector as an individual. The disadvantage of doing so is that the federal tax-breaks for individually purchased health insurance are not as large as those for employer-group coverage.[52]

iii. Advantages of a Single Payer System

The single payer approach to a universal health care system effectively addresses the issue of cost containment for health care expenditures.[53] The for-profit element of health care would dramatically decrease and the system would transition into a market of non-for-profit services. Using government agencies (or government subcontracting agencies) as liaisons between small businesses and individual health

consumers creates bargaining power for consumers to negotiate discounts with health care providers and suppliers. In addition, single payer systems naturally utilize centralized electronic medical record databases that facilitate patient care and help prevent medical errors. Physicians, pharmacists, and other health care providers can access information from different offices and across state lines, making medical records truly portable.

In a proposed single payer system for the United States, there would be no preferred providers (i.e., no distinction between in-network physicians and out-of-network physicians).[54] Covered individuals would have the freedom to choose their own physician. The new "health care system would be fundamentally accountable to the public, so decisions about the allocation of healthcare resources (e.g., how much to spend, what to pay for, whom to pay for) would be public decisions."[55] Such freedom will ultimately expand participant choice as well as increase consumer power.

iv. Disadvantages of a Single Payer System

Concerned consumers raise privacy concerns that the government could access this central database of medical and personal information. While this "single repository" benefits public health planning and allows for efficient medical treatment between different providers, citizens fear that the government would track individual health care outcomes, leading to discrimination.

A single payer system in the United States would also be vulnerable to the prevailing political party. For example, opponents of the single payer system may underfund it.[56] In addition, physicians worry about lower reimbursements due to the government's increased bargaining power. Yet, any income reduction a physician might experience could be mitigated by decreased overhead and malpractice costs.

Finally, a single payer system with few financial barriers may encourage over-consumption of resources, straining the capacity and effectiveness of health care delivery. Under a *pure* single payer system, the government might provide only one basic insurance plan without coverage options; thus, those who prefer a different option may view the pure single payer system as a disadvantage.

B. Multi-Payer Systems

While the term "universal health care" generally refers to a single payer system, it can also be achieved through a multi-payer system. In a multi-payer system, health care services are financed by both public and private contributions. Citizens are protected by a "safety net" (the minimal public insurance plans available to all persons). They also may purchase alternative private plans in place of the public insurance options.[57] The government is not responsible for administering private plans; however, it does ensure that private plans contain the same options as public insurance plans. [58]

i. Examples of Multi-Payer Systems

a) Germany

In 1883, Germany became the first country to develop a national health insurance system.[59] Germany's annual health expenditures account for 10.6 percent of its GDP, approximately $3,171 per person. The infant mortality rate is five per 1,000 live births, and life expectancy is 76 years for men and 82 years for women.[60] Every German citizen is eligible for public health insurance, and individuals above a specified income level may purchase private coverage. Only 0.2 percent of the population lacks health insurance.[61]

The German health care system employs Sickness Insurance Funds (SIFs). SIFs receive funding through compulsory payroll contributions (14 percent of wages), equally shared by employers and employees. Also, SIFs cover 92 percent of insured individuals and 81 percent of health expenditures overall.[62] Citizens who are affluent, self-employed, or civil servants are covered by private insurance, financed by voluntary individual contributions.

> "Using government agencies . . . as liaisons between small businesses and individual health consumers creates bargaining power for consumers . . . .

General practitioners do not serve as gatekeepers to health services or specialty care. Private physicians are paid on a fee-for-service basis at rates negotiated by SIFs' representatives.[63]

b) France

France's annual health expenditures account for 10.5 percent of its GDP, approximately $3,040 per person. The infant mortality rate is five per 1,000 live births, and life expectancy is 77 years for men and 84 years for women.[64]

Similar to Germany, the French health care system is primarily funded by SIFs financed through compulsory payroll contributions – 70 percent

from employers and 30 percent from employees. France's system operates as an autonomous, not-for-profit, government-regulated entity with national headquarters and regional networks.[65] SIFs cover 99 percent of the population and account for 75 percent of health expenditures. The central government, patients' out-of-pocket payments, and Mutual Insurance Funds (MIFs) pay the remaining health expenditures. MIFs cover 80 percent of the population, and account for 6 percent of health expenditures.[66]

Patients are free to choose their own providers and are not limited to the number of services they may receive. General practitioners do not serve as gatekeepers. Private physicians are paid on a fee-for-service basis and patients are subsequently partially or fully reimbursed as appropriate.[67]

c) Japan

Japan's universal health care program began in 1958.[68] Its annual health expenditures account for 7.8 percent of its GDP, approximately $2,293 per person.[69] The infant mortality rate is four per 1,000 live births, and its life expectancy at birth is 79 years for men and 86 years for women.[70]

Japan's program contains two principal systems. First, similar to both Germany and France, Japan has an Employee Health Insurance System financed by compulsory payroll contributions (8 percent of wages). These contributors are equally shared by employers and employees and cover employees and their dependents.[71] Second, there is a National Health Insurance System that covers self-employed individuals or pensioners and their dependents.

In both systems, the local government acts as the insurer. Premiums are based on (1) the individual income; (2) the number of individuals in the insured household; and (3) assets. These premiums fund 57 percent of health expenditures, while the federal government contributes 24 percent and local governments contribute 7 percent.[72]

About 80 percent of hospitals and 94 percent of clinics in Japan are privately owned and operated. Some public not-for-profit hospitals do exist, but the law prohibits investor-owned, for-profit hospitals.[73] Patients are free to choose their own general practitioners who do not serve as gatekeepers. Medical and pharmaceutical practices operate jointly; thus, prescription fees generate a large portion of physician income.

ii. Advantages of a Multi-Payer System

For both public and private consumers, the chief advantage of having a multi-payer system is freedom of choice. Each person has the right to health care and has access to necessary services regardless of employment, age, socioeconomic status, or health. Those who desire additional coverage may purchase it from private companies. Patients opting for publicly funded plans would not be restricted in choosing their doctor. In addition, government administration of public insurance will decrease spending by eliminating duplicate administrative activities and negotiating reasonable reimbursement rates for providers. A multi-payer system may be more practical than a single payer system because it does not completely eliminate insurance companies or the revenue generated from the insurance marketplace.[74] Competition will still remain between companies to provide supplemental insurance plans.

iii. Disadvantage of a Multi-Payer System

Despite scaling back the for-profit insurance industry, competition between insurance carriers, motivated by increased profits, will still exist.[75] Additionally, stratification between socio-economic groups is less likely to diminish.

C. Federalist Approach

The federalist approach is a system incorporating a partnership between federal and state governments. States receive federal funding to provide universal health care to their residents. To receive funds, states must design systems according to specific federal guidelines. Administering the plan would be based on local conditions and terms. In this manner, states may have the opportunity to customize an insurance program that most efficiently meets the needs of their residents.[76]

i. Advantages of the Federalist Approach

The federalist strategy recognizes varying social and political climates in different geographical areas. Accordingly, one federal solution cannot apply to every state. States will have autonomy to implement plans over a period of time, allowing for incremental changes, by collecting data from earlier ventures to determine ideal solutions.

ii. Disadvantages of the Federalist Approach

Some argue that large businesses will ultimately prefer a uniform, federal solution to achieve consistency rather than a system with 50 different sets of regulations. Then again, state regulations can lead to a national program. For instance, Canada's national health care system was developed province-by-province and

> "[Under the federalist approach] states may have the opportunity to customize an insurance program that most efficiently meets the needs of their residents."

demonstrates that building a health care system state-by-state can eventually lead to a national universal health care system. Accordingly, a universal health care system in the United States could also develop from a state-by-state system.

D. Alternative Financing Options for Universal Health Insurance Programs

In addition to reducing the number of uninsured individuals and increasing the affordability of health insurance as outlined above, proponents of universal health care suggest tax credits, medical savings accounts, and managed competition to fund a universal health care program.

i.Tax Credits

Under the current health care system in the United States, self-employed individuals and workers who do not receive health benefits from their employers generally pay higher insurance premiums and have higher co-payments. Allowing income tax credits to subsidize the cost of insurance would eliminate a portion of this financial burden.[77]

In addition to incentivizing individuals to purchase health insurance, tax credits would be easy to implement and insurance plans, overall, would be more affordable for the average person. Additionally, insurance companies would not have to surrender their economic interest in the marketplace. Tax credits also retain citizens' freedom of choice and do not hinder personal autonomy.

Tax credits alone can only provide increased access. People who do not want to purchase health insurance would not be required to do so. Consequently, tax credits do not guarantee that all persons will have coverage. In addition, tax credits will reduce, but not eliminate, the cost of health insurance. Moreover, tax credits would only apply to those persons who are employed and file income taxes. People who are not employed, or do not earn enough money to file tax returns, will not benefit.

ii. Medical Savings Accounts

Medical Savings Accounts (MSAs) are based on the theory that the cost of health care is inflated because people are over-insured. Broad insurance coverage encourages people to use medical resources more frequently. Since they have already paid for insurance, patients do not hesitate to see doctors for even the smallest problem because medical care is covered by their insurance plan. This results in over-consumption of medical resources, which results in higher costs.[78]

In alternative MSAs, employers (or the government) deposit money into an account on the insured's behalf and the money is used to purchase basic coverage.[79] Some of the money in the MSA is used to purchase a high-deductible, low-premium catastrophic insurance plan. The remaining money is used for other health care expenses. Costs that exceed available MSA funds are paid for by individuals out-of-pocket. Any unspent money remains in the account for future use. Accordingly, people have an incentive to reduce costs when forced to pay out of their own pocket.[80]

Minimizing costs is not an option when serious medical problems arise, leaving individuals extremely vulnerable. MSAs attempt to balance economic efficiency and patient protection. Utilizing fewer medical resources will reduce prices, making care more accessible for everyone. Yet people are still secure in knowing that they will be protected if something critical happens.

MSAs do not solve the problems of the low-income uninsured population who will still likely be unable to pay for out-of-pocket costs. Persons who cannot afford health care will have access to emergency treatment but will have little-to-no access to preventive or basic medical care. MSAs also discourage patients from seeking medical care, unless there are clear signs of illness.[81]

iii. Managed Competition

Managed competition is a system that combines market forces with patient pooling to improve access. Employers and individuals join health-care purchasing groups (or health alliances) which negotiate

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benefits with different private insurers. The theory of managed competition is that grouping people into certain "alliances" gives them bargaining power to obtain insurance at reasonable prices.[82] The government establishes a minimum set of benefits that insurance plans must offer. Every member in the plan is charged the same premium rate regardless of health status.[83] Employers may cover most of these premiums; public subsidies cover the remainder. If people want additional coverage, they must pay out-of-pocket for all services exceeding minimal coverage. Requiring companies to offer a standard set of minimum benefits ensures that patients will not select a low-quality plan simply to save money. Consequently, health care becomes more affordable and more accessible.[84]

Managed competition programs would be particularly beneficial to small employers, who currently are unable to offer benefits, and those individuals who pay for health care out-of-pocket. Insurance companies would still be motivated to maximize profit, even at the patients' expense. The cost-cutting practices they presently employ, such as requiring patients to stay within a particular network of physicians, will likely continue. Physicians will face similar limitations on patient treatment and resource utilization. As a result, administrators will closely scrutinize their medical decisions, emphasizing cost effectiveness rather than medical efficacy.

Insurers have an incentive because insurance providers will most likely need to accept both sick and healthy patients. When sick patients choose among available plans, they will select the one that offers them the best care for their illness. The patient will likely not select a plan that has poor treatment options. The result is that the insurance company saves money by not treating a patient's potentially expensive ailment. Similarly, insurance providers will have little reason to improve technology and treatment for the unhealthy. Most of their focus towards the sick will be trying to convince those who are ill not to enroll in their plan.

III. Conclusion: Is America Ready for a National Universal Health Care System?

Experts and citizens agree that our current health care system is inefficient. The United States has the financial power and advanced technology to support an excellent health care system but, in reality, today's health care system is simply a repository of unused potential. As statistics show, Americans have more negative health outcomes, such as higher infant mortality rates and lower life expectancies than other countries.

In theory, universal health care would be ideal. The United States has the ability to save lives but, with so many people unable to afford health insurance, a healthy life is only reasonably attainable by some. With a national health care system, all citizens would have coverage regardless of their ability to pay, thus replacing the current unjust system with one of fairness, equity, and quality.

The real issue is precisely how the United States could implement a meaningful, effective, and sustainable change. In the United States, citizens prefer as little government involvement in their lives as possible. Thus, a strict single payer system is unlikely to gain the necessary support from American voters. A hybrid of the methods implemented in other countries, and similar to the MHRA, is likely to lower health care costs to consumers and reduce the health disparities present across the lines of ethnicity, race, and financial status.

1 *See* World Health Organization, World Health Statistics 2006, at 58-64 (2006), *available at* http://www.who.int/whosis/en/ (last visited Nov. 5, 2007).
2 *See* National Coalition on Healthcare Website, Facts on Health Care Costs (2007), http://www.nchc.org/facts/cost.shtml (last visited Sept. 17, 2007).
3 *See generally* U.S. Census Bureau, Health Status, Health Insurance, and Health Services Utilization: 2001, 10-12 (2006), http://www.census.gov/prod/2006pubs/p70-106.pdf (discussing U.S. health status and demographics correlations with health insurance rates).
4 *See* Chris Hafner-Eaton, *Physician Utilization Disparities Between the Uninsured and Insured: Comparisons of the Chronically Ill, Acutely Ill, and Well Nonelderly Populations*, 269 J. Am. Med. Assoc. 787, 790-91 (1993).
5 *See id.*
6 *See* The Henry J. Kaiser Family Foundation, Health Care in America 2006 Survey 12 (2006), http://www.kff.org/kaiserpolls/upload/7572.pdf.
7 *See id.*
8 *See* Jack Hadley, *Sicker and Poorer—The Consequences of Being Uninsured,* 60 Med. Care Res. & Rev., pt. 2, at 3, 76 (2003).
9 *See* Institute of Medicine, Insuring America's Health: Principles and Recommendations 1, 8, 14 (2004), *available at* http://www.iom.edu/?id=17848 (last visited Sept. 17, 2007).
10 *See* Nat'l Health Care for the Homeless Council Website, Single Payer Universal Health Insurance, http://www.nhchc.org/singlepayer.html (last visited Sept. 17, 2007).
11 *See* U.S. Census Bureau, Income, Poverty, and Health Insurance Coverage in the United States: 2005, 20-22 (2006), http://www.census.gov/prod/2006pubs/p60-231.pdf.
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13 *See* The Henry J. Kaiser Family Found., Kaiser Comm'n Medicaid and the Uninsured, The Uninsured: A Primer, Key Facts About Americans without Health Insurance 3-5 (2006), http://www.kff.org/uninsured/upload/7451.pdf.
14 *See* The Henry J. Kaiser Family Found., Kaiser Comm'n on Medicaid and the Uninsured, Who are the Uninsured? A Consistent Profile Across National Surveys 1 (2006), http://www.kff.org/uninsured/upload/7553.pdf (reviewing results from three major national research surveys: the U.S. Census Bureau Current Population Survey, the Medical Expenditure Panel Survey, and the National Health Interview Survey).
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The Legal And Moral Implications Of Growth Attenuation

*By Meryl Eschen Mills**

I. Introduction

One of the goals of the *Healthy People 2010* initiative, advanced by the U.S. Department of Health and Human Services is to "[r]educe the number of people with disabilities in congregate care facilities" to zero by the year 2010.[1] According to the American Academy of Pediatrics Committee Section on Children with Disabilities, "[m]ost parents desire to raise their children with special health care needs at home."[2] However, caring for a child with profound developmental disabilities can be particularly difficult as the child matures into adulthood. A child's continued physical growth may impose significant limitations on a parent's ability to care for the child.

As a result, some doctors have proposed a controversial method of "treatment," designed to mitigate particular challenges that caregivers face due to the continued growth of a child with severe disabilities. This treatment, termed "growth-attenuation therapy" consists of using treatments of high-dose estrogen at an early age in order to stimulate growth of the epiphyseal growth plates, which in turn permanently attenuates physical size.[3] "[A]chieving permanent growth attenuation while the child is still young and of manageable size would remove one of the major obstacles to family care and might extend the time that parents with the ability, resources, and inclination to care for their child at home might be able to do so."[4]

Not surprisingly, this controversial method of intervention has caused considerable debate both in the United States and abroad. Ashley, a nine-year-old girl with severe cognitive and developmental disabilities is at the center of this controversy. At the request of Ashley's parents, doctors have attenuated Ashley's growth, and performed other procedures, believing that such measures will provide a better "adult quality of life" for their daughter.[5]

This article explores the legal and ethical implications of Ashley's "treatment." Although there is no explicit legal prohibition on growth attenuation, the fact that doctors are *capable* of performing a particular intervention does not necessarily mean they *should*. This article juxtaposes the moral question at issue with an analysis of the legal rights available to the parents and child, respectively.

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II. Background

Ashley is a nine-year-old girl who was born with static encephalopathy, a medical condition resulting in severe developmental and cognitive deficiencies.[6] Ashley requires assistance moving her body, is fed through a gastronomy tube,[7] and her mental development has remained and will likely continue to remain that of an infant.[8] Her parents call her their "Pillow Angel, since she is so sweet and stays right where [they] place her – usually on a pillow."[9]

When Ashley was six-years-old, she started showing signs of puberty.[10] Ashley was growing quickly and had already started developing breasts.[11] Ashley's early pubertal development prompted fear in her parents: Ashley's "continued growth eventually would make it untenable for them to care for their daughter at home, despite their strong desire to do so."[12] Ashley's parents expressed concern over one day having to place her "in the hands of strangers."[13] They were also concerned with the potential complications of puberty, including what would happen if their daughter started menstruating.[14]

To "significantly elevate Ashley's adult quality of life," her parents and doctors developed a plan for Ashley involving growth attenuation, a hysterectomy, and breast bud removal.[15] The parents termed this collective set of medical procedures, "Ashley's Treatment."[16] The purpose of the hysterectomy was to "prevent the discomfort, pain, cramps and bleeding that are so commonly associated with the menstrual cycle."[17] Ashley's parents noted that additional benefits included "avoiding the possibility of pregnancy" in case Ashley is abused, eliminating the risk of uterine cancer,[18] and further claimed that she "has no need [for her uterus] . . . since she will not be bearing children."[19] Although doctors removed Ashley's uterus, they did not remove her ovaries in order to ensure that she will maintain "her hormonal cycle and the generation of her natural hormones."[20] "This onetime [sic] procedure eliminates the complications of menses," sparing Ashley and her parents "the expense, pain, and inconvenience of a lifetime of hormone injections."[21]

Ashley's parents based their decision to remove Ashley's breast buds on family history since large breasts

run in Ashley's mother's family.[22] Ashley's parents contend that large breasts would be uncomfortable for Ashley, and may impede their ability to safely secure Ashley in her wheelchair.[23] Incidental benefits include eliminating the risk of breast cancer and fibrocystic growths, both of which also run in Ashley's family.[24] Ashley's parents were further concerned that large breasts might "sexualize" her towards her potential caregivers, especially if touched accidentally during Ashley's care.

The onset of puberty typically causes a child to grow significantly. Doctors have found that premature exposure to sex steroids, such as estrogen, can stunt final adult height by inducing the quick maturation of growth plates.[25] The earlier a child is exposed to such steroids, the more significant the growth attenuation will be.[26] Since Ashley first underwent such treatment when she was merely six-years-old, her height will likely never exceed four feet, five inches, and her weight will remain approximately 75 pounds.[27]

This is not the first time such treatment has been used to stunt a child's growth. The first reported use of high-dose estrogen as a means to attenuate growth was reported in 1956.[28] Such treatment was often used on girls who were considered "too tall" before reaching puberty to minimize additional growth.[29] While doctors still use growth attenuation as a treatment option today, it is far less common, as the stigma previously associated with women of tall stature has decreased significantly.[30]

Potential side effects of the treatment are somewhat uncertain since doctors have limited experience with the use of growth attenuation in young children.[31] Doctors believe the side effects associated with this treatment may be significant, causing early onset of breast development and uterine bleeding.[32] The potential for these side effects to develop in the future contributed to the rationale for removing Ashley's uterus and breast buds.

III. Legal Implications

Courts generally afford substantial deference to parents making "important decisions for their children."[33] State and federal law grants parents decision-making authority with regard to choices involving children's health care.[34] While there is a presumption in favor of a parent's autonomy over health care decisions, courts may overrule a parent's wishes in certain circumstances. When a parent chooses to withhold certain treatment for reasons unrelated to the well-being of the child, for example, a court may order treatment for the child if it is not highly invasive and if it is likely to have significant health benefits.[35] Where the treatment's success is lower or substantially uncertain, courts may be less likely to overrule the parents' or child's wishes.[36]

Some states, such as Washington, where Ashley and her family currently reside, require court approval of certain health care decisions before they are performed.[37] These health care decisions include those that are "highly invasive and irreversible," such as involuntary sterilization.[38]

Washington law is clear about involuntary sterilization. In *In re Guardianship of Hayes*, the Washington Supreme Court considered whether a mother could consent to the sterilization of her child, who had severe mental retardation.[39] The court held that "in any proceedings to determine whether an order for sterilization should issue, the retarded person must be represented, as here, by a disinterested guardian *ad litem*."[40] The court found that a guardian is necessary in such cases because "unlike the situation of a normal and necessary medical procedure, in the question of sterilization the interests of the parents of a retarded person cannot be presumed to be identical to those of the child."[41] Thus, "[t]here is a heavy presumption against sterilization of an individual incapable of informed consent….[t]his burden will be even harder to overcome in the case of a minor incompetent."[42]

Ashley's hysterectomy rendered her sterile. Because her parents did not seek a court order or request the appointment of a guardian *ad litem* before consenting to the hysterectomy, the Washington Protection and Advocacy System found that this aspect of "Ashley's Treatment" violated both the United States Constitution and Washington state law.[43] Whether other procedures associated with "Ashley's Treatment," also violated Washington law remains unclear. The Washington Protection and Advocacy System argues that the removal of Ashley's breast buds, the hormone therapy, and the other procedures associated with Ashley's treatment also violate her constitutional rights because they are "highly invasive and irreversible, particularly when implemented together."[44]

Interestingly, all arguments supporting and opposing Ashley's treatment, including of the Washington Protection and Advocacy System, seem to assume that the array of procedures actually constitutes medical "treatment" protected by constitutional and common law. The American Association on Intellectual and Developmental Disabilities (AAIDD) points out that the doctors exploring growth attenuation as a treatment for children with Ashley's condition "seemed to implicitly accept the idea that growth attenuation is in fact a type of therapy . . . .Given that therapy is intended to

"The Washington Protection and Advocacy System argues that the removal of Ashley's breast buds, the hormone therapy, and the other procedures associated with Ashley's treatment also violate her constitutional rights because they are "highly invasive and irreversible, particularly when implemented together."

address a condition of a patient, the target in this case would have to be the growth and maturation expected as a consequence of Ashley's normal development."[45]

A preliminary review of the case law reveals no judicial definitions of "medical treatment." Courts frequently pass judgment on the appropriateness of parents' medical treatment decisions on behalf of their children, particularly when such decisions are not religiously motivated. For example, in *In re Cicero*, the Supreme Court of New York considered whether to appoint a guardian for an infant born with spina bifida because the infant's parents refused to consent to surgery to help repair the infant's condition.[46] If treated, the court found that the infant's "extremity deficits will, hopefully, be only at the leg level below the ankles. Additionally, she will lack sphincter control of the bladder and anus; but modern medicine and surgery can ameliorate these conditions too. She should be able to walk with short leg braces and hopefully have a 'normal' intellectual development."[47]

The court granted the appointment of a guardian, reasoning:

> This is not a case where the court is asked to preserve an existence which cannot be a life. What is asked is that a child born with handicaps be given a reasonable opportunity to live, to grow and hopefully to surmount those handicaps. If the power to make that choice is vested in the court, there can be no doubt as to what the choice must be.[48] The court distinguished between "hopeless" lives and the case at bar, without defining what a "hopeless" life entailed. The court continued:
>
> There is a hint in this proceeding of a philosophy that newborn, 'hopeless' lives should be permitted to expire without an effort to save those lives. Fortunately, the medical evidence here is such that we do not confront a 'hopeless' life. As Justice Asch has pointed out [citation omitted] '(t)here is a strident cry in America to terminate the lives of *other* people—deemed physically or mentally defective.'

This court was not constituted to heed that cry. Rather, to paraphrase Justice Asch [citation omitted] it is our function to secure to each his opportunity for 'life, liberty and the pursuit of happiness.'[49]

A case before the Supreme Court of Massachusetts, however, provides an example of a "hopeless life."[50] In *In re Custody of a Minor*, the court affirmed a "no code" order for a four-and-one-half-month-old infant suffering from cyanotic heart disease, a condition without a cure, which would cause fatal complications for the infant within a year regardless of whether the hospital administered treatment.[51] The court reasoned that "[a] 'full code' order would involve a substantial degree of bodily invasion, accompanied by discomfort and pain, and would do nothing but prolong the child's 'agony and suffering.'"[52]

In deciding whether to intervene with parents' medical decisions on behalf of their children, courts seem to draw the line at whether a child's situation is hopeless and death is imminent regardless of treatment, or whether treatment might help the child. In Ashley's case, her condition does not pose an imminent threat to her health. Therefore, one must question whether measures taken allegedly to improve Ashley's quality of life should also be subject to judicial intervention.

The Access to Medical Treatment Act, a recently proposed bill, would "permit an individual to be treated by a health care practitioner with any method of medical treatment such individual requests, and for other purposes."[53] While it is unclear whether the bill addresses treatment for children whose parents request medical treatment on their behalf,[54] it defines "medical treatment" as "any food, drug, device, or procedure that is used and intended as a cure, mitigation, treatment, or prevention of disease or a health condition."[55]

In Ashley's case, the treatment regimen will not *cure* her underlying condition. Whether Ashley's full-term growth would constitute a "disease" or "health condition" is also unclear. Ashley's treatment may *mitigate* her condition in the sense of making her more comfortable. For example, Ashley's doctors argue that "[a] child who is easier to move will in all likelihood be moved more frequently. Being easier to move

"In Ashley's case, the treatment regimen will not cure her underlying condition . . . .[but it] may mitigate her condition in the sense of making her more comfortable."

means more stimulation, fewer medical complications, and more social interactions."[56]

Courts also consider the mental capacity of the child when evaluating a parent's medical treatment decision. For example, in the case of the child with spina bifida, the court carefully pointed out that the child would likely have "normal" intellectual development. While Ashley's condition does not pose an imminent threat to her health, her mental development will not be "normal." One should consider how, if at all, Ashley's mental capacity should influence a court's decision as to whether to allow her parents' proposed treatment.

Courts may use mental capacity as criteria in assessing whether certain medical decisions are appropriate. For example, courts have allowed caregivers to terminate a child's life in cases where the child has minimal brain function, such as a child in a persistent vegetative state.[57] Therefore, it becomes important to determine where courts "draw the line" regarding the appropriateness of certain medical procedures given the mental capacity of the patient.

In balancing whether to approve a medical procedure for a minor, a court may also look at the minor's health care wishes. In Ashley's case, however, her wishes are not ascertainable due to her cognitive disabilities. Therefore, her parents will be responsible for making all of her health care decisions. Where a parent makes a health care decision for a child whose health care wishes are not ascertainable, the court may use one of two standards to determine whether the parents' wishes should be upheld. These standards are: (1) the "substituted judgment" standard;[58] and (2) the "best interest" standard. For example, the law allows parents of a patient in a persistent vegetative state, or of an anencephalic child, to make decisions regarding treatment options. In the case of a patient in a persistent vegetative state, the law allows the patient's proxy to make choices for the patient, based on what the patient likely would have wanted. This type of proxy decision making is called "substituted judgment."[59] In the case of an anencephalic child whose wishes could not be known, the law allows the proxy to make decisions based on the best interests of the patient.[60]

Courts have applied the substituted judgment standard in cases involving patients with profound mental retardation. In *Superintendent of Belchertown State School v. Saikewicz*, the Supreme Court of Massachusetts applied the substituted judgment standard in affirming the lower court's decision to withhold chemotherapy for Mr. Saikewicz, a 67-year-old man with profound mental retardation.[61] Though today such a measurement is considered somewhat misleading,[62] the court found that the 67-year-old man had "a mental age of approximately two years and eight months," and an "I.Q. of ten."[63]

In applying the substituted judgment standard, the court looked at "the decision . . . which would be made by the incompetent person, if that person was competent . . . ."[64] In particular, the court considered several factors favoring the administration of chemotherapy, including: (1) the fact that, if given a choice, most people would likely elect to have chemotherapy in this situation; and (2) the possibility that such treatment would prolong Saikewicz's life.[65] The court assumed that since this treatment is what "most people" would have wanted, it must be what Saikewicz likely would have wanted had he been competent to make such a decision.

The court found six factors opposing the administration of chemotherapy, including: (1) Saikewicz's advanced age; (2) the possible side effects of the chemotherapy; (3) the fact that the chemotherapy would not likely cause the leukemia to go into remission; (4) the fact that the chemotherapy would cause suffering; (5) Saikewicz's inability to cooperate with the treatment, given his insufficient comprehension; and (6) Saikewicz's potentially diminished quality of life even if the chemotherapy did work.[66] Since the factors opposing the treatment outweighed those supporting it, the court ruled to withhold the treatment.

If a court were to examine Ashley's treatment under the substituted judgment standard, it would likely not find such treatment options preferable. Since Ashley has never been competent, a court applying the *Saikewicz* substituted judgment standard would evaluate whether Ashley would want such medical procedures if she had been competent. A six-year-old girl would most likely not want to have a hysterectomy, breast bud removal, or hormone therapy to keep her small. Ashley's case differs from Saikewicz's in that her treatment serves to prevent the occurrence of certain life stages *because* Ashley has mental disabilities, whereas the purpose of Saikewicz's treatment was intended to combat his leukemia. Ashley's parents might argue that she would prefer such treatment if it enabled her to remain a part of her family. Her parents would want a court to apply the substituted judgment analysis by asking not what a *competent* Ashley would choose in this situation, but rather, what a competent Ashley would choose if she knew she was going to be *incompetent*.

Ashley's parents would likely fare better in a court that applied a best interest analysis. In a best interest analysis, "[t]he decision is not based on the surrogate's view of quality of life, but 'the value that the continuation of life has for the patient . . .' not 'the value that others find in the continuation of the patient's life . . . .'"[67] In making such a decision, the court must evaluate objective, societally shared criteria. The best interests standard rests on the protection of patients' welfare rather than on the value of self-determination. "In assessing whether a procedure or course of treatment would be in a patient's best interests, the surrogate must take into account factors such as the relief of suffering . . . and the quality as well as the extent of life sustained."[68]

> "In the case of a patient in a persistent vegetative state, the law allows the patient's proxy to make choices for the patient, based on what the patient likely would have wanted.

Potential benefits to Ashley may include greater stimulation, more social interactions with family and friends, and fewer medical complications from puberty.[69] Another potential benefit would be that "growth attenuation may offer some parents at least the opportunity to extend the time they can care for their child at home, whereas otherwise institutionalization, or foster care, might be the only alternative."[70] Ashley's parents argue that these benefits serve to alleviate Ashley's suffering and improve her quality of life, both of which satisfy the criteria under a best interest analysis.

Ashley's parents' argument, however, involves several assumptions. Notably, they assume that home care is objectively better than care provided at a specialized institution. They also assume that they are, in fact, correct in their predicted inability to care for Ashley in their home if she were permitted to grow to her natural size without growth attenuation treatment. Such assumptions need to be evaluated on a case-by-case basis.

As for the relief of suffering, the treatment is not without potential side effects. One possible risk of the treatment is thrombosis, a potentially fatal formation of a blood clot in an artery or vein.[71] Furthermore, Ashley's doctors may not have considered the potential emotional effects that stunted growth, hysterectomy, or breast bud removal could have on Ashley. Quite possibly, such procedures could have a profound effect on Ashley. While her doctors assert that "it is unlikely that such 'infantilization' harms a person whose mental capacity will always remain that of a young child,"[72] children, even those with severe mental disabilities, may still react to environmental stimuli. Despite her mental incapacity, Ashley may find the surgery, therapy, or side effects both physically and emotionally painful.

Ashley's doctors apparently evaluated the benefits and risks of Ashley's treatment based upon how they perceive Ashley would fit into traditional society. They argue:

> Height and normal stature clearly have social value for most individuals. Being taller has been associated with enhanced social stature, greater pay, greater success in attracting a mate, and other social benefits. However, a nonambulatory, severely impaired child is not someone who will experience these benefits of tall stature and therefore will not suffer their loss if kept short. For an individual who will never be capable of holding a job, establishing a romantic relationship, or interacting as an adult, it is hard to imagine how being smaller would be socially disadvantageous.[73]

In fact, the doctors assert that it might be advantageous for Ashley to look young and remain small because "for a person with a developmental age of an infant, smaller stature may actually constitute an advantage because others probably would be more likely to interact in ways that are more appropriate to that person's developmental age."[74]

One could argue that Ashley's doctors' reasoning is right—that allowing Ashley to grow "naturally" is really not "natural" for her at all. Generally, it is presumed that physical development will be concurrent with mental development, and thus expected that a person with the "mental capacity" of a six year old will look like a six year old. Therefore, one might justify Ashley's growth attenuation treatment by arguing that it would be unnatural for Ashley to develop to her expected normal size because her mental capacity will never be that of an adult.

Were it the accepted norm for individuals' physical sizes to be altered to more accurately comport with their intellectual capacity, society would need to determine where to draw the line. For example, society might find it more justifiable to stunt the growth of a child whose mental capacity will remain similar to an infant's. Society may find it less palatable to stunt the growth of a child whose mental capacity will not exceed that of a twelve year old, since many would perceive this child as having a more fulfilling quality of life. At precisely what level of mental development it would be appropriate to attenuate growth as opposed to allowing full physical development to occur naturally remains unclear. If Ashley's parents and doctors are able to justify keeping her small based upon her mental capacity, it may open the door for abuse of other individuals with varying degrees of mental retardation.

"[A] court would likely need to conduct a balancing test in order to weigh the potential harms and benefits of Ashley's treatment."

Overall, a court would likely need to conduct a balancing test in order to weigh the potential harms and benefits of Ashley's treatment. In *In re Phillip B.*, the California Appellate Court proposed such a balancing test in considering whether the trial court erroneously denied a petition requesting that a child with Down syndrome be considered a dependent child because the child's parents refused to consent to heart surgery that would prolong the child's life.[75] The parents refused to consent to the surgery because they thought that it "would be merely life-prolonging rather than life-saving, presenting the possibility that they would be unable to care for [their child] during his later years."[76] The parents clearly based their decision on their son's mental retardation, as the father testified that he would have consented to the surgery if it had been required for his other sons, all of whom did not have intellectual disabilities.[77]

The court affirmed the trial court's decision and found that the state did not meet the burden of proof necessary to intervene in the parents' medical decision. The court held:

> Several factors must be taken into consideration before a state insists upon medical treatment rejected by the parents. The state should examine the seriousness of the harm the child is suffering or the substantial likelihood that he will suffer

> serious harm; the evaluation for the treatment by the medical profession; the risks involved in medically treating the child; and the expressed preferences of the child.[78]

In re Guardianship of Phillip addressed a situation where the parents *refused* to consent to medical treatment and the state intervened. In Ashley's case, her parents are attempting to *proceed* with a proposed treatment, and if the state became involved, the state would most likely try to intervene in order to prevent her parents from proceeding with the treatment. A court would still likely conduct a balancing test to ensure that the treatment is in the child's best interest. In a case like Ashley's, it would be difficult for a court to balance the potential harms and benefits because there is a great deal of uncertainty. For example, it is possible that Ashley's doctors are incorrect about her social and physical potential. Given that little is known about the potential mental abilities of those with profound mental retardation, it is entirely possible that Ashley actually has or will have more advanced mental capacities than initially predicted and there is simply a disconnect between her mental capabilities and her ability to express them.

Where there is so much uncertainty, a court may choose to err on the side of caution. For example, even though Ashley may receive benefits from her proposed course of treatment, a court may nonetheless find that the parents should choose the least drastic alternatives possible. If they had chosen less invasive or reversible alternatives instead of the performed invasive and irreversible procedures and sought the court's permission, Ashley's parents likely would have been allowed to proceed with their treatment with the court's authorization. By following this course of action, the parents would have eliminated all questions as to whether the family had potentially violated Washington state law for failing to obtain a court order.

IV. Moral Implications

The moral implications of allowing Ashley to endure this course of treatment, particularly in light of the bioethical principles of respect for persons, nonmaleficence, and beneficence, must be considered. Laws often reflect what a society deems as moral and immoral; however, the manifestation of moral principles in law often lags behind society's general acceptance of those same moral principles. In this straightforward regard, law is a product of the government's decision to impose moral duties on its citizens.

The principle of respect for persons emphasizes that individuals have the right to make decisions about what happens to their own bodies, and that society should respect these decisions. In an influential report published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Commission described "respect for persons" as follows:

> Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.[79]

Therefore, in evaluating Ashley's treatment from a-respect-for-persons perspective, whether the treatment serves to acknowledge and protect Ashley's autonomy must be examined.

Those persons in support of Ashley's treatment may argue that the treatment improves her quality of life by allowing her to be as independent and comfortable as physically possible, and thus acknowledges her autonomy. The lack of menses means one less bodily function that a caregiver must address, meaning less interference for Ashley. The lack of developing breasts may afford Ashley greater comfort while she lies down, sits in her chair, or plays. Without intervention, Ashley likely would have developed large breasts, given her family history, which could have seriously impeded her ability to move as she wished.[80]

In addition to autonomy, the concept of "dignity" is another moral gauge by which Ashley's treatment should be evaluated. Dignity may be considered in one of two ways: as an inherent quality humans possess (i.e., humans are "dignified"); or as a way of describing how we treat others (i.e., we must treat others "with dignity"). Both supporters and critics of Ashley's parents' decision discuss "dignity" in the context of whether the treatment will either deprive or restore

> One could argue that Ashley's doctors' reasoning is right -- that allowing Ashley to grow "naturally" is really not "natural" for her at all.

> The best interests standard rests on the protection of patients' welfare rather than on the value of self-determination.

> The principle of respect for persons emphasizes that individuals have the right to make decisions about what happens to their own bodies, and that society should respect these decisions.

Ashley's dignity. While Ashley's parents claim that she "will retain more dignity in a body that is healthier, more of a comfort to her, and more suited to her state of development,"[81] critics argue that the treatment violates Ashley's dignity.

Peter Singer, a bioethicist at Princeton University, however, views the concept of dignity somewhat differently. He claims that the concept of human dignity is fundamentally flawed, and, therefore, does not think that Ashley's treatment should be judged solely by whether it violates her dignity.[82] Singer argues that, while personal dignity is certainly possible, it requires that the subject have a cognitive awareness of dignity.[83] Because Ashley does not possess the level of self-awareness necessary to understand the concept of dignity, Singer argues that Ashley should be valued by what she brings to her family, rather than merely valued because she is a human being.[84] In other words, Ashley's value should be measured not by her nature as a living person, but by what she means to others. Therefore, Singer would likely analyze the question of whether the treatment respects Ashley as a person by not only assessing the ways in which it improves Ashley's quality of life, but also by analyzing how the results of the treatment would improve the lives of her family members.

If Singer's appraisal of personal dignity is correct, then his theory raises several claims that are contrary to sound public policy. For example, under Singer's logic, those who do not want to care for a family member with a seriously diminished mental capacity would be justified in terminating that family member's life, because the family member has little value to the family and little worth to society as an individual. This unseemly proposition would likely horrify much of society.

Even if one does not extend Singer's line of reasoning to such an extreme level, under his theory, a family is left with virtually unfettered authority regarding the life of a family member with diminished mental capacity. This hypothesis allows the family to consider its own interests in addition to those of the family member. For example, Singer's argument would allow Ashley's parents to consider their own convenience in deciding what course of treatment to take for Ashley. If Ashley is valuable only insofar as she improves the life of her family, then based on this premise, the family could determine which medical interventions to order for Ashley based, in part, on their contemplation of how the adjustments would make her care more convenient. Again, such unfettered decision-making authority is inconsistent with public policy.

In addition to autonomy, one can morally gauge an individual's conduct using the principles of non-maleficence and beneficence. Nonmaleficence is the duty not to inflict harm, or risk harm to others, and is typically associated with the Hippocratic Oath that doctors take. Beneficence is the duty to help others by acting in their interest. Ashley's parents and doctors express the belief that they are helping Ashley with the treatment, rather than harming her. There is no direct correlation, however, between the course of treatment and the intended cure. Instead, the benefits of this treatment are more indirect and circuitous. As such, society must consider whether "medical and surgical interventions with significant risk to the individual with intellectual disabilities, [can] ever be justified by indirect benefits to the individual when most [of the] direct benefits accrue to other caregivers such as family members."[85]

If the answer is yes and the benefits to other caregivers are deemed adequate justification for procedures that provide limited benefits to the patient, there is a risk that this validation may open a Pandora's Box to unanticipated and undesirable ramifications. Dick Sobsey, the director of a health ethics center at the University of Alberta, Canada, provides this illustrative comparison of ways in which the indirect-benefit rationale can run afoul: in some countries, families will request that physicians amputate or medically mutilate a child with a disability in order to make the child a more productive beggar.[86] While this image may be repulsive, the justifications underlying the decision are not that dissimilar to those being advanced by Ashley's family. Caring for a child with a disability can be costly, and a poor family may not have the resources to care for the child at home, despite the family's desire to do so. If the child can beg more productively as a result of his or her exaggerated condition, the family will, in turn, have greater resources to devote to caring for the child.[87] Alternatively, if a child is not able to leave the home to earn money in this manner, then the family may be forced to leave the child at home, possibly tethered to a piece of furniture to ensure that the child will refrain from hurting himself or others in their absence.[88]

Ashley's case is analogous to the beggar's case in the sense that the parents in both situations would choose a procedure to alter what would otherwise naturally occur for the child. Further, in both cases, the parents' decision also enables the family to provide improved care for the child and ensure that the child will be able to remain with the family. In Ashley's case, her parents argue that the results of the treatment will make it easier for the family to care for her at home,

allowing Ashley the opportunity to be more involved in family events. In the beggar's case, the parents' supplemented income allows them to afford better medical treatment for the child, and remain with the child during the day while he joins them in begging.

There are also significant differences between Ashley's circumstances and the beggar's case. For example, in the case of the beggars' child, the surgery will dramatically change the child's appearance. In Ashley's case, the surgery will actually *prevent* Ashley's appearance from changing and will ensure that she looks like a six-year-old for the remainder of her life. Furthermore, assuming that the benefits Ashley's parents propose are realized by the treatment, there seems to be a greater correlation between Ashley's procedures and her condition, as opposed to the less apparent link between beggars' child's surgery and his condition. Ashley will arguably obtain some direct benefits from her surgery as she will avoid the discomfort and potential emotional trauma of puberty and may be more physically comfortable with her smaller stature. The beggars' child, however, does not obtain any direct benefit from his surgery. The benefit to the child would be extremely indirect – the surgery may make the child a more productive beggar, allowing the parents to obtain greater income as a result of the child's condition and subsequently use the money to finance the child's care. In this instance, the amputation itself will not directly alleviate any problems associated with the child's condition.

AAIDD identifies other negative consequences associated with the slippery slope of allowing growth attenuation:

> With a damning combination of uncertain benefits and unknown risks, growth attenuation as described by Gunther and Diekema is bad medicine, but this practice has even more troubling implications. By extension, if weight ever becomes a difficulty due to age-associated loss of strength for the parents (rather than obesity of the child), then the rationale would suggest that bariatric surgery or severe restriction in caloric intake would be a form of therapy. If that proves insufficient, the goal of reducing the size of the child could be addressed by 'amputation-therapy,' justified by the fact that the patient would never be ambulatory in any event.[89]

Essentially, AAIDD questions where the line should be drawn with respect to such therapies. Ashley's parents argue that they are justified in removing Ashley's breasts and uterus because she has no need for them since she will never give birth and will never breastfeed. According to that line of reasoning, the parents would also be justified in amputating Ashley's legs, because Ashley will never be able to walk. Presumably, it is not likely that Ashley's parents would consider ordering such a course of action.

Perhaps Ashley's parents are more at ease requesting Ashley's hysterectomy rather than requesting amputation because society generally accepts hysterectomies, as they are commonly performed, and are elected voluntarily. Amputation, on the other hand, is frequently viewed as a last resort when all other treatment options fail, and very few if any individuals would voluntarily have their limbs amputated. In light of the parents' reasoning for the procedures, forcing Ashley to undergo a hysterectomy, breast bud removal, and growth attenuation therapy is no different from requesting that her limbs be amputated to keep her small.

Given the treatment's "enormous potential for abuse,"[90] hospital ethics committees should seriously consider whether to allow such treatment and, if deemed permissible, must ensure that adequate procedural safeguards are in place to protect patients.

V. Analysis

Whether Ashley's parents made the right or wrong decision regarding their daughter's health remains unclear. The fact that their decision strikes some members of society as repulsive does not necessarily mean that courts should prohibit it.[91] Furthermore, it is possible that courts should not take an active involvement in the issue and society should be left to judge whether it is appropriate. As two doctors posit, "[i]f high-dose estrogen treatment is on the right track, the collective community response will bestow general approval on growth attenuation; if not, the criticism may suffice to proscribe this mode of treatment."[92]

Even though courts traditionally afford strong deference to parents' rights to make medical decisions for their children, a court would likely decide that Ashley's treatment is legally and morally unacceptable. First, a hysterectomy is akin to sterilization—due to the procedure, Ashley will not be able to procreate. Though the involuntary sterilization of a child with diminished mental capacity is not explicitly prohibited by *Hayes*, Ashley's parents will likely not be able to overcome the legal presumptions against such action. One factor justifying the presumption against involuntary sterilization is that "the individual is . . . likely to engage in sexual activity at the present or in the near future under circumstances likely to result in pregnancy."[93] In their blog, Ashley's parents imply that the only way Ashley will become pregnant is if she is abused. Due to her mental condition, she is not likely to engage in sexual activity on her own. Therefore, Ashley's condition might represent an exception to the *Hayes* standard because her mental condition could not allow her to consciously choose to engage in sexual activity.

> Singer argues that, while personal dignity is certainly possible, it requires that the subject have a cognitive awareness of dignity.

Since Ashley's treatment affects her ability to procreate, this chosen course of action may also implicate a constitutional issue. The right to procreate is a fundamental right protected by the United States Constitution.[94] Whether an individual can assert the protection for the right to procreate if he or she is legally incapable of exercising it remains questionable. From a strictly abstract legal perspective, Ashley could be considered sterile; there is no way for her to legally consent to sexual intercourse due to her diminished mental capacity. Therefore, she could not become pregnant without having been abused. One could argue, therefore, that although Ashley has the same "basic civil right" to procreate that other individuals have, she cannot exercise it because she is incapable of ever voluntarily or legally consenting. Her parents then could argue that the hysterectomy would not prevent Ashley from exercising an otherwise exercisable right. Yet, this would raise another slippery slope argument and could run the risk

of becoming over-exclusive in practice. For example, the circumstances of people sentenced to life in prison without the possibility of parole prevent the prisoners from being able to exercise an otherwise exercisable right, namely: the right to procreate. Ashley has the right to procreate, but is prevented from exercising it because of her mental capacity. Prisoners have the right to procreate, but lack the ability to exercise that right. This argument would justify such persons being forcibly sterilized—something the law does not permit.[95]

One might question whether Ashley's parents would be allowed to exercise Ashley's right to procreate on her behalf and would be allowed to artificially inseminate Ashley once she was older so that she could bear a child. Assume that Ashley were an only child, her parents could not have any more children, and she was likely to die fairly young albeit past an appropriate childbearing age. Further, assume that artificially inseminating Ashley would not harm her in any way, and that she would only suffer from the typical pains associated with pregnancy and childbirth. Individuals may be more likely to support this medical procedure than the procedures that have already been performed on Ashley.

This would be especially true if society were to use a substituted judgment analysis to evaluate this hypothetical situation. Under a substituted judgment analysis, supporters of the artificial insemination might argue that, since most women want to become pregnant and have children, it is likely that if Ashley were competent, she would choose to do so as well. The legality of the procedure may turn on whether Ashley, in fact, has a constitutionally protected right to procreate. And, it would further depend on whether, given her legal status as an individual with diminished capacity, she could exercise this right, or others could exercise it for her.

Even if Ashley does not have a constitutionally protected right to procreate so as to prevent her parents from authorizing her involuntary hysterectomy, there may be other less invasive alternatives. Another factor addressed in *Hayes* was whether "all less drastic contraceptive methods . . . have been proved unworkable or inapplicable."[96] Here, Ashley's parents have not shown why other, less invasive and irreversible contraceptive measures that do not result in sterilization would be inadequate. They profess that the sole purpose of the hysterectomy is to prevent her from experiencing the pains associated with puberty, rather than sterilizing her, which is purely an incidental benefit.

Even if a court declines to extend the reasoning in *Hayes* to Ashley's other procedures, a court would likely err on the side of requiring less invasive measures in an effort to reduce the potential harm to Ashley in the face of such substantial uncertainty. For example, while large breasts may make Ashley uncomfortable in certain chair straps, it is possible that Ashley's parents could find chair straps that are "more suitable for a larger breast size."[97]

Furthermore, while fear of cancer and fibrocystic growths may be reasonable, especially where there is a family history, a court would likely find that this concern is too speculative to require such invasive treatment before it is medically necessary. Given her family history, doctors could simply monitor Ashley's breasts with regular checkups, as they do with other women with a higher risk for developing cancer or fibrocystic growths.

Finally, her parents' argument that large breasts would "sexualize" Ashley, making her more prone to abuse, is unpersuasive; it is equally as likely that "someone might sexually abuse Ashley whether she has breasts or not."[98] Ashley's parents argue that if she were to be abused, her hysterectomy would prevent her from getting pregnant. Arguably, an abortion in response to a pregnancy would be less invasive to Ashley than a pre-emptive hysterectomy. Because none of these treatments will actually *prevent* or *reduce* the likelihood that Ashley will be abused, a court should find that they are too extreme given the conditions they seek to address.

Should the treatment pass legal muster, it does not mean that the treatment is morally sound. Ashley's case raises significant moral implications. For example, this treatment has significant implications regarding the autonomy of a child with a disability. If, following Singer's logic, humans only have value based on their ability to comprehend their own value or by their affect on others, parents of children who cannot comprehend their own value may be allowed to do a variety of unconscionable things to their children. While Gunther and Diekema advise that "[g]rowth attenuation should be considered only after careful consideration of the risks and benefits to each patient on an individual basis,"[99] explicit standards and criteria would need to be developed to ensure patient protection. The factor of "convenience" may subconsciously slip into the equation. While such convenience may disguise itself as a benefit in terms of enabling potentially better care, without clear restraints it runs the risk of justifying such behavior as the amputation and mutilation of children to create more productive beggars. While convenience may enable one family to take better care of a child, convenience for another family may result in parental laziness and neglect of the child.

"The legality of the procedure may turn on whether Ashley . . . has a constitutionally protected right to procreate."

Even if one agrees with the extrapolation based on Singer's philosophy that, without self awareness, humans have no inherent value except as to what they bring to others, this treatment is still morally questionable because of the substantial uncertainty involved. While Ashley's parents, doctors, and media reports describe Ashley as having the mental capacity of an infant, this description is not entirely accurate. The Supreme Court has held that the "'mental age' concept, irrespective of its intuitive appeal, is problematic in several respects."[100] Relying on an amicus brief submitted by the American Association on Intellectual and Individual Disabilities, the Court found that "[t]he 'mental age' concept may underestimate the life experiences of retarded adults, while it may overestimate the ability of retarded adults to use logic and foresight to solve problems."[101]

Accordingly, Ashley is not an infant; she is a nine-year-old with severe cognitive disabilities. Ashley appears to be aware of her environment and interacts, in her own way, with her family members.[102] Ashley even interacts with others outside of her family, as she attends a school for special needs children.[103]

Therefore, given how little is known about what Ashley is thinking or feeling, a court may be premature in allowing for such invasive procedures without fully comprehending the potentially profound side effects Ashley's treatment could have on her emotional well-being. The treatment will significantly alter Ashley's appearance vis-à-vis how it would otherwise develop. Sobsey states that "the long-term effects of high-dose estrogen applied to a six-year-old child are likely to result in highly atypical physical appearance that is at least as dramatic as simple amputation. The effects are likely to include extremely short stature, infantilization of long-bone body proportions…acne, and ironically, increased body fat and weight gain."[104] As Ashley matures and sees her classmates around her mature, it is possible that she will notice, and somehow internalize, the difference between her appearance and those of her classmates. In order to respect Ashley's autonomy and act in her best interest, more information is needed as to the potential emotional effects such treatment could have on a child in Ashley's condition.

Courts should also acknowledge that procedures deemed to be legal today could be perceived as shocking to one's conscience tomorrow. This has been especially true of society's historical treatment of persons with disabilities. For example, the eugenic movement of the early 1900s encouraged society to take action to prevent the production of children with mental retardation. "Defective" infants were allowed to die, certain couples were prevented from marrying, and more horrifically, many persons with mental retardation were sterilized against their will.[105] Perhaps most troubling, the Supreme Court decision in *Buck v. Bell*,[106] which upheld such involuntary sterilization laws, technically remains on the books as good law.

If "Ashley's treatment" becomes a nationally accepted method of treating children with profound mental and physical disabilities, then hospitals must be sure to develop thorough guidelines to ensure that the treatment is performed only when it is, in fact, in the child's best interest. In the event that judicial intervention is necessary, courts should appoint guardians on behalf of children who are possible recipients of the treatment to ensure their moral and legal rights are protected. Treatment should be evaluated on a case-by-case basis by hospital's ethics committees. Further, a court order should be required where the hospital questions the ethical nature of the procedure.

VI. Conclusion

Persons with disabilities have a long history of suffering abuse in this country. Whatever irreversible measures are taken in the name of "treatment" must be scrutinized with extreme care. Third parties to this debate, as a whole, have not been privy to or personally involved in the individualized and highly personal decisions that Ashley's parents have grappled with in recent years. The medical community and laypersons, alike, should be wary of endorsing these treatment options without more information and research. While Ashley's parents likely are well-intentioned, good intentions do not always provide for the best interests of the child.

Ashley's parents say that they "did not pursue this treatment with the intention of prolonging Ashley's care at home…[and that they] would never turn the care of Ashley over to strangers even if she had grown tall and heavy."[107] They profess that, even if Ashley weighed 300 pounds, they would find a way to continue caring for her in their home.[108] If that is the case, then one must wonder why the family has insisted on performing the treatment at all. Conceivably, the family could resort to other, less intrusive measures to enable Ashley to be included in more family events.

Even though scientific progress should not stop because of uncertainty, at the least, such uncertainty should lead members of society to pause and reflect. We are not sure what kind of treatment would be in Ashley's best interests. We do not know what she is thinking or feeling. We do, however, know that the kind of treatment her parents have prescribed for Ashley is irreversible and could have profound psychological and physiological side effects. Perhaps science should

"Even though scientific progress should not stop because of uncertainty, at the least, such uncertainty should lead members of society to pause and relfect."

focus on better understanding the brain and inner-workings of a child with severe cognitive disabilities. Only then will society really be able to know what will be in such a child's best interest.

1 *See* U.S. Department of Health and Human Services, Healthy People 2010: Understanding and Improving Health 6-17 (2d ed. 2000), http://www.healthypeople.gov/document/pdf/Volume1/06Disability.pdf.
2 *See* Chris Plauche Johnson, et al., *Helping Families Raise Children with Special Health Care Needs at Home*, 115 Pediatrics 507, 507 (2005).
3 *See* Daniel F. Gunther & Douglas S. Diekema, *Attenuating Growth in Children with Profound Developmental Disability*, 160 Archives Pediatrics & Adolescent Med. 1013, 1013 (2006).
4 *Id.*
5 *See* The "Ashley Treatment:" Towards a Better Quality of Life for "Pillow Angels" Blog (Mar. 25, 2007), http://ashleytreatment.spaces.live.com/blog/cns!E25811FD0AF7C45C!1837.entry?_c=BlogPart (last visited Oct. 30, 2007) [hereinafter Parents' Blog].
6 *See id.*
7 *See id.*
8 *See* Catharine Paddock, *Public Debates Decision to Keep Disabled Girl's Growth Stunted*, Medical News Today, Jan. 5, 2007, *available at* http://www.medicalnewstoday.com/healthnews.php?newsid=60268 (last visited Oct. 30, 2007).
9 *See* Parents' Blog, *supra* note 5.
10 *See* Gunther & Diekema, *supra* note 3, at 1014.
11 *See id.*
12 *See id.*
13 *See id.*
14 *See id.*
15 *See* Parents' Blog, *supra* note 5.
16 *See id.*
17 *See id.*
18 *See id.*
19 *See id.*
20 *See id*
21 Gunther & Diekema, *supra* note 3, at 1015.
22 *See* Parents' Blog, *supra* note 5.
23 *See id.*
24 *See id.*
25 *See* Gunther & Diekema, *supra* note 3, at 1014.
26 *See id*
27 *See* Paddock, *supra* note 8.
28 *See* Gunther & Diekema, *supra* note 3, at 1014.
29 *See id.*
30 *See id.* at 1014-15.
31 *See id.* at 1015.
32 *See id.*
33 *See* Newmark v. Williams/DCPS, 588 A.2d 1108, 1110 (Del. 1991).
34 *See* Parham v. J.R., 442 U.S. 584 (1979).
35 *See*, *e.g.*, Wisconsin v. Yoder, 406 U.S. 205, 233-34 (1972) (holding that "[t]o be sure, the power of the parent, even when linked to a free exercise claim, may be subject to limitation under *Prince* if it appears that parental decisions will jeopardize the health or safety of the child, or have a potential for significant social burdens").
36 *See e.g.*, *In re* Phillip B., 92 Cal.App.3d 796, 802 (1979) (finding that "[s]everal relevant factors must be taken into consideration before a state can insist upon medical treatment rejected by the parents. The state should examine the seriousness of the harm the child is suffering or the substantial likelihood that he will suffer serious harm; the evaluation for the treatment by the medical profession; the risks involved in medically treating the child; and the expressed preferences of the child.").
37 *See* David Carlson & Deborah Dorfman, Washington Protection & Advocacy System, Investigative Report Regarding the "Ashley Treatment" 17 (2007), *available at* http://www.disabilityrightswa.org/news-1/ashley-treatment-investigation (last visited Oct. 17, 2007).
38 *See id.*
39 *See* 608 P.2d 635 (Wash. 1980).
40 *See id.* at 640.
41 *See id.*
42 *Id.* at 641.
43 *See* Carlson & Dorfman, *supra* at 37.
44 *See id.* note 36, at 24.
45 *See* The Board of Directors of the American Association on Intellectual and Developmental Disabilities, Board Position Statement: Growth Attenuation Issue, *available at* http://www.aaidd.org/Policies/board_positions/growth.shtml (last visited Oct. 17, 2007).
46 *See* 421 N.Y.S.2d 965, 966 (1979).
47 *See id.* at 967.
48 *See id.*
49 *Id.* at 968.
50 *See* Larry Gostin, *A Moment in Human Development: Legal Protection, Ethical Standards and Social Policy on the Selective Non-Treatment of Handicapped Neonates*, 11 Amer. J. L. & Med. 31, 58 (1985).
51 434 N.E. 2d 601, 604-05 (Mass. 1982).
52 *Id.* at 609.
53 *See* Access to Medical Treatment Act , H.R. 2792, 109th Cong. (June 8, 2005), *available at* http://www.govtrack.us/congress/billtext.xpd?bill=h109-2792 (last visited Oct. 17, 2007).
54 *See* Access to Medical Treatment Act, *supra* note 53, § 2(13) (defining "patient" as "any individual who seeks medical treatment from a health care practitioner for a disease or health condition").
55 *See id.* § 2(12).
56 Gunther & Diekema, *supra* note 3, at 1016.
57 *See* Cruzan v. Director, Missouri Dept. of Health, 497 U.S. 261 (1990). While the Court did not specifically find that there exists a constitutionally protected right to die, it did uphold a state statute allowing for the removal of artificial hydration and nutrition for patients with certain conditions if a high evidentiary standard is met.
58 *See* Superintendent of Belchertown State School v. Saikewicz, 370 N.E.2d 417, 431 (Mass. 1977) (using a substituted judgment analysis in deciding not to approve treatment for a 67-year-old patient with mental retardation suffering from a fatal form of leukemia.).
59 *See*, *e.g.*, Brophy v. New England Sinai Hospital, Inc., 497 N.E.2d 626 (Mass. 1986) (honoring the substituted judgment of a patient in a persistent vegetative state by allowing the removal of the patient's gastronomy tube); *In re* Eichner, 420 N.E.2d 64 (1981) (relying on a substituted judgment analysis in deciding to remove a patient in a vegetative coma from a respirator).
60 Courts seem more hesitant to apply this standard than the substituted judgment standard for patients that were at one time mentally capable. *See In re* Conroy, 486 A.2d 1209, 1232 (N.J. 1985) (ranking various judgment standards and proposing to apply a best interest analysis only "in the absence of trustworthy evidence, or indeed any evidence at all, that the patient would have declined the treatment . . . [and if] the net burdens of the patient's life with the treatment should clearly and markedly outweigh the benefits that the patient derives from life.").
61 *See* 370 N.E.2d 417, 419-20 (Mass. 1977).
62 *See* Penry v. Lynaugh, 492 U.S. 302, 339 (1989) (overruled on other grounds by Atkins v. Virginia, 536 U.S. 304 (2002)).
63 *See Saikewicz,* 370 N.E. 2d at 420.
64 *See id.* at 431.
65 *See id.*
66 *See id.* at 432.
67 *See* Woods *ex rel* Simpson v. Commonwealth, 142 S.W.3d 24, 34-35 (Ky. 2004) (quoting, 741 P.2d 674, 689, n.23 (Ariz. 1987)).
68 *Id.* at 35 (citing the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Deciding to Forego Life-Sustaining Treatment, at 134-35 (1983)).
69 *See* Gunther & Diekema, *supra* note 3, at 1016.
70 *See id.*
71 *See id.*
72 *See id.*
73 *Id.*
74 *See id.*
75 92 Cal. App.3d 796 (1979).
76 *See In re* Guardianship, 139 Cal. App.3d 407, 418 (1983).
77 *Id.* at 418, n.9.
78 *Guardianship of Phillip*, 92 Cal. App.3d at 802.

79 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Dep't of Health and Human Services, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979), *available at* http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm (last visited Oct. 17, 2007).
80 *See* Parents' Blog, *supra* note 5.
81 *See id.*
82 *See* Peter Singer, Op-Ed., *A Convenient Truth*, N.Y. Times, Jan. 26, 2007, at A21.
83 *See id.*
84 *See id.*
85 *See* Dick Sobsey, *Growth Attenuation and Indirect-Benefit Rationale*, 10 Newsletter Network on Ethics & Intell. Disability, 1, 2 (Winter 2007).
86 *See id.* at 2.
87 *See id.*
88 *See id.* at 7.
89 The Board of Directors of the American Association on Intellectual and Developmental Disabilities, *supra* note 45.
90 *See id.*
91 *See* Singer, *supra* note 82.
92 *See* Jeffrey P. Brosco & Chris Feudtner, *Growth Attenuation: A Diminutive Solution to a Daunting Problem*, 160 Archives. Pediatrics & Adolescent Med. 1077, 1078 (2006).
93 *See In re Guardianship of Hayes*, 608 P.2d at 641.
94 *See* Skinner v. Oklahoma, 316 U.S. 535, 541 (1942).
95 *See id.*
96 *See In re Guardianship of Hayes*, 608 P.2d at 641.
97 *See* S. Matthew Liao, Julian Savulescu, Mark Sheehan, *The Ashley Treatment: Best Interests, Convenience, and Parental Decision-Making*, 37 Hastings Center Report 16, 18 (2007).
98 *See id.*
99 Gunther & Diekema, *supra* note 3, at 1014 (emphasis added).
100 *See Penry*, 492 U.S. 302 at 339 (1989).
101 *See id.*
102 *See* Parents' Blog, *supra* note 5.
103 *See id.*
104 *See* Sobsey, *supra* note 85, at 7.
105 *See* Brosco & Feudtner, *supra* note 92, at 1078.
106 *See* 274 U.S. 200 (1927).
107 *See* Parents' Blog, *supra* note 5.
108 *See id.*

Where The Action Is: Innovative State Health Care Initiatives

*By Nalini K. Pande**

I. Introduction

One of the major issues highlighted at the February 2007 Symposium on Innovative State Health Care Initiatives is recent state initiatives to increase access to health care and contain costs through managed care. Recently, Pennsylvania has capped the surplus of non-profit health plans to improve access to health care and contain costs; however, there are unintended consequences of such actions and alternative policy options exist. The Lewin Group, a health care policy research and management consulting firm, analyzed the capping of non-profit health plans' surplus by the Pennsylvania Insurance Department (PID). This article is a summary of that report.

Pennsylvania House Resolution 865 of 2004 directed the Legislative Budget and Finance Committee to examine the Commonwealth's options with respect to the regulation, oversight, and disposition of the reserves and surpluses of health insurers in Pennsylvania, specifically Blue Cross and Blue Shield plans. The resolution directed the Committee to analyze pertinent statutes, regulations, and other measures in effect that regulate such surpluses with particular attention paid to other states' laws and practices. It also requested the Committee to focus on potential alternatives with respect to the use of any excess capital surpluses to reduce premiums or to delay or moderate premium increases. The Committee then issued a competitive request for proposals for assistance in fulfilling the charge and awarded a contract to The Lewin Group.

II. Background

Pennsylvania has four not-for-profit Blue Cross and Blue Shield health plans (Pennsylvania Blue plans): (1) Blue Cross of Northeastern Pennsylvania, based in Wilkes-Barre; (2) Capital Blue Cross, based in Harrisburg; (3) Highmark, headquartered in Pittsburgh; and (4) Independence Blue Cross, based in Philadelphia. Prior to the Lewin study, the public focus on the Pennsylvania Blue plans' financial activities had intensified. First, the Pennsylvania Blue plans, like health insurers nationwide, began to experience large increases in their earnings. Second, the softening of the economy at the same time that health care costs swelled increased the number of uninsured residents in Pennsylvania and made it more difficult for those with insurance to afford it. Some stakeholders argued that the Pennsylvania Blue plans should contribute portions of their surpluses to help make health coverage more affordable. In February 2005, the PID took action to address these issues.

II. Key Questions

The Lewin Group report[1] examined several key questions:

- Why do health plans need surplus?
- Is there a "right" amount of surplus for health plans?
- How are plan surpluses generally regulated and what has been the experience with the Pennsylvania Blue plans?
- What are the consequences of capping surplus and what are the alternatives to doing so?
- How have other states approached the issue?

First, why do health plans need a surplus? Most insurers contend, similar to the Pennsylvania Blue plans, that an insurer needs an adequate margin of safety to endure periods of adverse experience without triggering any form of regulatory intervention. Also, many health plans target surplus levels to cushion against a downturn in the underwriting cycle.[2]

Second, is there a "right" amount of plan surplus? Or, in other words, how much surplus is too much? An adequate margin of safety is especially important for Pennsylvania Blue plans because they are not eligible to participate in the state guaranty fund which protects consumers and health care providers if an insurer fails to meet its obligations. Lacking access to this safety net, Pennsylvania Blue plans must maintain larger surpluses to account for unforeseen risks.

Third, how are plan surpluses generally regulated and what has been the experience with the Pennsylvania Blues plans? In the past, the PID, like its counterparts in other states, focused on making sure that the Pennsylvania Blues plans held sufficient, *minimum* reserves and surpluses to ensure against insolvency. Pennsylvania joined most other states in enacting a variation of the National Association of Insurance Commissioners model health risk-based capital act, which addressed the minimums needed to ensure solvency.

> "Most insurers contend, similar to the Pennsylvania Blue plans, that an insurer needs an adequate margin of safety to endure periods of adverse experience without triggering any form of regulatory intervention."

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In addition to regulating surplus minimums, the PID also has statutory authority to govern Pennsylvania Blue plans' social missions, though at least one Pennsylvania Blue plan does not agree with the Department's view of the charitable obligations of the Pennsylvania Blue plans.[3] States have varied widely in their interpretations of "charitable and benevolent," a phrase within many not-for-profit Blue plans' enabling legislation. Whereas in Pennsylvania, the Pennsylvania Blues plans have traditionally served as insurers of last resort, in some states, the Pennsylvania Blues plans have operated like commercial insurers and generally have not been expected to provide significant levels of community benefit. In fact, the precise nature of the community benefit requirements stemming from this language has been a subject of much litigation.[4]

Prior to 2005, a combination of statutory expectations and company missions drove the Pennsylvania Blue plans' community benefit activities. For example, recent laws forced the Pennsylvania Blues plans to bid to participate in the Commonwealth's Children's Health Insurance Program (CHIP) and adultBasic programs,[5] in addition to offering coverage to individuals who meet specific criteria set out by the federal Health Insurance Portability and Accountability Act (HIPAA). Nationwide, only Pennsylvania and Michigan implemented HIPAA's requirements by designating their Blue Cross and Blue Shield plans as the sole carriers to offer coverage which must be offered regardless of health status or pre-existing conditions. In 2003, the Pennsylvania Blues plans also voluntarily committed to participate in the federal Health Coverage Tax Credit (HCTC) program created under the Trade Assistance Act.

Additionally, the Pennsylvania Blues plans' role as insurer of last resort has led the plans to offer subsidized coverage to any individual regardless of health status, even if the individual is not eligible under HIPAA (this is termed "guarantee issue coverage"). In contrast, insurers in most other states may decline to issue policies to individuals with serious health conditions, or may charge extremely high rates. Thus, Pennsylvania Blues plans —given Pennsylvania's statutory requirements in adultBasic, CHIP, HIPAA, as well as the Pennsylvania Blues plans' voluntary commitment to HCTC, subsidized guarantee issue coverage in the individual market, and direct charitable giving programs—are allocating percentage amounts of community benefit funding that are at least as generous as, if not more generous than, the amounts allocated by their counterparts elsewhere.

What has the PID done to regulate the Pennsylvania Blue plans' surpluses? In 2004, the PID asked the Pennsylvania Blues plans to justify their surpluses and explain how the plans contribute to their communities. In February 2005, the PID released two key documents. The first document, a Determination and Order, outlined acceptable ranges for the Blue plans' level of surplus capital—efficient, sufficient, or inefficient. This document reported that none of the plans held excess capital and declared that any Blue plan having "sufficient" capital—three of the four plans stood in this category (at the time)—would not be allowed to include "risk and contingency factors" in its future rate requests.[6] Risk and contingency factors are margins that insurers build into rates to cover unforeseen events and fluctuations in medical claims. In the past, the PID has permitted up to a 5 percent risk and contingency factor in addition to projected medical claims and administrative costs for Blue plans and a factor of 5 percent or more for commercial insurers. The second issuance, "Agreement on Community Health Reinvestment,"[7] was executed by the Deputy Insurance Commissioner and the heads of the four Pennsylvania Blue plans and set forth a program in which the Blues plans, for the years 2005-2010, pledged more than one percent of their premium revenues to community benefits. The aggregate value of the pledges would total $950 million, although not all of the funding was new. Notably, the agreement supplanted an order that had been in place since 1996 for Highmark, the largest of the plans and likely source for more than half of future community health reinvestment dollars. When the consolidation of two predecessor entities formed Highmark in 1996, the Insurance Commissioner ordered Highmark, and Highmark alone, to allocate at least 1.25 percent of direct written premium to social mission programs. That order had no end date and as of 2004, Highmark spent about $40-$50 million annually on community benefits. Highmark projected 2004 outlays of $94 million—about double its formal obligation under the 1996 order.

"In fact, the precise nature of the community benefit requirements stemming from this language has been a subject of much litigation.

With the PID taking these two major steps to regulate Pennsylvania Blue plan surpluses, one should consider the consequences of regulating plan

surpluses. Rigid caps on surpluses could undermine competition if not managed prudently. The primary advantage of capping surplus levels is that it may slow the rate of premium growth if an insurer has surplus capital that is at or near its ceiling. However, an insurer may react by draining surplus in ways that do not involve rate relief, such as simply spending more on staff and infrastructure improvements. Also, the plan could create additional community benefit outlays, though this could conflict with an insurer's interest in building market share and improving performance.

In addition to uncertain benefits, negative consequences may also result from placing a numeric cap on insurers' surpluses, particularly if set at a low level. First, the intervention could create market instability if it resulted in artificially low premiums. Depending on the scale of the impact on premium rates, some competitors might be forced to exit the market, leaving consumers fewer choices. Second, the short-term savings could be followed later by pricing increases. Lastly, when insurers have less capital, insurers face lower credit ratings from independent rating agencies, forcing the plans to pay higher interest costs whenever they need to borrow.

Given these consequences, what are the alternatives to capping surplus? Traditionally, state insurance departments have attempted to influence premium levels in a number of ways: underwriting and rate-making rules, especially in the small-group and non-group segments; rate filing and approval processes; and setting minimum medical loss ratios. These regulations focus on insurers' abilities to generate earnings, rather than on how much surplus can be kept once earned. Because these approaches affect the rate-making process, they have a more direct and predictable impact on premium affordability compared to capping surplus levels. However, any type of rate regulation must consider carrier solvency and the importance of regulating carriers on a level playing field. Further, any type of regulation that interferes excessively with traditional market forces and market pricing can have the unintended consequence of forcing carriers out of the market.

"In addition to uncertain benefits, negative consequences may also result from placing a numeric cap on insurers' sur-pluses, particularly if set at a low level.

An important component of The Lewin Group report was to review other states' approaches in response to these issues. Very few states have chosen to regulate the upper bounds of surplus capital accumulation. Until June 2006, Hawaii capped surplus at the level at which a non-profit carrier's net worth exceeded 50 percent of its annual health care expenditures and operating expenditures as reported on the plan's most recent financial statement filed with the Commissioner.[8] Alternatively, Michigan caps its risk based capital ratio (RBC) at 1,000 percent for Blue Cross Blue Shield of Michigan.[9] In comparison, Pennsylvania uses different RBC target ranges for its four Blue plans (550 percent to 750 percent for its larger plans, Highmark and Independence Blue Cross; and 750 percent to 950 percent for its smaller plans, Blue Cross of Northeastern Pennsylvania and Capital Blue Cross).

Some states have worked with large non-profit carriers to direct high surpluses toward community benefit health care initiatives. As discussed, in Pennsylvania, the state formalized the prospective "community activities" of its four Blues plans and the plans voluntarily agreed to commit $150 million annually to a six-year community health reinvestment program. Until the creation of the Community Health Reinvestment Agreement in February 2005, only one other state, Maryland, had a formal requirement for community benefit outlays that applied exclusively to a Blue plan. Since then, Massachusetts has created formal community-benefit guidelines for non-profit HMOs in the state. This program included $85 million to support basic health coverage for low-income and uninsured residents with the remaining $65 million for other health care related community activities.[10]

Most recently, CareFirst announced a $92 million initiative intended to address community benefits with $60 million from a reduction in premiums against anticipated 2005 levels. This was in response to increased public scrutiny, especially by the Appleseed Foundation and hearings by the D.C. Insurance Commissioner on CareFirst BlueCross Blue Shield's D.C. affiliate, Group Hospitalization and Medical Services, Inc.'s (GHMSI) charitable obligation to the community.[11] It is important to note that the unintended consequence of imposing community benefit requirements on non-profit carriers is that such requirements serve as an indirect tax on carrier members who subsidize their community-benefit initiatives with their premiums. Some members prefer reduced premiums instead of using premium profits for these initiatives that serve the community as a whole.

Conclusion

There are a myriad of ways to regulate surpluses in order to increase access to health care—each with its own intended and unintended consequences. Focusing on increased transparency can improve competition and efficiency, and stronger regulatory authority and oversight can provide a first step in addressing concerns of surplus accumulation. Targeting appropriate surplus levels is critical for managing financial risk. It is even more important for non-profit organizations which do not have access to equity markets and must fund investments in new products and infrastructure out of operating results' surplus or debt instruments. Surplus levels, which are held too low, may expose the organization to risk of failure during predictable periods of downturns in the underwriting cycle. They also limit the organization's ability to respond to changes in business conditions and demands for new products. But surplus levels that are too high may affect product affordability and could subject organizations to unwanted regulatory scrutiny. Since most states do not impose maximum surplus levels, it is incumbent on state insurance departments to review these issues in light of the circumstances and the critical considerations outlined above to increase access to health care and contain costs.

1 *See* The Lewin Group, Considerations for Regulating Surplus Accumulation and Community Benefit Activities of Pennsylvania's Blue Cross and Blue Shield Plans (June 13, 2005), *available at* http://www.lewin.com/NR/rdonlyres/E38A1263-0410-4E37-A300-4A1A4AC4EF3B/0/3192.pdf (last visited Oct. 21, 2007). The Pennsylvania Legislative Budget and Finance Committee commissioned Lewin to conduct a study of the regulation and disposition of reserves and surpluses of the four Blue plans. Lewin found that the upper limits on surplus were reasonable.

2 *See* How Much Is Enough? Capital and Surplus Management for Health Entities, Society of Actuaries, http://library.soa.org/library-pdf/rsa03v29n220pd.pdf.

3 *See* Letter from Steven B. Davis, Chief Counsel, Office of Chief Counsel,

Penn. Insur. Dept. to Senator Gibson E. Armstrong, Chairman, Banking and Insurance Committee, Senate of Pennsylvania, regarding April 12, 2005 Hearing on the Pennsylvania Blue plans' Agreement on Community Health Reinvestment (April 27, 2005) (available as Appendix E in http://www.lewin.com/NR/rdonlyres/E38A1263-0410-4E37-A300-4A1A4AC4EF3B/0/3192.pdf) (stating that PID has traditionally interpreted the Pennsylvania Blue plans' enabling legislation to require that the Pennsylvania Blue plans act as insurers of last resort, and thus, the plans must offer open enrollment).

4 *See* Jane M. Von Bergen, *Pennsylvania Blue Plans Again Face Suit over Surplus*, The Phila. Inquirer, Nov. 30, 2006 at A1. The Pennsylvania Supreme Court recently revived a lawsuit filed five years ago by the owner of a Bensalem, Pennsylvania appliance store, who wants Independence Blue Cross to return part of the surplus to insurance buyers. On Nov. 22, 2006 the Pennsylvania Supreme Court reversed a December 2002 Commonwealth Court decision dismissing the case. The class-action lawsuit will now go back to the lower courts along with three similar ones, each against one of the state's four Blue Cross and Blue Shield health plans. The cases have yet to address whether the surpluses are excessive and who has authority to determine whether the Pennsylvania Blue plans breached their obligations as nonprofits by holding too much surplus and not using such surplus to lower premiums or help the uninsured. Both the Pennsylvania Blue plans and the Insurance Department in Pennsylvania argue that the size of the surplus is a regulatory matter for the state Insurance Department.

5 *See* 35 Pa. Cons. Stat. Ann. § 5701.1303(g) (2001); Stan Dorn & Jack Meyer, Pennsylvania: A Case Study in Childless Adult Coverage State Report (Economic and Social Research Institute 2004).

6 *See* Insurance Department of the Commonwealth of Pennsylvania, Determination and Order, February 9, 2005.

7 Agreement on Community Health Reinvestment between Insurance Department of the Commonwealth of Pennsylvania and Capital Blue Cross, Highmark Inc, Independence Blue Cross, and Hospital Service Association of Northeastern Pennsylvania, Blue Cross of Northeastern Pennsylvania, Appendix D at 13 (Feb. 2, 2005), *available at* http://www.lewin.com/NR/rdonlyres/E38A1263-0410-4E37-A300-4A1A4AC4EF3B/0/3192.pdf (stating the Agreement specifically requires that the "Annual Community Health Reinvestment for each Plan shall be expended, distributed or utilized in the respective area of that Plan and solely for Permitted Community Health Reinvestment Endeavors. Sixty percent of the Annual Community Health Reinvestment for each calendar year . . . shall be dedicated to providing health insurance through state-approved programs for persons of low-income, including but not limited to adultBasic . . . .").

8 *See* Haw. Rev. Stat. §§ 431:14F-101, 431:14F-106(a) (2006) (repealed 2006); *See also* Telephone interview with Lim Lloyd, Administrator of Health Insurance Branch, Insurance Division, Hawaii Department of Commerce and Consumer Affairs (Nov. 2, 2006).

9 *See* Mich. Comp. Laws Ann. ch. 550, §1204 (2003).

10 *See* Health Insurance Premiums, the Underwriting Cycle, and Carrier Surpluses, Spotlight on Md. (Md. Health Care Commission, Balt. Md.) (Mar. 2005).

11 *See* Press Release, CareFirst Blue Cross Blue Shield, CareFirst Affiliate, GHMSI, Pledges to Improve Affordability of Insurance, Expand Charitable and Community Investments (Mar. 24, 2005), *available at* http://www.carefirst.com/media/NewsReleasesDetails/NewsReleasesDetails_20050324.html (last visited Oct. 21, 2007).

CAFTA-DR, TRIPS, And Pharmaceuticals

*By Jennifer Cadena**

> TRIPS permits a WTO nation to access international trade markets from a more advantageous standpoint, provided that the nation accessing the markets conforms to the stringent intellectual property laws outlined in TRIPS' provisions.

I. Introduction

In 2002, combined profits for the ten largest United States drug manufacturers' combined profits totaled $35.9 billion, more than five-and-one-half times the mean profit grossed by all other industries represented in the Fortune 500.[1] Drug companies' profits continue to escalate exponentially, in part due to an increase in the purchase price of pharmaceuticals.[2] Critics of the industry contend that higher purchase prices bar indigent individuals' access to affordable pharmaceuticals, including live-saving medicines.[3] In response, drug companies emphasize that expensive research and development costs are driving the high prices.[4] Pharmaceutical companies profess the need to gross more profit in order to offset these costs; accordingly, the pharmaceutical industry supports strong intellectual property rights to protect against the unauthorized production of generic medicines ("generics") that might detract from their profits.

In most nations, prior the World Trade Organization's (WTO) ratification of *Trade-Related Aspects of Intellectual Property Rights* (TRIPS)[5] in 1994, domestic pharmaceutical companies manufactured generics without restraint and sold them at reduced retail prices.[6] Although TRIPS imposed some restraints on these manufacturers, many WTO members recognized the importance of public health considerations. Accordingly, to circumvent these restraints, TRIPS includes provisions which allow WTO members to manufacture generics in certain situations.

In contrast, U.S. multilateral trade agreements, such as the *Central American Free Trade Agreement – Dominican Republic* (CAFTA-DR), prohibit smaller pharmaceutical companies from manufacturing generics, even in situations that are permissible under TRIPS. CAFTA-DR reinforces the status quo by shielding large pharmaceutical companies from lost profits and preventing poor consumers from accessing affordable medications by (1) extending the length of patent terms; (2) failing to explicitly permit compulsory licenses; and (3) requiring a five-year data exclusivity period.

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A. The TRIPS Agreement

Developed nations generally advocate for strong international intellectual property rights because businesses, such as pharmaceutical companies, that design innovative products are located within their borders. TRIPS evolved in response to intense lobbying from the U.S., European Union, and Japan for the WTO to expand intellectual property rights to an international scope.[7] TRIPS permits a WTO nation to access international trade markets from a more advantageous standpoint, provided that the nation accessing the markets conforms to the stringent intellectual property laws outlined in TRIPS' provisions.

At the time of TRIPS enactment, many WTO members believed that it was inappropriate for a state to issue pharmaceutical patents, or had never before issued such patents within their borders.[8] Thus, members purposefully incorporated exceptions into TRIPS that allow a state to circumvent intellectual property patent requirements with respect to pharmaceuticals.[9] For instance, compulsory licenses allow a state to compel a pharmaceutical manufacturer to relinquish its patent rights to a particular drug. In this situation, the WTO member nation grants a compulsory license to an alternate pharmaceutical company to manufacture an equivalent medicine.[10] Normally, a patent would have prevented the alternate pharmaceutical company from manufacturing the drug.[11] Under this exception, a state can grant a compulsory license to a pharmaceutical company at any time as long as the state requests permission and compensates the patent-holding pharmaceutical company. A state need not request permission from the patent holder, however, before issuing a compulsory license during a national emergency or circumstance, an extreme urgency, or for public non-commercial consumption.[12]

For many years, developing nations were unsure of how these flexible provisions would be interpreted. They consequently feared using them without first receiving further clarification as to how the compulsory license provisions would function. The request for further clarification led member nations to convene at a conference in Doha, Qatar, to enact the *Declaration on the TRIPS Agreement and Public Health* (Doha Declaration).[13]

B. The Doha Declaration and Paragraph 6

During the Doha convention in 2001, each government entity reiterated that TRIPS contains flexible provisions to circumvent pharmaceutical patents in order to ensure that governments can protect public health.[14] The Doha Declaration not only affirmed that states should implement and interpret TRIPS to support public health by promoting access to medicines, it also emphasized that states are entitled to issue compulsory licenses and permit parallel imports.[15] Essentially, the Doha Declaration forced WTO members to acknowledge that a balance must exist between strict intellectual property rights and public health. WTO Director-General Mike Moore stated that TRIPS ". . . strikes a carefully-negotiated balance between providing intellectual property protection . . . and allowing nations the flexibility to ensure that treatments reach the world's poorest and most vulnerable people. Countries must feel secure that they can use this flexibility."[16]

Even more significantly, the Doha Declaration ordered WTO members to further negotiate and formulate a solution whereby nations lacking domestic manufacturing capabilities would still have the opportunity to import generics.[17] Two years later, in 2003, WTO members enacted Paragraph 6 of the Doha Declaration, explicitly permitting WTO nations to issue compulsory licenses to export generic drugs to other nations which had not previously issued a patent for a certain pharmaceutical.[18] Prior to the adoption of Paragraph 6, a WTO member could only issue compulsory licenses for drugs which would be primarily consumed within the country's own borders.[19]

II. CAFTA-DR

In spite of lobbying efforts, the United States failed to obtain the level of intellectual property protection that it had originally sought during the TRIPS negotiations. Specifically, the U.S. feared the overuse of compulsory licensing and had desired lengthier patents and data exclusivity to prevent "unfair commercial use." Instead, the U.S. adopted bilateral and multilateral trade agreements to incorporate these measures.[20] These aggressive agreements impose strict intellectual property rights standards on all countries that are a party to them and, in turn, help soothe investors' worries about losing profit to generic drug manufacturers.[21] CAFTA-DR stretches patent protection to an extreme level which effectively bars domestic manufacturers from producing generics during the patent term. Consequently, many citizens in Central America are denied access to essential medicines due to the lack of affordable generics.

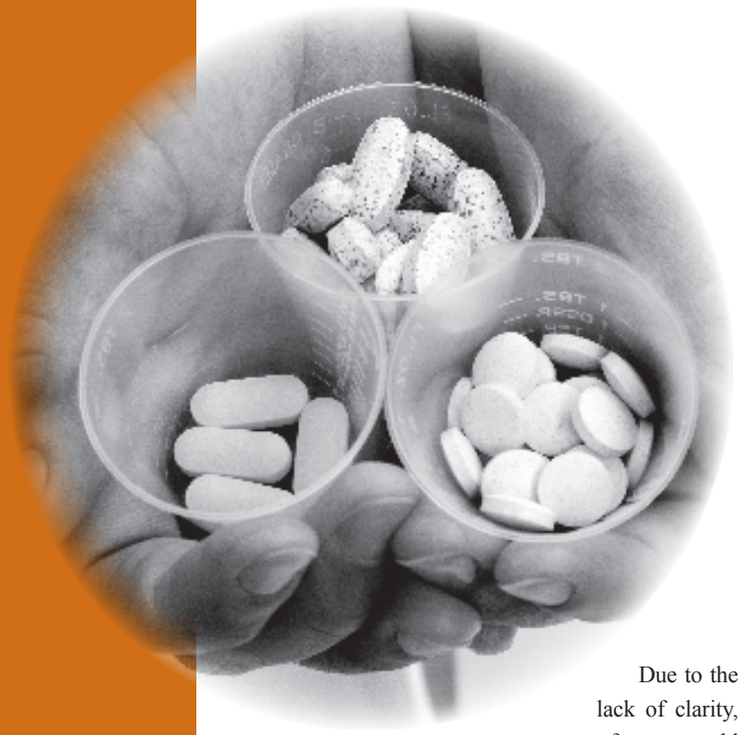
CAFTA-DR is a multilateral trade agreement enacted between the United States and Costa Rica, the Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua that restricts these Latin American countries' ability to manufacture generic drugs.[22] In addition to this central treaty, each state has signed multiple side letters with the United States. A side letter provides an additional understanding between the parties that goes beyond the main text of a multilateral trade agreement. *Understanding Regarding Certain Public Health Measures* is a side letter which has been adopted by all parties to CAFTA-DR.[23] This agreement, however, does not expand the state's ability to issue patents to a domestic pharmaceutical company to manufacture generics.

A. CAFTA-DR Extends the Length of a Patent

CAFTA-DR impedes the ability of domestic drug companies to manufacture generic medicines by extending patent lengths. First, CAFTA-DR Article 15.9 § 6(a) obligates states to adjust the length of a patent to compensate for unreasonable delays.[24] An "unreasonable delay" occurs when it takes a state longer than five years to issue a patent.[25] In these situations, if requested by the pharmaceutical company, the patent-issuing state *must* adjust the length of the patent term to compensate for the delay.[26] In TRIPS, however, the patent term is limited to twenty years.[27] Although WTO members raised the prospect of extending patent terms to compensate for regulatory delays, the WTO failed to enact this provision in TRIPS; thus, TRIPS does not obligate states in the same manner as CAFTA-DR in this regard.[28]

Moreover, CAFTA-DR Article 15.9 § 6(b) further extends patent lengths by demanding that nations automatically toll the original patent term if an "unreasonable curtailment" occurs during the marketing process. [29] Although CAFTA-DR Article 15.9 § 6(a) provides examples of an "unreasonable delay," the meaning of the term "unreasonable curtailment" is left ambiguous. Thus, it is unclear how a WTO member should interpret an "unreasonable curtailment." In layman's terms, the definition of "curtailment" is "to make less by or in some way cut off some part."[30] Read narrowly in CAFTA-DR, the term "unreasonable" would modify curtailment; hence, only a drastic impediment or situation arising during the marketing process would force a state to reinstate the full patent term. Yet, read broadly, an "unreasonable curtailment" could apply to *any* delay during the marketing process.

"CAFTA-DR stretches patent protection to an extreme level which effectively bars domestic manufacturers from producing generics during the patent term."



> . . . CAFTA-DR provides U.S. pharmaceutical companies far greater protections in foreign countries than they would receive under a patent filed in the United States.

Due to the lack of clarity, a manufacturer could conceivably argue that any and all delays during the marketing process are unreasonable up until the time the drug enters the market. In effect, unlike TRIPS, where the twenty-year patent term begins on the date of application, under CAFTA-DR, the twenty-year patent length can begin many years later. By way of this provision, CAFTA-DR provides U.S. pharmaceutical companies far greater protections in foreign countries than they would receive under a patent filed in the United States.

In sum, CAFTA-DR automatically extends the length of a patent term and thus prevents domestic manufacturers from developing generics without a compulsory license. In turn, the pharmaceutical company will hold a lengthier monopoly over the patent, making it more difficult for indigent persons to obtain reasonably priced drugs.

B. CAFTA-DR Does Not Protect Compulsory Licensing

CAFTA-DR fails to include the most integral public health provision in TRIPS – the provision pertaining to compulsory licensing. TRIPS Article 31 states that, if permitted by local laws, a nation can authorize a third party to disregard a pharmaceutical company's patent and produce generics if the state had previously requested permission from the patent holder and the request had been unfulfilled after a reasonable period of time.[31] Therefore, a state does not need to obtain actual authorization; rather, the state only needs to make efforts to obtain an authorization. Further, in cases of "a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use," TRIPS allows states even greater flexibility by eliminating the requirement to request permission from the patent holder altogether.[32] By explicitly permitting a state to waive a patent when necessary TRIPS gives a WTO member more extensive rights than the Central American countries are provided under CAFTA-DR.

The United States and the Central American nations have endorsed a side letter on public health, titled *Understanding Regarding Certain Public Health Measures*. This side letter attempts to reaffirm that CAFTA-DR does not encroach upon a state's ability to take necessary measures to protect public health.[33] Although this letter appears to offer assurances that Central American nations can grant compulsory licenses, it is unlikely that these assurances supersede CAFTA-DR Article 11 in Chapter Fifteen that states must adhere to patent obligations "except as [CAFTA-DR] provides otherwise."[34] Moreover, the explicit text of CAFTA-DR neither recognizes nor incorporates this side letter.

Further, these letters are only "commitments" and will not take the effect of law until the House and Senate pass legislation to implement the modifications.[35] If the United States violates this side letter, its reputation with regard to both trade agreements and side letters will sour tremendously, a risk the U.S. may not wish to take. Nevertheless, a belief that the U.S. will not violate a side letter for fear of ruining its reputation is not as compelling of a deterrent as a legal prohibition.

Even if this side letter ripens into an enforceable agreement, it still would not afford sufficient protection to Central American states to permit domestic manufacturers to produce generics without authorization. For example, the CAFTA-DR side letter is not as flexible as TRIPS because it requires that measures to protect health be "necessary," and only permits "access to medicines" with regards to epidemics, or circumstances of extreme emergencies such as HIV/AIDS, tuberculosis, malaria, and other epidemics.[36]

A "necessary" measure is a high standard that is narrowly defined to balance the dual goals of maintaining the freedom of members to set and achieve their own regulatory objectives and discouraging the adoption of measures which unduly restrict trade.[37] Necessity tests typically require that measures which restrict trade not exceed what is "necessary" to achieve a member's policy objective.[38] Under this framework, the implementing nation must prove that a regulation is necessary and effective, and that no less restrictive trade measures are available to achieve the same purpose.[39] In addition, the regulation should not be a "disguised

restriction on international trade" or amount to "arbitrary or unjustifiable discrimination."[40] Thus, if the public health measure is discriminatory to trade, the measure may be found to be in violation of trade rules, even if the state did not intend to discriminate. By incorporating the word "necessary" into the side letter of CAFTA-DR, the U.S. has dictated a burdensome standard that Central American nations must meet before they can possibly begin the production of generics.

Conversely, TRIPS does not require a member state to prove a legitimate reason for issuing a compulsory license with regard to national emergencies or extreme urgencies. Instead, under TRIPS, nations are afforded complete autonomy to define their own national emergencies and extreme urgencies. Unlike CAFTA-DR, TRIPS does not require member states to prove that the regulation is necessary or that there are less restrictive alternatives.

The CAFTA-DR side letter overly restricts public health by only permitting "access to medicines" during times of epidemics, national emergencies, or extreme circumstances. By listing specific diseases and epidemics, the side letter suggests that other public health concerns not explicitly mentioned may not be covered as a public health exception. As support that CAFTA-DR allows nations similar, if not identical, flexible provisions as provided in TRIPS, the United States contends that it supported both the 2001 Doha Declaration by stating that it would produce drugs needed to fight epidemics,[41] and also supported the 2003 consensus by allowing nations to import generic drugs to combat infectious epidemics.[42] This language remains inadequate because it restricts the rights of nations to manufacture generic drugs during epidemics. In contrast, TRIPS supports broader member rights than merely "producing drugs to fight epidemics" or "importing drugs needed for infectious epidemics" because it permits nations to produce generic drugs to protect the health of all persons beyond times of epidemic outbreaks.

C. CAFTA-DR Protects Data Exclusivity

Most nations require that safety and efficacy tests are performed before a pharmaceutical company is allowed to launch a new drug into the market. When generic manufacturers want to introduce a generic equivalent of the original drug, they typically draw on the safety and efficacy tests completed by the original patent holder and are only required to prove that the generic drug is therapeutically equivalent to the original.[43] Data exclusivity refers to a time period in which the original manufacturer possesses a monopoly over the safety and efficacy tests – a period during which a generic manufacture can not utilize these test results.[44] In theory, small generic manufacturers can introduce generics if they complete their own independent safety and efficacy tests; in practice, data exclusivity creates a monopoly for the original patent holder because it is unlikely that small generic manufacturers will have the financial means to conduct these tests.

CAFTA-DR imposes a mandatory five-year data exclusivity period on a drug once the original pharmaceutical company submits undisclosed data to the state. Article 15.10(a) states: "If a Party requires, as a condition of approving the marketing of a new pharmaceutical . . . product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products . . ."[45] In essence, when a state necessitates safety and efficacy testing, the state cannot permit a third party to manufacture a generic equivalent of the drug unless the third party performs its own safety and efficacy tests or receives approval from the original manufacturer.

". . . [I]n practice, data exclusivity creates a monopoly for the original patent holder because it is unlikely that small generic manufacturers will have the financial means to conduct these tests.

Unlike CAFTA-DR, TRIPS provides WTO members with extensive flexibility with regard to test data, only asserting that WTO members should protect "undisclosed test or other data" against unfair commercial use and disclosure.[46] During the TRIPS negotiations, developed nations zealously lobbied for the inclusion of a data exclusivity provision; however, this provision is noticeably absent. In fact, TRIPS provides that to protect the public, member nations can allow a generic manufacturer to utilize the patent holder's safety and efficacy results when necessary.

Finally, CAFTA-DR mandates protection of test data that has been submitted in a nation that is not a party to CAFTA-DR. Article 15.10(1)(b) forbids generic manufacturers from using safety and efficacy test results from a patent application filed in a separate state.[47] For example, the United States applies for a patent for Drug A in the Dominican Republic and submits results from the safety and efficacy tests. Thanks to CAFTA-DR, the U.S. now holds a virtual monopoly over the drug for a period of five years. Immediately before the five-year data exclusivity period ends, the U.S. applies for a patent for Drug A in Ecuador, beginning a new five-year data exclusivity period. Under the restrictions of CAFTA-DR, generic manufacturers in Ecuador were already unable to use safety and efficacy results submitted by the U.S. in the Dominican Republic. Once the U.S. submits safety and efficacy results for the Ecuadorian patent, a new five-year data exclusivity period begins in that country. In effect, Ecuador will be unable to access test results to produce generics of Drug A for a total of ten years – five years during the data exclusivity hold in the Dominican Republic and five years once the data was subsequently submitted in Ecuador.

Data exclusivity is a mechanism designed to delay the introduction of generic competition. By mandating five years in which third parties can not produce generics, CAFTA-DR, unlike TRIPS, even further prevents access to affordable generics by failing to include many of the flexibilities inherent in TRIPS.

III. Conclusion

WTO members purposefully incorporated flexibilities into TRIPS to protect public health, especially access to medicines by individuals, if needed. The U.S., on the other hand, was disappointed with the incorporation of these accommodating provisions and, in response,

promoted the adoption of more stringent intellectual property protections through bilateral and multilateral trade agreements. CAFTA-DR may economically benefit the Latin American countries that are parties to the treaty, but at the same time, it impinges on the ability of small pharmaceutical companies to manufacture generics. Consequently, intellectual property protections of this nature ultimately harm the impoverished individuals in foreign countries by limiting their access to affordable medicines.

1 *See* Public Citizen, 2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries 1 (June 2003), http://www.citizen.org/documents/Pharma_Report.pdf.
2 *See id.* at 4.
3 *See* Naomi A. Bass, *Implications of the TRIPS Agreement for Developing Nations: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 Geo. Wash.. Int'l L. Rev. 191, 191-92 (2003).
4 *See* Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. Int'l L. & Pol. 95, 95 (1997).
5 *See* Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Apr. 15, 1994, 1869 U.N.T.S. 299, *available at* http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm#article31 (last visited Sep. 28, 2007).
6 *See* Bass, *supra* note 3, at 191.
7 *See* The World Trade Organization, TRIPS Material, http://www.wto.org/english/thewto_e/whatis_e/tif_e/utw_chap2_e.pdf.
8 *See* Bass, *supra* note 3, at 201.
9 *See id.* at 198.
10 *See id.*
11 *See id.*
12 *See* TRIPS, *supra* note 5, art. 31.
13 *See generally* Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 Am. J. Int'l L. 317, 317 (2005).
14 *See* The World Trade Organization, *TRIPS Council: Governments Share Interpretations on TRIPS and Public Health*, WTO News, June 20, 2001, *available at* http://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm (last visited July 20, 2006).
15 *See* Declaration on the TRIPS Agreement and Public Health (Nov. 14, 2001), *available at* http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited Sept. 29, 2007).
16 *See* The World Trade Organization, *Moore: Nations Must Feel Secure That They Can Use TRIPS' Flexibility*, WTO News, June 20, 2001, *available at* http://www.wto.org/english/news_e/news01_e/dg_trips_medicines_010620_e.htm (last visited July 20, 2006).
17 *See* Declaration on TRIPS, *supra* note 15, para. 6, ("We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council . . . to find an expeditious solution . . .")
18 *See* Abbott, *supra* note 13, at 318-19.
19 *See id.* at 319.
20 *See* Frank J. Garcia, *Protection of Intellectual Property Rights in the North American Free Trade Agreement: A Successful Case of Regional Trade Regulation*, 8 Am. U. J. Int'l L. & Pol'y 817, 817 (1993).
21 *See* United States Trade Representative, Roundtable with Robert B. Zoellick US Trade Representative (June 23, 2003), http://www.ustr.gov/assets/Document_Library/Transcripts/2003/asset_upload_file118_3548.pdf.
22 *See* Office of the United States Trade Representative, CAFTA-DR Final Text, *available at* http://www.ustr.gov/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html?ht= (last visited July 22, 2006).
23 *See* Office of the United States Trade Representative, *Understanding Regarding Certain Public Health Measures*, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf.
24 *See* Central American Free Trade Agreement – Dominican Republic, Aug. 5, 2004, art. 15.9 § 6(a) & (b), http://www.usitc.gov/WAIS/pub3717.pdf.
25 *See id.*
26 *See id.*
27 *See* TRIPS, *supra* note 5, art. 33.
28 *See* The World Trade Organization, Pharmaceuticals and the TRIPS Agreement July 11, 2000, *available at* http://www.wto.org/english/tratop_e/trips_e/pharma_ato186_e.htm#fntext1 (last visited Aug. 1, 2006).
29 *See* CAFTA-DR, *supra* note 22, art. 15.9 6(b). ("With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.")
30 *See* The American Heritage Dictionary of the English Language 324 (Houghton Mifflin Company, 1980).
31 *See* TRIPS, *supra* note 5, art. 31.
32 *See id.*
33 *See* Office of the United States Trade Representative, *supra* note 23.
34 *See* CAFTA-DR, *supra* note 22, art. 15.1 11.
35 *See* Bob Inglis, *Q&A Central American Free Trade Agreement*, *available at* http://inglis.house.gov/issues.asp?content=sections/issues/current/cafta_QA (last visited July 22, 2006).
36 *See* Office of the United States Trade Representative, *supra* note 23.
37 *See* Center for Policy Analysis on Trade and Health, *CAFTA Side Letter Does Not Protect Access to Medicines*, Sept. 30, 2004, http://www.twnside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/CAFTASideLetterDoesNotProtectAccessToMedicines.pdf.
38 *See id.*
39 *See id.*
40 *See id.*
41 *See* Office of the United States Trade Representative, *CAFTA Facts: CAFTA and Access to Medicines 2/2005*, http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/Briefing_Book/asset_upload_file433_7198.pdf ("The U.S. played a key role in the Doha WTO Ministerial (Nov. 2001) reaffirmation

that global trade rules allow nations to decide what constitutes a health emergency and to issue compulsory licenses to produce drugs needed to fight epidemics.")

42 *See id.* ("In August of 2003, the U.S. led to work towards an WTO consensus that allows poor nations without domestic drug production capacity to issue compulsory licenses to import drugs needed to combat diseases such as HIV/AIDS, malaria, tuberculosis and other infectious epidemics.")

43 *See id.*

44 *See* Public Citizen, MSF Technical Brief, *Data Exclusivity In International Trade Agreements: What Consequences For Access of Medicines?*, May 2004, http://www.citizen.org/documents/DataExclusivityMay04.pdf.

45 *See* CAFTA-DR, *supra* note 22, art. 15.10(a)

46 *See* TRIPS, *supra* note 5, art. 39.3.

47 *See* CAFTA-DR, *supra* note 22, art. 15.10(1)(b).

The ERISA Roadblock: Can States Overcome ERISA Preemption and Enact Meaningful Health Care Reforms?

*By Sabrina Dunlap**

> When Congress enacted ERISA in 1974, it seemed no one could have predicted the problems with America's health care system today.

I. Introduction

In 1974, Congress enacted the Employee Retirement Income Security Act (ERISA) to regulate employee pension plans[1] as a response to turmoil caused by "highly publicized pension plan disasters,"[2] and as a way to regulate benefit and pension plans on a national level.[3] What began as a seemingly straightforward piece of legislation has grown and expanded into a complicated area of law, encompassing a broad range of statutes and regulations.[4]

Individual states now take on the financial burden of rising health care costs.[5] For instance, states are expanding health care funding for their poorest residents because little agreement at the federal level exists in how to respond to the problem of providing indigent individuals with adequate health care services.[6] Recent reports indicate that states pay 43 percent of total Medicaid costs and Medicaid spending comprises 22.9 percent of state budgets.[7] In light of this more active role for states, a question exists as to whether ERISA preemption will prevent significant health care reform at the state level.[8] According to the most recent court decisions, it appears that ERISA will continue to have a severe impact on state health care reforms.

II. Background

As America faces what can be characterized as a health care crisis, addressing the dual goals of containing costs while expanding access becomes increasingly important.[9] Aggregate health care costs in America are tremendous, making up roughly 16 percent of this country's gross domestic product.[10] One major problem is the impact on a health care system forced to absorb the cost of 46.1 million uninsured Americans.[11] Additionally, while the United States spends the most money on health care, Americans are among the least healthy people in the industrialized world.[12]

A.The Changing Landscape of Health Care in America

When Congress enacted ERISA in 1974, it seemed no one could have predicted the problems with America's health care system today. Few could have known that states would play such a crucial role in solving these problems. At the time of ERISA's enactment, the health care system in this country looked very different from how it does today.[13] For instance, the simple patient-doctor paradigm that existed in 1974 has been replaced by a much more complex system of Managed Care Organizations (MCO).[14] The rise of MCOs and the shifts in the financing of health care coverage have changed how – and even if – Americans are insured. The Health Maintenance Organization (HMO) Act of 1973 provided MCOs with an economic edge over more traditional forms of health insurance.[15] As a result, MCOs grew more competitive and began to offer better premiums to employers because MCOs could leverage their costs through contractual agreements with providers to give comprehensive coverage to members, financial incentives to use member providers, and accountability through quality assurance programs.[16] Attempting to appeal to employers providing health care, MCOs needed to improve their bottom line and achieved this by controlling costs and provider incentives.[17]

The shift to increased employer-provided coverage in the 1990's demonstrates how much health care systems have changed since ERISA's enactment.[18] The purpose of ERISA was to achieve uniformity in a regulatory scheme for employee benefits and, perhaps more importantly, pension funds. Congress, however, arguably "paid little heed to its implications for medical care."[19] Today, the reality is that many state laws seeking to regulate health care plans now face a high probability of ERISA preemption.[20] ERISA's language includes regulation of any "employee welfare benefit plan" and any plans provided by an employer to offer coverage of any "medical, surgical, or hospital care benefits." These regulations have had far-reaching effects on state laws that attempt to regulate such benefit plans.[21] ERISA's unforeseen intrusion into state sovereignty has also generated enormous amounts of litigation over state health care laws. In addition to states' inability to change substantially health care laws without the threat of ERISA preemption, individual patients cannot sue under state laws, which, more often than not, provide more relief for individual plaintiffs because ERISA enrollees may only receive ERISA remedies.[22]

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B. ERISA Preemption

Supreme Court decisions often turn on the Court's interpretation of ERISA's preemption clause. Section 514(a) of ERISA mandates the preemption of "any and all State laws insofar as they may now or hereafter relate to any employee benefit plan . . . . "[23] The purpose of this section was to ensure uniformity in laws regulating ERISA benefit plans; however, Supreme Court decisions have led to the preemption of various state health care laws.[24]

i. *Shaw v. Delta Airlines*

In *Shaw v. Delta*, the Supreme Court considered whether ERISA preempted a New York human rights law that prohibited discrimination in employment, including discrimination based on sex or pregnancy.[25] The law included pregnancy as a disability and required employer-provided coverage for pregnancy-related disabilities.[26] Delta Airlines and various other airlines that provided health benefits to employees through plans subject to ERISA brought a federal declaratory judgment action against New York state claiming that ERISA preempted the state's human rights and disability laws.[27]

The Supreme Court first looked to congressional intent regarding ERISA's Section 514(a) preemption clause.[28] In so doing, the Court took a textualist approach. Referring to Section 514(a)'s "relates to" language, the Court asserted that "[a] law 'relates to' an employee benefit plan, in the normal sense of the phrase, if it has a connection with or reference to such a plan."[29] The Court only looked to the plain language of New York laws and found that both laws related to plans for preemption purposes. Citing congressional intent, the Court reasoned that Congress could have decided to limit the preemption clause, leaving the Court to interpret the preemption clause as it saw fit; however, Congress failed to so act.[30]

Shaw virtually guaranteed ERISA preemption for state laws that regulated employee benefits.[31] The Court's interpretation of "relates to" preempted any state law that had any effect, even if indirectly, on employee benefit plans.[32] One judge's description of this broad interpretation as a "preemptive vortex that could swallow virtually any state remedial law" remained for years until the Court started to limit ERISA preemption.[33]

ii. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Insurance Co.*

In *New York State Conference of Blue Cross & Blue Shield v. Travelers Insurance Co.*, which challenged another New York law, the Supreme Court narrowed ERISA's preemption power.[34] New York required hospitals to take surcharges from patients covered by certain commercial insurers but did not require the same surcharge for Blue Cross/Blue Shield subscribers.[35] Commercial insurers brought suit in federal district court seeking to invalidate the surcharge statute under ERISA.[36] Consequently, the Court had to reassess the meaning of the "relates to" language of the preemption provision.[37]

As it had done in *Shaw*, the Supreme Court began its analysis by turning to the statutory language and congressional intent of Section 514(a).[38] The Court first acknowledged the important presumption that "Congress does not intend to supplant state law," thereby suggesting a narrower interpretation of Section 514(a) than in *Shaw*.[39] Looking at the plain language of Section 514(a), the Court noted that "[i]f 'relate to' were taken to extend to the furthest stretch of its indeterminacy, then for all practical purposes preemption would never run its course, for '[r]eally, universally, relations stop nowhere."[40]

Finding the statutory language unhelpful, the Court examined the purpose of ERISA.[41] Citing its own precedent, the Court held that Congress intended to ensure a "uniform body of benefits law" and to reduce the number of conflicting laws between states and/or between states and the federal government.[42] Further, the Court distinguished the surcharge law at issue from the laws in *Shaw*, which related to ERISA, because they mandated certain coverage requirements, while the purpose and effect of New York's surcharge law was different.[43] Rather than mandating certain coverage requirements, the surcharge statute merely had an "indirect economic effect on choices made by insurance buyers," by creating financial incentives to purchase a "Blues" plan over other commercial insurers.[44]

The Court thus found no grounds for ERISA preemption because the law only affected the costs of services – not the administration of ERISA plans or the uniformity of benefit plans.[45] Recognizing that various factors affect cost, the Court rejected Delta Airline's attempt at federal preemption because "nothing in the language of ERISA" indicated that Congress intended to "displace general health care regulation . . ."; which traditionally had been controlled at a state and local level.[46] *Travelers'* limited view of preemption essentially provided state laws, which would not have survived under *Shaw*, some hope of survival.[47] Nonetheless, ERISA preemption continues to prove a substantial obstacle to reform of state laws in health care.[48]

> "Supreme Court decisions often turn on the Court's interpretation of ERISA's preemption clause."

iii. *California Division of Labor Standards of Enforcement v. Dillingham Construction*

The Supreme Court continued its ERISA analysis in *California Division of Labor Standards Enforcement v. Dillingham*, a California case involving a prevailing wage law that required contractors on public works projects to pay a lower wage to workers in unapproved apprentice programs.[49] Two contractors argued that their apprenticeship programs were an "employee welfare benefit plan" qualifying as a plan under ERISA, which, according to the contractors, should preempt the prevailing California wage law.[50] Relying on *Travelers* and other cases, however, the Supreme Court rejected this argument.[51]

The *Dillingham* Court applied a two-part test to determine if the law "related" to an ERISA plan: "if [the law] (1) had a connection to or (2) reference to such a plan" then it would be considered to relate to an ERISA plan.[52] Similar to *Travelers*, the Court in *Dillingham* looked to congressional intent because a mere "uncritical literalism" application of this two-part test was insufficient to determine preemption.[53] Accordingly, the Court compared California's prevailing wage laws to the surcharge law in *Travelers* and found them indistinguishable. Similar to New York's law in *Travelers*, California's law did not "bind" ERISA plans to a certain structure, nor did it dictate the choices under the plan; it merely created incentives.[54] The Court concluded "[w]e could not hold pre-empted a state law in an area of traditional state regulation based on so tenuous a relation without doing grave violence to our presumption that Congress intended nothing of the sort."[55]

> "The *Egelhoff* Court distinguished this connection with a permissible "incidental effect" on ERISA, finding that this law went to a core element of ERISA – namely, regulating the payment of benefits."

iv. *Egelhoff v. Egelhoff*

Three years after *Dillingham*, however, the Court upheld federal preemption of a state law that could be characterized as having a "tenuous relation" with an ERISA plan. *Egelhoff* involved a Washington state statute that automatically revoked the designation of a spouse as a beneficiary of certain assets, including employee benefit plans, upon divorce.[56] As the named beneficiary of his plan, Mr. Egelhoff's ex-wife stood to collect his life insurance proceeds upon his death.[57] Mr. Egelhoff's children from a previous marriage sued, arguing their status as the true beneficiaries under Washington law.[58]

Applying the framework of *Shaw*, *Travelers*, and *Dillingham*, which looked to the objectives of ERISA to determine if a state law "related to" an ERISA plan, the Court found that the Washington statute had an "impermissible connection" to ERISA.[59] The *Egelhoff* Court distinguished this connection with a permissible "incidental effect" on ERISA, finding that the law went to a core element of ERISA – namely, regulating the payment of benefits.[60] Further, the Court held that the Washington law would force administrators to learn the laws of every state before paying out benefits, which is the sort of administrative burden Congress intended ERISA to prevent.[61]

In their dissent, Justices Breyer and Stevens noted that the Court should remember the "strong presumption against preemption" in this case because the Washington statute regulated family property law, which is an area of law traditionally dealt with exclusively by the states.[62] The dissent did not find a distinction between non-preempted laws that might in some way burden administrators of plans (such as the laws in *Travelers* and *Dillingham*) and a law, such as the Washington law, that eased the administration of benefits and yet was preempted.[63] In addition, the dissent warned that the majority's logic could eventually lead to federal preemption in other areas traditionally left to states.[64] Breyer and Stevens ultimately saw no conflict between this law and ERISA, and thus no reason to preempt it.[65]

v. *Retail Industry Leaders Association v. Fielder*

In *Retail Industry Leaders Associations v. Fielder*,[66] the Fourth Circuit Court of Appeals struck down Maryland's Fair Share Act aimed at forcing large employers in the state to pay a certain percent of revenue towards employees' health care benefits.[67] Faced with rising Medicaid costs, the Maryland legislature enacted this novel law to require employers with 10,000 or more employees to pay at least 8 percent of their payroll towards employee health benefits or pay the difference directly to the State.[68] Because Wal-Mart employed 16,000 workers in Maryland, it was the only corporation affected.[69]

In finding that ERISA preempted the Fair Share Act, the Fourth Circuit emphasized that ERISA's "primary objective" was to "provide a uniform regulatory regime over employee benefit plans."[70] Citing the decision in *Shaw*, the Fourth Circuit found that ERISA preempted this law because it directly regulated "employers' contributions to or structuring of their plans."[71] Although Wal-Mart technically had a choice in deciding whether to meet the 8 percent threshold, the Fourth Circuit stated that Wal-Mart's only "rational choice" was compliance, which, in turn mandated how Wal-Mart structured its benefit plans.[72] Additionally, the court found that this law interrupted Wal-Mart's ability to administer a uniform national benefit plan and that this "spending mandate would clash" with

other state laws, which is precisely what Congress intended to avoid with the enactment of ERISA.[73]

Though Maryland argued that the main purpose of the Fair Share Act was to increase its Medical Assistance Program funds, the Fourth Circuit court decided that the law's aim was to require employers to structure their benefit spending in a particular way.[74] This structured how ERISA benefit plans could provide certain benefits and spend their money,[75] which the Fourth Circuit characterized as impermissible under ERISA.[76]

The dissent, however, began its analysis by noting the state's extraordinary health care costs and characterizing the Fair Share Act as a legitimate response to what it viewed as a budgetary crisis.[77] In its view, the law was seen as a reasonable response to Congress' expectations that states would help with the growing costs of Medicaid and Medicare.[78] The dissent found that the Act made no reference to ERISA, and more importantly, did not dictate choices of ERISA plans; rather, it merely created incentives for employers to spend on health care in a particular way.[79]

Irrespective of the holding in *Retail Industry Leaders*, the case is an indication of things to come regarding how state laws regulate health care and ERISA preemption. In the aftermath of this decision, it is less certain whether states can in fact force employers to help cover the growing costs of health benefits.[80] As a result, future reform will likely avoid the Fair Share Act model and states will have to create mere incentives, not mandates, for providers in order to survive ERISA preemption.[81]

III. Analysis

Congress enacted ERISA for the narrow purpose of protecting individuals from the mismanagement of their pensions, not to "serve as a comprehensive federal health care regulation."[82] Yet despite ERISA's original intent, it has significantly affected states' abilities to enact substantial health care laws. *Retail Industry Leaders* serves as an additional example of a state legislature attempting to address a budget crisis by encouraging employers to share burdensome health care costs. While past court jurisprudence leaves room for states to remedy health care spending crises with laws that "relate to" ERISA, it remains unclear how the current Supreme Court might rule on a case similar to *Retail Industry Leaders*. If the Fourth Circuit was correct in its decision, then many other states' laws will face the same ERISA preemption as Maryland's Fair Share Act.

A. The Fourth Circuit Could Have Saved the Fair Share Act From Preemption

Given that Maryland enacted the Fair Share Act in response to a perceived state-wide health care crisis, the Fourth Circuit arguably could have decided against federal preemption. Under the Supreme Court's line of ERISA cases and *Retail Industry Leaders*, the court could have found a more tenuous connection to ERISA plans, such as with the surcharge law in *Travelers*. Perhaps, the Fourth Circuit should have given more weight to a legitimate state response to its health care spending crisis. Further, the Act had repercussions in public health, an area of law traditionally regulated by states.[83]

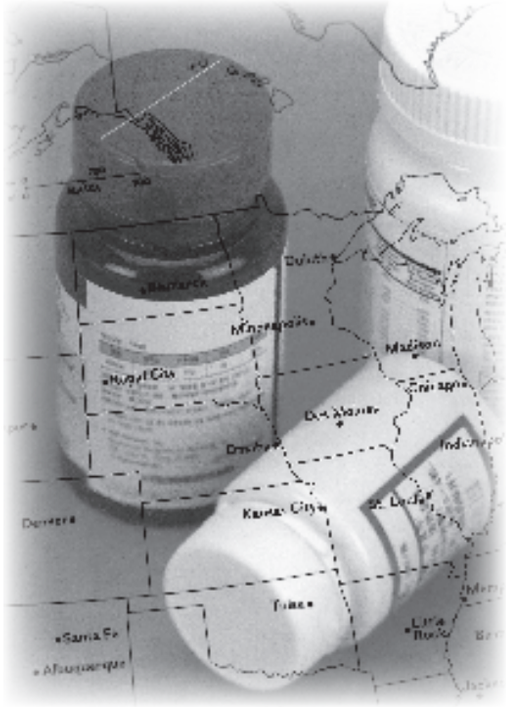
In *Retail Industry Leaders*, the Fourth Circuit first examined the scope of ERISA's preemption provision and the "nature and effect" of the Act to determine whether it was preempted by ERISA. The Fourth Circuit emphasized that Congress enacted ERISA to "provide a uniform regime over employee benefit plans" and to reduce administrative burdens on plans of complying with many varying state laws.[84] Under *Shaw*, the court next examined whether the Act "relate[d] to" an ERISA plan and, further, if this was the type of law that Congress intended to be preempted by ERISA.[85]

Additionally, the Act allowed for uniformity of administration of employee benefit plans. As the dissent in *Retail Industry Leaders* stated, a problem might have existed if the Act "dictated a plan's system for processing claims, paying benefits, or determining beneficiaries," as the Court found happened in *Egelhoff* – but that did not occur.[86] Instead, the only impact might have been a slight administrative inconvenience. For example, Wal-Mart may have had to report certain data about its Maryland employees and its spending on Maryland employees' health care.[87] This administrative burden is not enough to trigger ERISA preemption, but rather, amounts to an incidental inconvenience for employers to help defray rising health care costs. [88]

The Fourth Circuit's narrow approach failed to look at other jurisprudential guidance. *Keystone Chapter Associated Builders & Contractors, Inc. v. Bell Telephone Co.*, a Third Circuit case, is instructive, in that the court looked at whether a state law's effects on ERISA benefit plans "were optional or avoidable" under the statute.[89] By upholding Pennsylvania's Prevailing Wage Act, the Third Circuit found that the law survived "through means unconnected to ERISA plans.[90] While the Fourth Circuit could have contemplated this "optional or avoidable" approach, it instead summarily disposed of the issue of whether employers truly had a choice under the Fair Share Act. According to the Fourth Circuit, since adjusting a benefit plan to meet the 8 percent threshold would be a more logical choice for employers, rather than paying money to the State of Maryland, it really was the only choice.[91] If the court had looked at whether the effects were avoidable, it may have decided that paying money to state was, arguably, a real option that permitted Wal-Mart to avoid changing the administration of its benefit plans.[92]

> "... despite ERISA's original intent, it has significantly affected states' abilities to enact substantial health care laws.

Congress intended states to be "innovat[ors,]" to help curb the health care spending crisis.[93] If more courts follow the logic of *Retail Industry Leaders*, many states will likely be restricted from reaching this kind of innovation. The dissent in *Egelhoff* is especially informative in explaining that ERISA analyses should begin with the presumption that Congress did not intend to entirely remove state power to legislate health care issues.[94] This "pay or play" law was the first of its kind when the Maryland legislature first enacted it in 2006, though other states have since begun to enact similar laws.[95] Ultimately, whether ERISA preempts a state law will depend on how carefully legislators design the law so as to avoid excessive interference with ERISA plans. Other attempts to force employers to share in the burden of health care costs could face preemption, especially if they resemble Maryland's preempted Fair Share Act.



B. How the Maryland Fair Share Act Might Survive ERISA Preemption

The Act became widely known as the "Wal-Mart law," which probably contributed to the Fourth Circuit's rejection.[96] In fact, the court called it a "stretch to claim" that the Act was a "revenue statute of general application."[97] The majority speculated that the Maryland legislature intended for Wal-Mart to be the only employer covered by the Act, especially since the Act automatically exempted other large employers in the state. Also, Giant Food stores already met the 8 percent threshold and a later amendment worked to exclude Northrop Grumman.[98] The majority believed that the main purpose of Maryland's law was to force large employers to provide a certain amount of health care benefits to employees rather than to raise money to defray health care costs.[99] The fact that only Wal-Mart was affected was not sufficient to show this was the legislature's intent. The law also specifically created the "Health Care Fund" to support Maryland's Medical Assistance Program, which provides care for indigent individuals.[100]

The majority in *Retail Industry Leaders* also noted a lack of "meaningful alternatives" to adjusting benefit plans to comply with the law.[101] Maryland had argued that employers could comply by contributing to employee health care in non-ERISA spending by contributing to employees' Health Savings Accounts (HSAs). The majority rejected that proposition, opining that HSAs have limited availability, and that few Wal-Mart employees would likely make this election.[102]

In light of the Fourth Circuit's decision, the Maryland legislature might somehow adjust the Act to allow for more employer options. The state could also pursue other alternatives to HSAs for increasing non-ERISA spending, such as on-sight clinics.[103] Furthermore, it might also help to build in more flexibility so that employers have a meaningful alternative to changing the structure of benefit spending. Maryland could further emphasize that the law's core purpose is to defray its health care spending crisis. If other states can enact reforms that avoid the pitfalls of *Retail Industry Leaders*, then meaningful health care reform can exist at the state level.

IV. Reconciling State Reform with ERISA: Surviving Preemption

A. Massachusetts' Universal Health Care Plan

In April 2006, the Massachusetts legislature passed, by a significant majority, a universal health care plan that would aim to insure 90-95 percent of uninsured residents – about 500,000 people.[104] The law, which took effect in June 2007 is the first of its kind to require that all residents show proof of health insurance on their annual tax returns.[105] Failure to comply will result in the loss of the personal income tax deduction and further penalties.[106] The law also requires employers with ten or more employees to offer their employees health insurance or face annual assessments of $295 per employee.[107]

The Massachusetts law represents the result of extensive negotiations between businesses, health care providers, hospitals, and insurers in an attempt to force individuals and businesses to share responsibility for the costs of health care.[108] The state will subsidize the purchase of insurance plans for individuals who fall between 100 and 300 percent of the poverty level by requiring those who are healthy and uninsured to share the risk.[109] This sharing of risk involves spreading costs among a larger group of people and serves as a model of how insurance should function. Ultimately, the hope is that Massachusetts will be able to lower the costs of health care for all its residents.[110]

A key provision of the Massachusetts plan creates an "individual mandate" requiring every individual to purchase some form of coverage.[111] The question of ERISA preemption still exists, however, for the "employer mandate" that requires employee-provided coverage. Anticipated revenues from this "penalty" are about $50 million, but $295 per employee is arguably an insignificant financial incentive for employers.[112]

> "The majority believed that the main purpose of Maryland's law was to force large employers to provide a certain amount of health care benefits to employees rather than to raise money to defray health care costs."

There are a number of distinctions between the Massachusetts plan and Maryland's Fair Share Act at issue in *Retail Industry Leaders*. First, the Massachusetts law is not aimed at one particular employer. The Fourth Circuit in *Retail Industry Leaders* emphasized that the law seemed to focus on one employer, Wal-Mart, and was not really focused on raising revenue.[113] Many individuals involved in enacting the Massachusetts law believed that it "struck a balance" between businesses, insurers, and health care providers.[114]

Moreover, the Massachusetts plan does not appear to represent an impermissible "connection with" ERISA. Unlike the Fair Share Act, the contribution of employers is just one element of insurance coverage rather than exclusively employer participation. Under *Travelers* and *Dillingham*, it is unlikely that the Massachusetts law would "relate to" ERISA plans. Similar to *Travelers* and *Dillingham*, the Massachusetts law does not refer to ERISA plans, and does not affect the uniformity of administering ERISA benefits to warrant preemption.[115] At most, the annual penalty of $295 per employee could be characterized as a mere "incentive," like the surcharge law in *Travelers*. Further, this low fee provides a legitimate alternative for employers who do not wish to provide or contribute to benefit plans for employees. Massachusetts' law appears broad enough to survive ERISA preemption.[116]

B. California's Universal Health Care Plan

Notwithstanding the Massachusetts plan, California's proposed universal health care plan might be the most extensive plan in the country. California's plan attempts to cover every resident at a total cost of nearly $12 billion.[117] There are about 6.5 million uninsured Californians (about 19 percent of its 36 million residents) – the highest number of uninsured in the country.[118] The plan would require employers with ten or more employees to offer health care coverage or pay 4 percent of their payroll into a public health program intended to help cover the uninsured.[119] Additionally, physicians would pay 2 percent, and hospitals 4 percent, of their revenues to help cover residents enrolled in the State Medicaid program, Medi-Cal.[120]

In addition to likely challenges from health care industry lobbies, there are possible ERISA-preemption problems, as well, if the requirement on employers with ten or more employees to provide health insurance or pay 4 percent of their payrolls is viewed as a mandate.[121] The plan's alternative to providing health insurance (the payment of 4 percent of payrolls to a state-wide fund) would also need to represent a viable choice for employers to avoid having an "unavoidable effect" on ERISA plans,[122] especially since the lack of a reasonable choice for employers in *Retail Industry Leaders* was part of the Fourth Circuit's reasoning to determine that ERISA preempted the Act.

Similar to the Massachusetts plan, California's plan might survive preemption because it is clearly not intended to apply to any one particular employer in the state. Employers with ten or more employees include a large number of businesses. Also, employers under the plan have a viable alternative by paying 4 percent of total payrolls into a fund to help cover the uninsured. The California plan could also be construed as creating incentives for employers to provide health benefits to employees and not as a mandate, as the "indirect effect" language demonstrates an incentive rather than a mandate.[123] Due to the broad applicability of this law, and the alternatives designed to incentivize employers to comply, the California law has a high likelihood of surviving any potential ERISA preemption.

C. Recommendations

As states begin addressing the growing costs of health care, it is important to design laws to avoid ERISA conflicts. Massachusetts and California seem to have designed laws broad enough to cover a wide-range of employers and might successfully avoid the problem the Maryland legislature had in *Retail Industry Leaders*. A state law that merely has an indirect economic effect on plans, like in *Travelers*, should also survive. As the Supreme Court emphasized in *Travelers*, a law will likely survive so long as it does not adversely impact the uniform administration of ERISA plans.[124]

Despite past failures to amend ERISA, this still remains a valid objective.[125] ERISA's effect on health care appears to be partially unintended, since Congress initially enacted ERISA to regulate pension plans at a national level.[126] If states could design laws to address health care needs without the looming threat of ERISA preemption, they could more effectively address the needs of their citizens, who ultimately bear the brunt of ERISA preemption. Because courts are limited in restricting ERISA preemption, Congress should revisit this law. In the 33 years since Congress passed ERISA, enough has changed to warrant amendments allowing state innovation in health care reform.

V. Conclusion

In 2016, spending on health care in America is expected to reach $4.1 trillion – roughly 20 percent of this country's gross domestic product.[127] In addition to rising health care costs, 16 percent of the population lacks health insurance.[128] Whatever Congress intended ERISA to do with regard to health care, there is little question that ERISA represents a "substantial obstacle" to meaningful health care reform for states.[129] If states want their health reform laws to survive ERISA preemption, then legislatures must draft legislation that is broadly applicable and not aimed at a particular employer.[130] The president of the National Coalition on Health Care, Henry Simmons, aptly stated that: "[w]e can afford health-care reform . . . [w]hat we cannot afford is a continued failure to address the crisis in health care."[131] As health care costs and the number of uninsured increase, states must have the ability to address the health care needs of their residents. Given the potential ramifications and the jurisprudence on the issue, it is inconceivable that Congress would have intended ERISA to prevent states from achieving this goal.

"If states could design laws to address health care needs without the looming threat of ERISA preemption, they could more effectively address the needs of their citizens, who ultimately bear the brunt of ERISA preemption.

1 29 U.S.C. §1001 et seq.
2 *See* Jeffrey W. Stempel & Nadia von Magdenk, Doctors, HMOs, ERISA, and the Public Interest after Pegram v. Herdrich, 36 TORT & INS. L.J. 687, 687 (2001).
3 *See* Aaron S. Kesselheim & Troyen A. Brennan, The Swinging Pendulum: The Supreme Court Reverses Course on ERISA and Managed Care, 5 YALE J. HEALTH POL'Y L. & ETHICS, 451, 454 (2005).
4 *See* Stempel & von Madenko, *supra* note 2, at 687-88.
5 *See* Maureen McOwen, *Through the Eye of the Needle: How the New York City Health Care Security Act Will Escape ERISA Preemption*, 40 COLUM. J. L. & SOC. PROBS. 37, 38 (2006).
6 *See* Deborah Solomon & David Wessel, *Teed Up: Health-Insurance Gap Surges as Political Issue – Democrats, Governors, Business Push Change, But Fixes Vary Widely*, WALL ST. J., Jan. 19, 2007, at A1, *available at* http://online.wsj.com/articles/SB116916668142680899.html (last visited Sept. 6, 2007).
7 *See Hot Topic: States' New Health-Care Prescription*, WALL ST. J., Jan. 13, 2007, at A11, *available at* http://online.wsj.com/article/SB116865081505175856.html (last visited Sept. 28, 2007).
8 *See* Solomon & Wessel, *supra* note 6, at A1.
9 *See generally* Kesselheim & Brennan, *supra* note 3, at 451 (pointing out that the importance of health care costs will only continue to rise as the population of the United States changes demographically).
10 *See* Jane Zhang & Vanessa Fuhrmans, *Government Pays Growing Share of Health Costs*, WALL ST. J., Feb. 21, 2007, at A1, *available at* http://online.wsj.com/article/SB117203066837214609.html (last visited Oct. 28, 2007) (noting that by 2016 health care costs will have doubled from their current cost to $4.1 trillion).
11 *See* The Henry J. Kaiser Family Found., The Uninsured and Their Access to Health Care (2006), *available at* http://www.kff.org/uninsured/1420.cfm (last visited Sept. 28, 2007).
12 *See* McOwen, *supra* note 5, at 41-42.
13 *See* Lorraine Schmall & Brenda Stevens, *ERISA Preemption: A Move Towards Defederalizing Claims for Patients' Rights*, 42 BRANDEIS L. J. 529, 533-34 (2004).
14 See *id*. at 535-37.
15 *See* Kesselheim and Brennan, *supra* note 3, at 453.
16 *See id*.
17 *See* Schmall & Stevens, *supra* note 13, at 535-36.
18 *See generally id*. at 538 (pointing out that ERISA "so broadly affects national health policy because almost all insurance, other than Medicare, is provided through employer plans").
19 *See id*. at 542-43.
20 *See* Robert Rich and Christopher Erb, *The Two Faces of Managed Care Regulation & Policymaking*, 16 STAN. L. & POL'Y REV. 233, 242-43 (2005).
21 29 U.S.C. § 1002(1).
22 *See* Kesselheim & Brennan, *supra* note 3, at 455-56.
23 *See* 29 U.S.C. § 1144(a) (formerly §514(a)); *see also* Stempel & von Magdenko, *supra* note 2, at 699 (noting that this section is "often referred to as section 514 preemption" because that was the original code number; it is now codified as 29 U.S.C. §1144).
24 *See* Rich & Erb, *supra* note 16, at 242-43 (arguing that many attempts by states to regulate MCOs are very often preempted by ERISA as a result of the "adoption and continued strict application of this [ERISA] statute"); *see also* Elizabeth Barnidge, *What Lies Ahead for ERISA's Preemption Doctrine After a Judicial Call to Action is Issued in Aetna Health Inc. v. Davila*, 43 HOUS. L. REV. 125, 134 (2006) (pointing out that the purpose behind § 514(a) was to "avoid multiple and conflicting state laws").
25 *See* Shaw v. Delta, 463 US 85, 88-89 (1985).
26 *See id*. at 90.
27 *See id*. at 92.
28 *See id*. at 95.
29 *See id*. at 96-97.
30 *See id*. at 98-99 (pointing out that a narrower preemption clause had in fact been rejected by the Conference Committee).
31 *See* Rich & Erb, *supra* note 16, at 251.
32 *See* Barnidge, *supra* note 24.
33 *Id.* at 135 (quoting DiFelice v. Aetna U.S. Healthcare, 346 F. 3d 442, 456-57 (3d Cir. 2003) (Becker, J. concurring)).
34 *See* 514 U.S. 645, 649 (1995).
35 *See id*. at 649.
36 *See id*. at 651-52.
37 *See id*. at 649.
38 *See id*. at 655.
39 *See id.* at 654-55.
40 *See id*. at 655 (quoting Henry James, Roderick Hudson xli (New York ed., World's Classics 1980)).
41 *See id*. at 656.
42 *See id*. at 656-57 (quoting Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)).
43 *See id*. at 658.
44 *See id*. at 659.
45 *See id*. at 660.
46 *See id*. at 661.
47 *See id*. at 456-57.
48 *See* Retail Indus. Leaders Ass'n. v. Fielder, 475 F.3d 180 (4th Cir. 2007).
49 *See* Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc., 519 U.S. 316, 319 (1997).
50 *See id*. at 322.
51 *See id*. at 334.
52 *See id*. at 325.
53 *See id*.
54 *See id*. at 330-31, 334.
55 *Id.* at 334.
56 *See* Egelhoff v. Egelhoff, 532 U.S. 141, 144 (2001).
57 *See id*. at 144.
58 *See id*. at 145.
59 *See id*. at 147.
60 *See id*. at 147-48.
61 *See id*. at 149-50.
62 *See id*. at 156-57 (Breyer, J., and Stevens, J., dissenting) (emphasis in original).
63 *See id*. at 158.
64 *See id*. at 159-60 (stressing the importance that "ERISA preemption analysis . . . respect the separate sphere of state authority") (quoting Fort Halifax Packing Co. v. Coyne, 482 U.S. 1 (1987)) (internal quotations omitted).
65 *See id*. at 154.
66 475 F.3d 180 (4th Cir. 2007).
67 See Michael Barbaro, *Appeals Court Rules for Wal-Mart in Maryland Health Care Case,* N.Y. TIMES, Jan. 18, 2007, at C1, *available at* http://www.nytimes.com/2007/01/17/business/17cnd-walmart.html?ex=1326690000&en=1a25ee5ab511495b&ei=5088&partner=rss

nyt&emc=rss (last visited Sept. 28, 2007).
68 *See Retail Indus. Leaders Ass'n.*, 475 F.3d at 183.
69 *See id*. at 185 (stating that only four companies in Maryland employee at least 10,000 people: Johns Hopkins University, Giant Food, Northrop Grumman, and Wal-Mart; Johns Hopkins was excluded for being a non-profit, Giant Food met the 8 percent threshold, Northrop Grumman was excluded for technical reasons).
70 *See id*. at 191.
71 *See id*. at 192-93.
72 *See id*. at 193.
73 *See id*. at 194-95.
74 *See id*. at 194.
75 *See id*.
76 *See id.* at 193-94.
77 *See id*. at 198-99 (Michael, J., dissenting) (noting that in 2007 the projected spending on state Medicaid costs totaled $4.7 billion or 17 percent of the State's total budget).
78 *See id*. at 201.
79 *See id*. at 202.
80 *See* Barbaro, *supra* note 67.
81 *See id*. (quoting Naomi Walker, director of state legislative programs at the AFL-CIO as saying "[s]tate level health care reform is still possible, but it's not going to be the Maryland model . . . [w]e have to go back to the drawing board").
82 *See* McOwen, *supra* note 5, at 73.
83 85 *See generally id*. at 64 (noting that the New York City Health Care Security Act, enacted to control the costs of health care in New York, should not be preempted by ERISA because it was clearly within the regulation of health, which is traditionally an area of state concern).
84 *Retail Indus. Leaders Ass'n*, 475 F.3d at 191 (quoting Aetna Health Inc. v. Davila, 542 U.S. 200, 208 (2004) and Ingersoll-Rand Co. v. McClendon, 498 U.S. 133, 142 (1990)).
85 *See id*.
86 *See id*. at 202 (Michael, J., dissenting) (citing Egelhoff, 532 U.S. at 147).
87 *See id*.
88 *See id*.
89 *See* McOwen, *supra* note 5, at 50.
90 *See id*. at 50.
91 *Retail Indus. Leaders Ass'n*, 475 F.3d at 193.
92 *See id*. at 195 (pointing out that an employer can avoid the 8 percent threshold required by the Fair Share Act by (1) increasing its spending on employee health care that do not qualify as ERISA plans or (2) paying the State of Maryland the amount which the employer's spending fell short of the 8 percent threshold).
93 *See id*. at 200, 203-04 (Michael, J., dissenting).
94 *See* Egelhoff, 532 U.S. at 159-60. (Breyer, J., dissenting).
95 *See* McOwen, *supra* note 5, at 68, n. 168 (noting that the term "pay or play" is now widely used, and means that the employer can either pay the required amount to the State, or meet the required spending threshold—that is, "play").
96 *See* Barbaro, *supra* note 67.
97 *Retail Indus. Leaders Ass'n*, 475 F.3d at 194.
98 *See id*. at 185, 194
99 *See id*. at 194.
100 *See id*. at 200 (Michael, J., dissenting) (citing Md. Code Ann. Health-Gen. § 15-142); *see also* Md. Code Ann., Health-Gen § 15-103(a)2.
101 *See Retail Indus. Leaders Ass'n,* 475 F.3d at 196.
102 *See id*.
103 *See id*. at 196 (arguing that on-site clinics are not a viable option for employers to increase health care spending because they only allow treatment of minor injuries).
104 *See* Altman & Doonan, *supra*, note 83.
105 *See* States' New Health-Care Prescription, *supra* note 7.
106 *See* Pam Belluck, *Massachusetts Sets Benefits in Universal Health Care* Plan, N.Y. Times, Mar. 21, 2007, at A1, *available at* http://www.nytimes.com/2007/03/21/us/21mass.html (last visited Sept. 28, 2007).
107 *See id*.
108 *See* Stuart H. Altman & Michael Doonan, *Can Massachusetts Lead the Way in Health Care Reform?*, 354 New Eng. J. Med. 2093, 2093 (2006), *available at* http://content.nejm.org/cgi/content/short/354/20/2093?query=prevarrow (last visited Sept. 28, 2007).
109 *See id*. at 2094.
110 *See id*. at 2095.
111 Belluck, *supra* note 106.
112 *See* Robert Steinbrook, *Health Care Reform in Massachusetts—A Work in Progress*, 354 New Eng. J. Med. 2093, 2093 (2006), *available at* http://content.nejm.org/cgi/content/full/354/20/2095 (last visited Sept. 28, 2006) (noting that this portion of the law is the "fair share" portion; i.e. businesses are forced to pay their fair share of costs).
113 *See* 475 F.3d at 194.
114 Belluck, *supra* note 106.
115 *See generally* McOwen, *supra* note 5, at 48 (contending that part of the "connection" with inquiry must look at whether a state law is "optional or avoidable").
116 *See generally* Solomon & Wessel, *supra* note 6, at A1 (hypothesizing that the Massachusetts law would probably survive ERISA preemption because the "overhaul is broad and not targeted at a single employer").
117 *See* States' New Health-Care Prescription, *supra* note 7.
118 *See* Jennifer Steinhauer, *California Plan for Health Care Would Cover All*, N.Y. Times, Jan. 9, 2007, at A6, *available at* http://www.nytimes.com/2007/01/09/us/09calif.html?ex=1325998800&en=ecd2f5f234dac 789&ei=5088&partner=rssnyt&emc=rss (last visited Sept. 28, 2007).
119 *See* States' New Health-Care Prescription, *supra* note 7.
120 *See* Steinhauer, *supra* note 119.
121 *See* States' New Health-Care Prescription, *supra* note 7.
122 *See Retail Indus. Leaders Ass'n*, 475 F.3d at 193 (stating that "the only rational choice employers have under the Fair Share Act is to structure their ERISA healthcare benefit plans so as to meet the minimum spending threshold").
123 *See Travelers*, 514 U.S. at 659 (stating that the surcharge law merely had an "indirect economic effect on choices" made by plans, and did not "bind plan administrators to any particular choice").
124 *See id*. at 657.
125 *See* Kesselheim & Brennan, *supra* note 3, at 455.
126 *See* Barnidge, *supra* note 24, at 131.
127 *See* Zhang & Fuhrmans, *supra* note 10.
128 *See* McOwen, *supra* note 5, at 42.
129 *See id*. at 43.
130 *See* Solomon & Wessel, *supra* note 6.
131 *See id*.

The 'Benghazi Six' And International Medical Neutrality In Times Of War And Peace

*By Johanna Michaels Kreisel**

> "Medical professionals would benefit from a new definition of medical neutrality that is free from the confines of armed conflict."

I. Introduction

On December 19, 2006, a Libyan court condemned six foreign medical workers to death by firing squad for allegedly infecting 426 Libyan children with the HIV virus.[1] Over the course of the eight years before they were sentenced, the foreign medical workers were tortured, suffered undue delays in related judicial proceedings, and faced biased tribunals.[2]

Libya is not the first country to persecute medical personnel.[3] Previously, in the aftermath of the Nuremberg trials,[4] the international community codified ethical standards enforcing the concept that medical personnel are subject to a higher level of international responsibility.[5] Specific protections under international humanitarian law grant neutrality to humanitarian and medical workers providing aid in conflict, recognizing that medical personnel's ability to heal outweighs military objectives.[6] These ethical guidelines, however, often conflict with government and societal regulations and expectations.[7]

Currently, no clear dividing line exists between conflicts of an international character and non-conflict situations.[8] This leaves medical personnel extremely vulnerable when no international laws guarantee neutrality and instead protect only medical personnel and humanitarian societies who receive authorization to enter the country by parties involved in the conflict.[9] Medical professionals would benefit from a new definition of medical neutrality that is free from the confines of armed conflict.[10]

This article will discuss medical neutrality and the protections afforded to medical personnel in international humanitarian and human rights law. Part IIA provides an overview of the status and history of the Benghazi Six. Part IIB outlines the protections and obligations available to medical personnel under both international humanitarian law and human rights treaties. Part III analyzes the legal recourses that the Benghazi Six and medical personnel in general may employ. Part IV recommends that a stronger set of legal protections and a definition of medical neutrality not linked to armed conflict is needed to prevent further victimization of neutral medical personnel.

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II. Background

A. The Benghazi Six

Five Bulgarian nurses and one Palestinian physician were imprisoned in 1999 for allegedly infecting 426 Libyan children with the HIV virus.[11] The larger initial group of detained medical professionals included Libyan, Polish, Hungarian, and Filipino health professionals who worked at the Al-Fateh Children's Hospital in Benghazi.[12] The Libyan government later released all but the five Bulgarian nurses and the Palestinian physician who are known as the Benghazi Six.[13]

Libya postponed trial for the Benghazi Six 13 times,[14] while also denying them access to attorneys until after their hearings began.[15] In addition to other crimes, Libya charged the Benghazi Six with committing acts "leading to uncontrollable killing with the aim of assaulting the country" and "intentional killing with a lethal substance."[16] These charges were levied despite conclusive evidence that the strain of HIV present in the Libyan children was already detected and spreading in the 1990s, prior to the arrival of the Benghazi Six.[17] The charges demonstrate Libya's fear and ignorance toward the HIV infection,[18] and highlights problems created by conflict-defined medical neutrality in which ethics compel medical personnel to deliver care without protection or, at times, in contravention of international law.[19]

B. Medical Personnel in Crisis: Legal Rules and International Norms

i. Medical Workers in Peacetime: Exposed and Unprotected

In contrast to the laws of conflict, medical personnel[20] are not designated as neutral players[21] during peacetime.[22] In all international human rights law, no single treaty identifies special protections for medical personnel in non-conflict situations.[23]

The medical profession has a universal obligation to help those in need that extends beyond state borders.[24] If the situation is not recognized by the Geneva Conventions, medical personnel are subject to laws of individual states and are protected merely as civilians under the United Nations human rights treaties.[25] For instance, in proclaiming that all individuals are entitled basic political rights, the International Covenant

on Civil and Political Rights (ICCPR) may provide medical personnel the necessary protections.

Specifically, Article 9(1) of the ICCPR defines arbitrary arrest and detention, in addition to unnecessary deprivation of liberty.[26] The United Nations Working Group on Arbitrary Detention defines an arbitrary arrest as either procedures contrary to those stipulated by law, or adherence to laws which are incompatible with liberty and security.[27] Article 9(3) also mandates that detainees are entitled to a trial within a reasonable amount of time.[28]

Article 14 of the ICCPR outlines the requirements for a fair and independent trial.[29] Article 14(3)b requires that all individuals have access to counsel of their own choosing and adequate time to prepare for trial.[30] Article 14(3)g bars self-incrimination and compelled testimony at trial.[31] Both Article 7 of the ICCPR[32] and Article 2 of the International Convention Against Torture and Other Cruel, Inhuman Treatment (CAT) prohibit all forms of torture against individuals.[33]

Medical personnel do not receive special designation under International Labour Organization (ILO) treaties but may seek refuge as migrant workers under the International Covenant on the Protection of the Rights of all Migrant Workers and Members of their Families (Migrant Workers' Convention).[34] This treaty entitles migrant workers to political and social rights similar to those embodied in the ICCPR.[35] Article 16(2) ensures that all migrant workers are free from abuse and arbitrary detention.[36] Article 16(4) prohibits countries from exposing migrant workers to arbitrary arrest.[37] Article 16(7) guarantees migrant workers the right to communicate with representatives from their respective countries.[38] This treaty does not, however, specifically address the unique role of medical or health professionals who are migrant workers.[39] Similar to the ICCPR and CAT, Article 10 of the Migrant Workers' Convention prohibits all forms of torture against migrant workers and their family members.[40] Article 18 also mirrors the ICCPR in condemning arbitrary arrest and detention.[41]

ii. International Committee of the Red Cross: Establishing the Fundamentals for Medical Personnel

International humanitarian law establishes guiding principles for states and actors embroiled in international conflict.[42] The International Committee of the Red Cross (ICRC) significantly contributed to the development of international humanitarian law and enforcement of protections for civilians, humanitarian workers, and medical personnel during armed conflict.[43]

The ICRC principles of neutrality, impartiality, and independence are the basis for the original Geneva Conventions and subsequent protocols governing the laws of armed conflict.[44] The Geneva Conventions establish international legal norms to governing war between states[45] that apply exclusively to international armed conflicts.[46]

iii. Medical Personnel: Protections and Accountability

The history of medical neutrality demonstrates that since 1863, provisions for neutral protection of the sick and wounded form the basis of international humanitarian law.[47] All four Geneva Conventions have a Common Article 3 that govern hostilities which are non-international in character and prohibit violence to life and person, the taking of hostages, outrages upon personal dignity, and denial of judicial guarantees.[48]

The Additional Protocol II (Additional Protocol II) of the Geneva Convention applies only when guerrilla or dissident armed forces gain sufficient control over a signatory to Additional Protocol II and prevent the government from carrying out "sustained and concerted military operations."[49] Additional Protocol II does not punish medical personnel for providing care according to medical guidelines; specifically, medical personnel shall receive full protection while carrying out their professional duties.[50]

The original Geneva Convention suggests that medical neutrality was not traditionally limited to armed conflict.[51] The Geneva Conference of 1863 acknowledged full and absolute neutrality for official medical personnel, volunteers, and civilians who provide aid to the wounded.[52] The Geneva Convention

> "Medical personnel may seek relief, however, under the human rights treaties to which the parties are signatories."

> Libya did not notify the Bulgarian embassy of the detention of the Benghazi Six until February 1999, did not specify the reasons for their detention, and precluded access to their consular representatives...

of 1864 codified these protections.[53] An important aspect of the original Geneva Convention was the neutrality of volunteer aid societies during war and natural disasters, which was included in the later Geneva Conventions and Additional Protocol I.

III. Analysis

A. Libya's Treatment of the Benghazi Six Violated International Human Rights Laws

Unlike the protections available to medical personnel in international and domestic armed conflict, no special protections exist for medical personnel under international human rights law.[54] Medical personnel may seek relief, however, under the human rights treaties to which the parties are signatories.[55]

i. Article 9 of the International Convention on Civil and Political Rights

Bulgaria could claim the treatment of the five medical personnel violates of Article 9 of the International Covenant on Civil and Political Rights (ICCPR).[56] Both Libya and Bulgaria are signatories to this treaty without reservations.[57] Libya violated Article 9(1) of the treaty by subjecting the Benghazi Six to arbitrary arrest and detention.[58] Libya claimed that in addition to the alleged deliberate infection, the Benghazi Six failed to respect the country's political and religious laws.[59] The arrest for failure to adhere to Libyan religious beliefs is synonymous to an arrest for holding contrary or different political beliefs, and thus meets the United Nations Working Group's definition of arbitrary.[60] Documentation proving that the children contracted the illness before the medical personnel arrived in Libya serves as additional evidence that the charges were arbitrary.[61]

Libya violated Article 9(3), which prohibits unnecessary delays in judicial proceedings, by postponing the trial of the Benghazi Six on 13 separate occasions.[62] After their arrest, they did not have access to the Libyan judicial system for four months, which is significantly longer than the "few days" deemed reasonable by the Human Rights Committee.[63] Until their release in 2007, the Benghazi Six endured eight years of imprisonment due to delays in the Libyan judicial system.

ii. Libya Violated Article 14 of the ICCPR

Libya violated Article 14(1) of the ICCPR by failing to create a "fair, independent and impartial tribunal."[64] The Court ignored the weight of testimony of international researchers who presented evidence demonstrating the HIV infection occurred before the workers arrived in Libya. The researchers also demonstrated that many of the infected children had Hepatitis B and C, which tended to show that unsanitary practices in the hospital, rather than the deliberate acts of the Benghazi Six, caused contraction of HIV.[65]

Libya violated Article 14(3)b by failing to provide the medical personnel access to counsel until February 2000, after their initial trial started.[66] The three-month period between the arrest of the Benghazi Six and their access to counsel of their own choosing exceeded the reasonable 24 hour period required by the United Nations Special Rapporteur.[67] Libya also violated Article 14(3)g by utilizing torture tactics, such as beatings and electrocution to extricate confessions from the Benghazi Six.[68]

iii. Libya Violated Article 7 of the ICCPR and Article 2 of the Convention Against Torture and Other Cruel and Inhuman Treatment

Libya violated both ICCPR Article 7 and Article 2 of the Convention Against Torture and Other Cruel, Inhuman Treatment (CAT), which expressly prohibits the use of torture.[69] Libya deliberately used physical and mental abuse to extricate information from the Benghazi Six.[70] Interviews conducted by Amnesty International and the Human Rights Watch document severe abuse, including electric shocks, beatings, threats by barking dogs, rape, and *falaqa*,[71] all of which are considered torture under the definition set forth in the ICCPR. Under the pressure of the abuse, the Benghazi Six confessed to the alleged crimes.[72]

In failing to adopt legislative measures to criminalize torture or to investigate the allegations of torture, Libya violated Article 2(1) of the CAT.[73] The prosecution appointed a Libyan doctor who found that all six were tortured.[74] The prosecutor ignored these findings, however, and instead employed another Libyan doctor to refute the original doctor's conclusions.[75] Libya's failure to fully investigate the claims of torture and attempts to circumvent proper judicial measures violate the CAT.[76] Ten Libyans involved in the torture of the Benghazi Six were tried in June 2005.[77] A Tripoli Court acquitted eight police officers, a translator, and a doctor, of allegations of torture.[78]

iv. Libya Violated the International Labour Organization's Convention on Protection of Migrant Workers and Their Families

Both Bulgaria and Libya are signatories to the Migrant Workers' Convention and their families.[79] The Convention, which protects migrant workers, protects the Benghazi Six because they entered the country legally to work in the Al-Fateh hospital. Libya

violated Article 10 of the Convention, which prohibits all forms of torture against migrant workers, when it subjected the Benghazi Six to abuse and inhumane treatment.[80] In condoning the use of torture, Libya violated Article 16(2), which grants migrant workers freedom from injury by the state.[81] Libya violated Article 16(4) when it arbitrarily arrested the Benghazi Six.[82] Libya also violated Article 16(7), which allows migrant workers to notify, communicate, and meet with their consular representatives.[83] Libya did not notify the Bulgarian embassy of the detention of the Benghazi Six until February 1999, did not specify the reasons for their detention,[84] and precluded access to their consular representatives, violating Article 16(7)c.[85]

B. The Failure of Medical Neutrality in the Case of the Benghazi Six

i. Conflict Neutrality Does Not Apply to the Case of the Benghazi Six

While the Benghazi Six have no protection as medical personnel under current international law, if this were a conflict situation, the Benghazi Six could be protected as medical personnel under the Geneva Convention.[86] Further, if Libya designated the medical workers as permanent civilian medical staff under Article 8(c) of the Additional Protocol I, they would receive full immunity.[87] If imprisoned, they would be subject to all protections available to prisoners of war, including right to fair treatment and freedom from torture, rape, and abuse.[88]

If the Benghazi Six entered the country as part of a non-governmental organization and Libya consented to their presence in the country, they would be recognized under international medical neutrality as part of a non-governmental agency.[89] Both international and non-international conflicts require humanitarian societies to obtain consent prior to entry.[90]

ii. Conflict- Defined Neutrality Contravenes Historical Intent

Conflict-defined medical neutrality no longer meets the objectives envisioned by the founders of the Geneva Convention. The goal of medical neutrality, as defined in the original Geneva Convention, is to ensure that medical personnel have the necessary protection to eliminate suffering and deliver health care in situations of mass casualties,[91] including both man-made and natural disasters.[92]

The Benghazi Six could have recourse if the international community recognized that the intent of medical neutrality was to instill humanity in the population and is not limited to the governance of war.[93] The Council on Foreign Affairs recently noted that, similar to other African nations, Libya's struggle with HIV is both a health disaster and a security concern.[94] From a conflict perspective, the HIV epidemic in Libya could fall under the protections of international humanitarian law. Yet, even this classification would fail to grant medical neutrality to the Benghazi Six because they are not part of an official organization, such as a non-governmental organization or the Red Cross.[95]

iii. Conflict-Defined Neutrality Fails to Protect Medical Personnel

International law does not recognize the current situation in Libya as falling within the confines of international humanitarian law. This is not the first time, however, that violations of medical neutrality occurred in non-conflict situations, illustrating that, by inherent nature, conflicts alter the protections for medical personnel.[96] For one, conflicts today are no longer limited to battles between formerly recognized state armies. They instead take place within countries, involve non-state actors, and often lead to civilian engagement and casualties.[97] Moreover, guerrilla warfare often occurs without recognition from the international community.[98] As a result of the secrecy of the conflict and international law's emphasis on obtaining the consent of sovereign nations prior to entry, many conflicts do not invoke the protections of international medical neutrality.[99] In the case of the Benghazi Six, the Additional Protocol II would not apply, even though Libya is an unstable country, because the amount of violence and the violation of human rights laws do not invoke the protections of international humanitarian laws.[100]

iv. Future of International Law: Conflict-Defined Neutrality Leads to a Clash between International Sovereignty and Medical Ethics

In the future, medical personnel in the position of the Benghazi Six must monitor international breeches of medical neutrality to condemn the persecution of medical professionals in non-conflict situations.[101] Medical neutrality, unlike other concepts in international humanitarian and human rights law, directly conflicts with international regulations.[102] Organizations such as *Médecins Sans Frontières* (MSF) consequently choose to ignore international law and instead abide by the principles of medical ethics, which require medical personnel to deliver treatment to all individuals.[103] In Turkey, Liberia, Somalia, and Sudan, MSF physicians delivered humanitarian aid without the consent of the government or separatist factions.[104] In these situations, MSF medical personnel practiced medicine without the protection of medical neutrality, which often resulted in the death, torture, and kidnapping of medical staff.[105] In contrast, the Benghazi Six entered Libya legally with consent to practice medicine in the country.[106] Though they complied with international and domestic norms, the Benghazi Six still fell victim to the national conflict.[107]

> The international community needs to take additional measures to address the unique position of medical personnel and their role in international health and human rights.

IV. Recommendations

A. The United Nations Should Codify International Protections for Medical Personnel

The international community needs to take additional measures to address the unique position of medical personnel and their role in international health and human rights.[108] In 1949, the World Medical Association developed the *Declaration of Geneva* which codified the ethical responsibilities detailed in the *Oath of Hippocrates*.[109] This declaration requires medical professionals to adhere to the same ethical standards in both times of war and peace.[110] In the wake of the Nuremberg disaster, the World Medical Association also adopted the *International Code of Medical Ethics* to articulate international ethical standards.[111]

The United Nations General Assembly adopted the *Principles of Medical Ethics*, which is "relevant to the role of health personnel, particularly physicians, in the protection of prisoners and detainees against torture and other cruel, inhuman or degrading treatment and punishment."[112] Though it is recognized by the international community, this resolution does not legally bind United Nations members and signatories to adhere to its principles.[113]

Local governments accuse medical organizations of infringing on domestic jurisdiction, but the medical personnel respond that they have a higher obligation under the Hippocratic Oath to assist those in need.[114] In response, the MSF, along with the International Federation of Human Rights, developed the *Charter for the Protection of Medical Missions*.[115] This charter acknowledged the international right to health care and medical assistance, calling for a "no-border" policy where medical missions could freely deliver medical assistance without concern for their own safety and without violating national or local laws.[116] This charter aligns the goals and obligations of the medical community with those of international law by outlining the obligations of medical personnel and their right to protection during their missions.[117] The charter mandates that countries, rebel groups, and government organizations release any medical personnel captured in the course of conflict.[118] The charter also reinforces the ICRC protections and the ethical obligations of medical personnel.[119] The Council of Europe approved the resolution on June 30, 1988.[120] The charter for the Protection of Medical Missions has yet to be adopted, but the World Health Assembly has drafted a similar charter, entitled *Protection of Medical Missions During Armed Conflict*,[121] which reiterates the protections afforded to medical personnel under the Geneva Convention and the Additional Protocols.[122]

The 49th World Medical Association General Assembly adopted a proposal for *A Rapporteur on the Independence and Integrity of Health Professionals* that acknowledges the heightened dangers for and responsibilities to international medical professionals.[123] It requests the establishment of a UN rapporteur to protect health professionals who are in danger due to their professional actions.[124] This proposal is the most comprehensive analysis of the problem because it recognizes the need for international protections for and obligations of medical professionals.

B. Creation of an International Medical Tribunal to Address Violations of Medical Neutrality

These resolutions recognize the necessity for an international body to regulate medical personnel that would act beyond the scope of the Special Rapporteur on Health Professionals by creating an international medical tribunal.[125] Others have proposed the creation of an international medical tribunal to address egregious human rights abuses in the medical context.[126] A medical tribunal should not only address cases where physicians were criminally involved in medical negligence but should also set forth international regulations and a code of ethics to which all physicians should adhere.[127] Further, the international tribunal should hear all cases involving alleged violations and abuses of medical neutrality and subsequently deliver independent findings that are binding on all countries which recognize the tribunal's authority. More importantly, an international medical tribunal would provide structure and protection for groups such as MSF and others that often violate state sovereignty while providing humanitarian aid.

An international tribunal would serve as both the protector and arbiter of justice in the delivery of international health and humanitarian aid, and would address concerns that blanket neutrality gives medical personnel too much immunity. A tribunal could seamlessly be implemented based upon the international community's past experiences. For instance, a tribunal was successfully convened after World War II to try Nazi physicians for their participation in torture and human experimentation.[128]

A medical tribunal could also hear allegations of abuse, medical malpractice, and violations of medical neutrality, thereby creating a centralized depository for regulating international medicine. This would provide

"A medical tribunal should not only address cases where physicians were criminally involved in medical negligence but should also set forth international regulations and a code of ethics to which all physicians should adhere."

accountability for legal and ethical violations as well as protection for medical personnel. Further, it would codify detailing the obligations of and protections for medical personnel.[129]

V. Conclusion

Throughout history, medical personnel have played a unique and important role during wartime. The earliest versions of the Geneva Conventions recognized their fundamental role in aiding the sick and wounded in conflict. Given the shifting nature of health, war, and international conflict, however, it is clear that the legal protections provided to medical personnel during armed and non-armed conflict should be re-evaluated.

The international community must recognize that codification of international ethical obligations and protections for medical workers will ensure that medical personnel have the necessary legal tools to safeguard their work. Absent such protections, medical professionals may find themselves in the situation of the Benghazi Six, subject to the political and legal whims of an unstable democracy without international legal recourse. The situation of the Benghazi Six should send a strong message to the international medical community by exposing the weaknesses in the international safety net that could crush the spirit of humanitarian aid.

Addendum

After the completion of this article, the Benghazi Six were released on July 24, 2007. The release was the result of immense political pressure from the European Union, France, and England. The French President's wife, Cécilia Sarkovsky, negotiated the release of the prisoners with Colonel Muammar el-Qaddafi. Reports indicate that el-Qaddafi was persuaded to release the prisoners by his wife and daughter as well. The final agreement entailed payment of $1 million to each of the victims' families, amounting to $460 million. The European Union encouraged member countries to forgive Libya's debt and contribute to an international fund that will support the victims and their families. After eight years and enduring torture, abuse, and uncertainty towards their fate, the Benghazi Six finally returned home.[130]

1 *See* Laurie Garrett, *Six Imprisoned Health-Care Workers in Libya Are Pawns in a Far Larger Strategic Game*, Council on Foreign Relations, Oct. 26, 2006, *available at* http://www.cfr.org/publication/11821/six_imprisoned_health_care_workers_in_libya_are_pawns_in_a_far_larger_strategic_game_with_enormous_repercussions.html?breadcrumb=%2Fissue%2F89%2Fhuman_rights (last visited October 1, 2007) (asserting that the conviction of the Benghazi Six reflects larger geopolitical issues between Libya and the western world, the conflict between the scientific community, and the international implications of the spread of HIV).

2 *See* Michel Thieren, *Libyan Justice: Medicine on Death Row*, Open Democracy, Dec. 19, 2006, *available at* http://www.opendemocracy.net/globalization-vision_reflections/libya_bulgaria_4200.jsp (last visited Oct. 1, 2007) (maintaining that the Benghazi Six endured a "judicial nightmare").

3 *See generally* American Association for the Advancement of Science Website, AAAS Human Rights Action Network, http://shr.aaas.org/aaashran/ (last visited Oct. 10, 2007) (documenting worldwide cases of human rights violations of medical professionals).

4 *See* George J. Annas & Michael A. Grodin, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 Hofstra L. & Pol'y Symp. 111, 113 (1999)(concluding that the 1946 trial of Nazi doctors led to the creation of the Nuremberg Code, which outlines ethics for the treatment of human being in medical experiments).

5 *See* Principle of Medical Ethics Relevant to the Role of Health Personnel, Particularly Physicians, in the Protection of Prisoners and Detainees Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, G.A. Res. 37/194, Annex, U.N. Doc. A/37/51 (Dec. 18, 1982) (emphasizing the "contravention of medical ethics" created when medical personnel interact with a prisoner for a purpose other than evaluating, improving, or protecting their physical or mental health).

6 *See* Geneva Convention for the Amelioration of the Wounded and Sick in Armed Forces in the Field art. 19, Aug. 12, 1949, 6 U.S.T. 3114, 75 U.N.T.S. 31 [hereinafter Geneva Convention I] (allowing enemy parties to employ medical personnel to aid the wounded and sick).

7 *See* Victor W. Sidel, *The Roles and Ethics of Health Professionals in War*, *in* War and Public Health 281, 282 (Barry S. Levy and Victor W. Sidel eds., 1997) (observing the conflict of interest between physicians as impartial healers and allegiance to their country).

8 *See* Protocol Additional to the Geneva Conventions of 12 Aug. 1949, and Relating to the Protection of Victims of Non-International Armed Conflicts (Protocol II) art. 1(2), (Dec. 7, 1978), 1125 U.N.T.S. 609 [hereinafter Additional Protocol II] (reiterating that random acts of violence within a country are not conflicts as defined by international law).

9 *See* Yves Beigbeder, The Role and Status of International Humanitarian Volunteers and Organizations: The Right and Duty to Humanitarian Assistance 348 (Martinus Nijhoff 1991)(stressing that medical organizations break the law when they enter a country without permission); *see generally*, International Committee of the Red Cross, International Humanitarian Law and Human Rights Law, *available at* http://www.icrc.org/Web/eng/siteeng0.nsf/htmlall/section_ihl_and_human_rights (last visited Mar. 2, 2007) (comparing international humanitarian law, which exclusively regulates armed conflict, and international human rights law, which applies in both war and peacetime).

10 *See* Michael L. Gross, *From Medical Neutrality to Medical Immunity*, 9 American Med. Ass'n J. of Ethics 718, 719 (2007), *available at* http://virtualmentor.ama-assn.org/2007/10/mhst1-0710.html (last visited Oct. 10, 2007)("Nonmilitary medical personnel required immunity because they were, in fact, neutral, unarmed, and incidental to the war.")

11 *See Six Imprisoned Health-Care Workers*, *supra* note 1 (decrying the validity of the charges against the foreign workers when local medical personnel believed that the unsanitary reuse of syringes caused the HIV transmission).

12 *See* Int'l Gay and Lesbian Human Rights Commission (IGLHRC), Action Alert: AIDS Panic in Libyan Arab Jamahiriya: Medical Professionals Charged in "Doctors' Plot" Could Face Death Penalty, *available at* http://www.bghelsinki.org/press/2000/en/11-03.htm (last visited Sept. 17, 2007) [hereinafter IGLHRC] (noting that Libya released the Polish, Hungarian, and Filipino workers based on agreements with their respective countries).

13 *See id.* (stressing that Libya released the Libyan medical workers, and held the six foreign workers without bail).

14 *See* British Broadcasting Corporation, *Timeline: Bulgarian Medics Trial* (Dec. 19, 2006), *available at* http://news.bbc.co.uk/2/hi/africa/6192439.stm (last visited Sept. 17, 2007) [hereinafter *Timeline*] (providing a timeline for the Bulgarian medical workers' trials which began in February 2000, one year after their arrest).

15 *See* IGLHRC, *supra* note 12 (condoning the ten month period in which the Benghazi Six did not have access to legal representation).

16 *See id.* (observing Libya's claim that the foreign medical workers compromised state security through the deliberate transmission of HIV).

17 *See* Declan Butler, *Molecular HIV Evidence Backs Accused Medics* 444 Nature 2006, 658-59 (2006) (reiterating that independent genetic information traced the mutations of the outbreak to strains from West Africa, which indicates that natural introduction combined with poor hygiene at the Al-Fateh hospital caused the HIV outbreak).

18 *See* Laurie Garrett, Council on Foreign Relations, HIV and National Security: Where Are the Links? 35 (2005), http://www.cfr.org/content/publications/attachments/HIV_National_Security.pdf (last visited Oct. 10, 2007) [hereinafter HIV and National Security] (finding that Libya and other countries view HIV as a security threat that is deliberately spread by other nations).

19 *See e.g.*, British Med. Association., The Medical Profession & Human Rights: Handbook for a Changing Agenda 248-49 (Zed Books 2001) (providing that Turkish physicians who treat Kurdish dissidents are

threatened, imprisoned, and possibly murdered as an example of a breach in medical neutrality).

20 *See* Protocol I Additional to the Geneva Conventions of 12, Aug., 1949, and Relating to the Protection of Victims of International Armed Conflict, art. 8(c) Dec. 7, 1978, 1125 U.N.T.S. [hereinafter Additional Protocol I] (defining medical personnel as "those persons assigned, by a Party to the conflict" for medical purposes, including Red Cross personnel, medical transport units, and other recognized volunteer aid societies).

21 *See e.g.,* Frits Kalshoven, *International Humanitarian Law and Violation of Medical Neutrality in* Violation of Medical Neutrality 21, 21 (G.L. Wackers & C.T.M. Wennekes eds., 1992) (emphasizing that neutrality relates both to the duty of medical personnel during wartime as well as the duty of others to respect and protect medical personnel in times of danger).

22 *See* British Med. Ass'n, *supra* note 19, at 250 (analyzing the limits of medical neutrality to non-traditional types of international and domestic conflicts).

23 *See e.g.,* International Convention on the Protection of Rights of All Migrant Workers and Members of their Families, arts. 58, 59, 60, 61, 62, 63, July 1, 2003, G.A. res. 45/158, annex, U.N. GAOR Supp. (No. 49A) at 262, U.N. Doc. A/45/49 (Jul. 1, 2003) [hereinafter Migrant Workers' Convention] (failing to provide a special designation for medical personnel in its special categories of migrant workers).

24 *See* Stephen Bach, *International Migration of Health Workers: Labour and Social Issues* 1 (International Labour Office, Working Paper No. 209, July 2003), http://www.ilo.org/public/english/dialogue/sector/papers/health/wp209.pdf (documenting international migration of health workers and the need for international standards).

25 *See e.g.,* Migrant Workers' Convention, *supra* note 23, art. 92 (codifying protections for migrant workers); Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment, G.A. res. 39/46, annex, 39 U.N. GAOR Supp. (No. 51) at 197, U.N. Doc. A/39/51 (June 26, 1987) [hereinafter Convention Against Torture] (prohibiting all forms of torture against all individuals); International Covenant on Civil and Political Rights art. 9, March 23 1976, 999 U.N.T.S. 171 [hereinafter ICCPR] (outlining basic political and civil rights, such as the right to a fair and independent judiciary, the right to be free from arbitrary detentions and the right to counsel); International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI), 21 U.N. GAOR Supp. (No.16) at 49, U.N. Doc. A/6316, 993 U.N.T.S. 3 (January 3, 1976) (recognizing equality for men and women and asserting freedom from discriminatory practices); Universal Declaration of Human Rights, G.A. Res. 217A (III), U.N. Doc. A/810 at 71 (1948) (delineating basic principles of equality, life, and liberty for all individuals).

26 *See* ICCPR, *supra* note 25, art. 9(1).

27 *See* Reed Brody, *The United Nations Creates a Working Group on Arbitrary Detention* 85 Am. J. Int.'L 709, 713 (quoting the United Nations Working Group on Arbitrary Detention that "arbitrary is not synonymous with illegal" and listing detaining without a judicial warrant, kidnapping of national residents from abroad and forcing return to homeland, prolonging a detention after completion of a sentence, and detaining by reason of their political views as examples).

28 *See* ICCPR, *supra* note 25, art. 9(3); *see also* United Nations Human Rights Committee, General Comment 8, Article 9, Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, para. 2, U.N. Doc. HR1\GEN\1\Rev.1\ at 8 (1994) [hereinafter General Comment 8] (defining reasonable amount of time as to "not exceed a few days").

29 *See* ICCPR, *supra* note 25, art. 14(1) (stating that all individuals are entitled to a free, impartial, and competent trial); *see also* United Nations Human Rights Committee, General Comment 13, art. 14 in Compilation of General Comments and Recommendations Adopted by Human Rights Treaty Bodies U.N. Doc. HR1\GEN\1\Rev.1 at 14, paras. 8-9 (1994) *available at* http://www1.umn.edu/humanrts/gencomm/hrcom13.htm (last visited Sept. 19, 2007) (noting the minimum guarantees of fairness and justice).

30 *See* ICCPR, *supra* note 25, art. 14(3)(b); *see also* Amnesty Int'l, *Fair Trials Manual*, *available at* http://www.amnestyusa.org/international_justice/fair_trials/manual/3.html (last visited Mar. 1, 2007) (citing the United Nations Special Rapporteur on Torture's requirement that individuals have access to counsel within twenty-four hours of arrest).

31 *See* ICCPR, *supra* note 25, art. 14(3)g; *see also Fair Trials Manual*, *supra* note 30, para. 9.2 (citing cases requiring the "absence of any direct or indirect physical or psychological pressure from the investigating authorities on the accused, with a view to obtaining a confession of guilt").

32 *See* Convention Against Torture, *supra* note 25, art. 1 (defining torture as "any act by which severe pain or suffering, whether physical or mental, is intentionally inflicted on a person for such purposes as obtaining from him or a third person information or a confession").

33 *See* Convention Against Torture, *supra* note 25, art. 2(1) (requiring all parties to the Convention to take judicial, legislative, and administrative actions to prevent torture).

34 *See* Migrant Workers' Convention, *supra* note 23, art. 2(1)a (defining "migrant worker" as an individual engaged in "a remunerated activity in a State of which he or she is not a national").

35 *See id.* art. 92 (affording migrant workers basic human rights protections).

36 *See id.* art. 16(3).

37 *See id.* art. 16(2) (stressing that migrant workers should receive "effective protection by the State" from violence, abuse, torture from both public and private officials).

38 *See id.* art. 7(a) (affirming that migrant workers have the right to request that their home state including the right to communicate with officials his country and gain access to an attorney).

39 *Contra id.* art. 92 (ignoring the special needs and protections of health professionals who are migrant workers).

40 *See id.* art. 10 (calling for elimination of all forms of torture against migrant workers and their families including cruel, inhuman, and degrading treatment).

41 *See id.* art. 18 (prohibiting arbitrary arrest of migrant workers).

42 *See generally* International Committee of the Red Cross (ICRC) Website, International Humanitarian Law in Brief, *available at* http://www.icrc.org/web/eng/siteeng0.nsf/htmlall/ihl?OpenDocument (last visited Oct. 6, 2007) (distinguishing between the laws of war regarding when a state may actually wage war, and international humanitarian law which governs the conduct of war itself).

43 *See* Francois Bugnion, *The Role of the Red Cross in the Development of International Humanitarian Law: The International Committee of the Red Cross and the Development of International Humanitarian Law*, 5 Chi. J. Int.'l L. 191, 191 (2004) (voicing the opinion that ICRC is the "driving force" in the creation of international humanitarian law).

44 *See* David P. Forsythe, *International Humanitarian Assistance: The Role of the Red Cross* 3 Buff. Jour. Int.'l L. 237 (1996) 237 (asserting that international humanitarian laws infer "a right to humanitarian assistance").

45 *See* Bugnion, *supra* note 43, at 193 (stating that the original Geneva Convention for the Amelioration of the Condition of the Wounded in Armies in the Field proclaims that wounded combatants and medical personnel treating those combatants should be given full protection during wartime).

46 *See* Hans-Ulrich Baer, *International Humanitarian Law: An Introduction*, 167 Military Medicine 8 (2002) (defining international armed conflict as armed confrontation between two or more states).

47 *See* Randall G. Anderson, Historical Analysis of the Geneva and Hague Conventions and Their Protection of Military Medical Personnel, Facilities, and Transport During World War I 7 (1998) (unpublished Masters of Military Art and Science thesis, Bemidji State University) (on file with the Canadian Agriculture Library) (asserting that the need for protection of medical personnel led to the development of the first Geneva Convention).

48 *See e.g.*, Geneva Convention (I) Relative for the Amelioration of the Condition of the Wounded and Sick in Armed Forces in the Field art. 3, Oct. 21, 1950, 6 U.S.T. 3114, 75 U.N.T.S. 31 (noting that to achieve the goal of protecting the wounded, all individuals outside of combat are entitled to protection under international humanitarian law).

49 *See* Additional Protocol II, *supra* note 8, art. 1(1).

50 *See id.* arts. 9, 10.

51 *See* Percy Bordwell, The Law of War Between Belligerents: A History and Commentary 86 (Chicago Callahan & Co. 1908) (asserting that the purpose behind the law of war and, specifically neutrality, was not a novel idea, but rather, driven by a "humanitarian spirit of the age.").

52 *See* L.C. Green, *War Law and the Medical Profession*, *in* Essays on the Modern Law of War 489, 492 (Transnational Publishers 1988) (acknowledging that medical personnel in conflict have traditionally been considered with regard to their work to protect the wounded).

53 *See* Convention for the Amelioration of the Condition of Wounded in Armies in the Field, art. 2, Aug. 22, 1864, 129 Consol T.S. 361 (declaring neutrality for all medical personnel aiding the wounded).
54 *See e.g.*, ICCPR, *supra* note 25 (overlooking the necessity of special provisions for international medical personnel).
55 *See e.g.*, *id.* art. 41(1)b (permitting parties to the Convention to allege violations before the Human Rights Committee after first communicating with the offending party).
56 *See id.* art. 9 (prohibiting arbitrary arrest, detention and deprivation of liberty).
57 *See* Office of the United Nations High Commissioner for Human Rights, Status of Ratifications of the Principal International Human Rights Treaties, 7 (June 9, 2004), http://www.unhchr.ch/pdf/report.pdf [hereinafter Ratification] (documenting Libya's accession to the ICCPR on Mar. 23, 1976, and Bulgaria's ratification of the ICCPR on Mar. 23, 1976).
58 *See* ICCPR, *supra* note 25, art. 9(1).
59 *See* European Parliament, *Resolution on the Conviction and Imprisonment by Libya of Five Bulgarian Nurses and a Palestinian Doctor*, Eur. Parl. P6-TA-2007 para. 3, *available at* http://www.europarl.europa.eu/sides/getDoc.do?Type=TA&Reference=P6-TA-2007-0007&language=EN (last visited Oct. 6, 2007) (voicing Libya's disregard for the findings that the HIV virus was present prior to the Benghazi Six's arrival in Libya and that "strong evidence of the innocence of the defendants has been disregarded and ignored").
60 *See* Brody, *supra* note 27, at 713 (citing to the Human Rights Committee's belief that "arbitrary is not to be equated with against the law, but must be interpreted more broadly to include elements of inappropriateness, injustice and lack of predictability").
61 *See* Butler, *supra* note 17, at 658-59 (2006) (providing DNA forensics that show the strain of HIV contracted by the children in the Al-Fateh hospital were already present and spreading in the mid-1990s after the Benghazi Six arrived in Libya in 1998).
62 *See* Calling on the Government of Libya to Review Legal Actions Taken Against Bulgarian Medical Workers H.R. Res. 733, 108th Cong. (2004) (condemning the delay in the trial of the Benghazi Six).
63 *See* General Comment 8, *supra* note 28 (reiterating that reasonable detention is no more than a few days); *see also* Bulgarian News Agency Website, Chronology of Events, *available at* http://www.bta.bg/site/libya/en/02chronology.htm (last visited Sept. 20, 2007) [hereinafter Bulgarian News Agency] (demonstrating that Libya did not grant access to defense attorneys until after the charges were filed).
64 *See* Butler, *supra* note 17 (stressing that the Libyan court prohibited the submission of evidence exonerating the Benghazi Six).
65 *See id.* (tracing the family tree of the HIV infection).
66 *See* Bulgarian News Agency, *supra* note 63 (finding that after many negotiations, Libya finally agreed to allow the Benghazi Six to choose their own lawyer).
67 *See Fair Trials Manual*, *supra* note 34, para. 20.3 (emphasizing that the Human Rights Committee held that in a capital case, the trial should not proceed if the defendant is without counsel).
68 *See* Amnesty Int'l, *Libya: Time to Make Human Rights a Reality*, 34, AI Index MDE 19/002/2004, April 2004, *available at* http://web.amnesty.org/library/index/engmde190022004 (last visited Oct. 1, 2007) [hereinafter Amnesty Int'l] (describing how the nurses confessed in order to stop the electric shock torture).
69 *See* ICCPR, *supra* note 25, art. 7 (prohibiting all forms of torture); *see also* Convention Against Torture, *supra* note 25, art. 1 (defining torture as any physical or mental suffering for the purposes of obtaining a confession).
70 *See* Michael Garcia, U.N. Convention Against Torture (CAT): Overview and Application to Interrogation Techniques 2 (Congressional Research Service, 2004) http://www.fas.org/irp/crs/RL32438.pdf, (noting the Convention Against Torture's definition of torture as "systematic beating, application of electric currents to sensitive parts of the body, and tying up or hanging in positions that cause extreme pain").
71 *See* Amnesty Int'l, *supra* note 68, at 34 (describing *falaqa* as beating the soles of the feet with electric cables).
72 *See* Human Rights Watch, Words to Deeds: The Urgent Need for Human Rights Reform 49 (2006), http://hrw.org/reports/2006/libya0106/ [hereinafter Human Rights Watch] (interviewing nurse who stated that Libyan interrogators hit her with an electric stick on her breast and genital area, and said, "we were ready to sign anything just to stop the torture").
73 *See* Convention Against Torture, *supra* note 25, art. 12; *see also* ICCPR, *supra* note 25, art. 2.
74 *See* Amnesty Int'l, *supra* note 68, at 35 (stressing the lack of impartiality in the judicial treatment of the Benghazi Six).
75 *See id.* ("This evidence was subsequently refuted in court by another Libyan doctor, called to give expert opinion, who argued that it would have been impossible to identify traces of torture after so much time had passed but did not examine the defendants himself.")
76 *See id.* (noting that the doctor never actually examined the prisoners).
77 *See* Human Rights Watch, *supra* note 72, at 50 (quoting Libyan policeman that "[t]hey were treated well and enjoyed all legal rights"). *Contra*, Dimitar Tabakov, *Bulgaria Sues Nurses' Torturers*, News.bg (Jan. 31, 2007), *available at* http://international.ibox.bg/news/id_137911897 (last visited Oct. 6, 2007) (citing to Bulgarian authorities who believe that they have sufficient evidence to try the Libyan police for committing torture).
78 *See* Human Rights Watch, *supra* note 72, at 50.
79 *See* Ratification, *supra* note 57.
80 *See* Migrant Workers' Convention, *supra* note 23, art. 10.
81 *See id.* art. 16(2).
82 *See id.* art. 16(4).
83 *See id.* arts. 16(7)a, 16(7)b, 16(7)c.
84 *See* Bulgarian News Agency, *supra* note 63 (indicating that the Bulgarian embassy went a week without official notification of the detention of the Benghazi Six).
85 *See* Amnesty Int'l, *supra* note 68, at 33 (recounting that during the first nine months of their imprisonment, the Benghazi Six met with Bulgarian authorities only three times).
86 *See generally* Geneva Convention I, *supra* note 6, arts. 24-27).
87 *See* Beigbeder, *supra* note 9, at 338 (justifying not granting immunity to medical personnel who do not receive special assignment from the State party in order to ensure that the country could control and monitor any abuses of the medical privilege).
88 *See* Additional Protocol I, *supra* note 20, art. 21 (citing to the protections in Geneva Convention I, Article 35 that medical personnel could not be fired on, nor prevented from, carrying out their work in the hospital); *see also* Geneva Convention I, *supra* note 6, art.28 (delineating that captured medical personnel are not considered prisoners of war, but should be entitled to services in "accordance with their professional ethics").
89 *See* Geneva Convention I, *supra* note 6, art. 27 (requiring members of a neutral volunteer society to not only obtain consent prior to intervention but to also notify the opposing party).
90 *See* Beigbeder, *supra* note 9, at 345.
91 *See* British Med. Ass'n, *supra* note 19, at 244 (affirming the origin of medical neutrality as to ensure non-discrimination in the provision of medical care).
92 *See* Laura Lopez, *Uncivil Wars: The Challenge of Applying International Humanitarian Law to Internal Armed Conflict* 69 N.Y.U. L. Rev. 916, 919 (stating that the original intent of international humanitarian law "lie[s] in the suffering it seeks to prevent").
93 *See* Bordwell, *supra* note 51, at 257-58 (interpreting the Geneva Convention of 1909 to assume that volunteer societies could use the protection and immunity of the Red Cross emblem in both war and peace where it is necessary).
94 *See e.g.*, HIV and National Security, *supra* note 18, at 35 (documenting the use of HIV as a weapon and accusation, such as in India where the government claimed that the "promiscuous Pakistanis" used the deliberate infections of HIV as part of their "Islamic jihad").
95 *See* Beigbeder, *supra* note 9, at 343 (reiterating that medical volunteers must be attached to a neutral society recognized by the parties to the conflict).
96 *See* British Med. Ass'n, *supra* note 19, at 249-50 (documenting violations of medical neutrality that fall outside international humanitarian law).
97 *See id.* at 242 (emphasizing that civilian deaths in non-traditional conflicts were greater than military personnel casualties).
98 *See* Beigbeder, *supra* note 9, at 347-48 (stating that this type of warfare is effective because it is covert).
99 *See* British Med. Ass'n, supra note 19, at 250 (citing to the United Nations Sub-Commission on Prevention of Discrimination and Protection of Minorities that the "main difficulties are in determining which situations the

rules regulating non-international armed conflict become operable, and the fact that some situations of internal violations fall outside the law").
100 *See* Amnesty Int'l, *supra* note 68, at 6-7 (documenting arbitrary arrests, detentions, and disappearances in Libya in the late 1980s).
101 *See* British Med. Ass'n, *supra* note 19, at 251 (voicing concern for the absence of international bodies available to report on medical neutrality violations fall outside of the Geneva Convention and the Additional Protocols).
102 *See* Beigbeder, *supra* note 9, at 348 (emphasizing that medical personnel's ethical obligations to take care of those in need directly conflicts with the current international law's recognition of state sovereignty).
103 *See* Roelf Padt, The Meaning of Medical Neutrality and its Consequences in Violation of Medical Neutrality, 48, 53 (G.L. Wackers & C.T.M. Wennekes eds., 1992) (asserting that MSF believe that medical assistance prevails over the right of national sovereignty).
104 *See id*. at 49-50 (describing situations where MSF volunteers entered countries without the protection of international medical neutrality).
105 *See* Beigbeder, *supra* note 9, at 271 (noting instances where MSF volunteers entered countries without the consent of the government).
106 *See* IGLHRC, *supra* note 12 (stressing that the Benghazi Six entered Libya legally as guests for the purpose of working and studying).
107 *See* Beigbeder, *supra* note 9, at 348 (noting that medical associations who choose to adhere to ethics over international sovereignty find themselves victims).
108 *See* Padt, *supra* note 103, at 51 (finding that because medical neutrality has no meaning without the consent of sovereign governments, it often fails to protect medical personnel).
109 *See* Beigbeder, *supra* note 9, at 339.
110 *See id.*
111 *See* The World Medical Ass'n Website, World Medical Association International Code of Medical Ethics, http://www.wma.net/e/policy/c8.htm (enforcing the notion that physicians should act solely towards the best interests of the patient).
112 *See* Beigbeder, *supra* note 9, at 340.
113 *See id*. at 349 (distinguishing between the principles of the United Nations Resolution and the reality of medical practice where no universal standards apply and adherence to international humanitarian law is limited to agreement by the respective parties involved in the actual conflict).
114 *See id*. (arguing that medical personnel should have a right to protection based on their roles as medical personnel, rather than as individuals).
115 *See id*. at 348.
116 *See id.*
117 *See* Beigbeder, *supra* note 9, at 348 (calling for across the board protection for all humanitarian efforts).
118 *See id*. (recognizing the necessity of dealing with non-state actors in modern conflict situations).
119 *See id.*
120 *See id*. at 349 (noting that the resolution urges respect for the ICRC activities).
121 *See* World Health Assembly, Protection of Medical Missions During Armed Conflict, World Health Assembly Resolution A55/VR/9, http://www.who.int/gb/ebwha/pdf_files/WHA55/ewha5513.pdf (reaffirming principles of medical neutrality in light of an increase in attacks on medical personnel).
122 *See id*. (emphasizing the importance of adherence to the Geneva Conventions, and the protective status of medical personnel during armed conflict).
123 *See* World Medical Association, Proposal for a United Nations Rapporteur on the Independence and Integrity of Health Professionals (Nov. 1997), *available at* http://www.wma.net/e/policy/h19.htm (last visited Oct. 6, 2007) (stressing that physicians should have freedom of movement in both conflict and non-conflict situations).
124 *See id.* (encouraging the reporting of human rights violations by health professionals).
125 *See* Annas, *supra* note 4, at 119-20 (describing the formation of an international medical tribunal).
126 *See id.* (stressing the importance of using criminal sanctions against physicians who contravene international law and medical ethics).
127 *See id.* at 120-21 (outlining the Tribunal's functions to include hearing cases, developing international regulations, and, if necessary, spurring public condemnation where international law does not exercise jurisdiction).
128 *See* Benjamin Mason Meier, *International Protection of Persons Undergoing Medical Experimentation: Protecting the Right of Informed Consent*, 20 Berkeley J. Int'l L. 513, 523 (noting that two hundred German physicians took part in the alleged medical experimentation and torture).
129 *See* Sidel, *supra* note 7, at 282 (stressing how ethical guidelines require physicians to treat all individuals, while military and international codes reject such widespread impartiality and neutrality).
130 *See* Matthew Brunwasser & Elaine Sciolino, *Libya's Release of 6 Prisoners Raises Criticism*, N.Y. Times, July 25, 2007, *available at* http://www.nytimes.com/2007/07/25/world/europe/25libya.html?pagewanted=1&_r=1&emc=eta1 (last visited Oct. 20, 2007).

Washingon Update: News From Our Nation's Capital

Congress Fails to Override President's Veto of SCHIP Bill

The State Children's Health Insurance Program (SCHIP) is a national program which began in 1997. SCHIP provides health insurance for those families who cannot afford private insurance, but whose incomes are not low enough to qualify them for Medicaid. SCHIP was created in an effort to quell the rising numbers of children lacking health coverage.

SCHIP is a partnership between federal and state governments. Each state runs its program pursuant to provisions issued by the Center for Medicare and Medicaid Services (CMS). SCHIP gives states the flexibility to design their programs separately from Medicaid, use funds from SCHIP to expand their Medicaid program, or combine SCHIP and Medicaid. According to CMS, SCHIP covered 6.9 million children in 2006.

Despite the successes of the SCHIP program, the number of uninsured children continues to rise; several states have not had sufficient funding to successfully implement the program. The federal law authorizing SCHIP expired in September 2007. Until the bill is reauthorized, no new federal SCHIP funds will be made available for the upcoming and future fiscal years. This fall, both the House and the Senate passed a bipartisan measure to expand the program under H.R. 976. The proposed bill, the Children's Health Insurance Program Reauthorization Act of 2007, would expand coverage to include more than 4 million additional participants over the next five years. The bill also called for a $35 billion budget increase for five years, increasing SCHIP spending to $60 billion through 2010. Under the bill, the expansion of the SCHIP program would be funded by a nationwide tax increase of 61 cents per cigarette pack.

On October 3, 2007, President Bush vetoed the reauthorization of the legislation, claiming that enactment of the bill would lead to health care federalization and expand SCHIP beyond its original purpose. President Bush stated he would be open to a compromise, but would not agree to endorse a proposal that would expand the number of children covered by SCHIP. On October 18, 2007, the House fell 13 votes short (273-156) of the two-thirds majority required to override the President's veto. On October 25, 2007, the House passed a revised version of the vetoed bill, with a vote of 265-142. However, the subsequent revised version was seven votes short of overriding the President's veto.

The revised bill maintained the $35 billion expansion proposed in the first version, but also was amended to include concessions to some of the President's objections. The added provisions include making illegal immigrants ineligible for coverage, and phasing adults out of the program one year earlier than had been proposed in the original bill. Notably, the cigarette tax, which Bush also opposed, was reintroduced in the revised bill in spite of the President's objection. Despite the noted concessions in the bill, it is expected that President Bush's veto will not be overturned.

OIG Releases Report on FDA's Oversight of Clinical Trials

Before being introduced into the marketplace, federal law requires that all new drugs and medical devices are to be tested in clinical trials to ensure their safety and effectiveness. The Food and Drug Administration's (FDA) oversight of clinical trials ensures that those responsible for conducting or overseeing clinical trials – sponsors of a new drug or medical device, clinical investigators, and institutional review boards (IRB) – comply with regulations designed to advance the public's health and protect the rights, safety, and well-being of study participants.

Prompted by a congressional inquiry regarding weaknesses in the FDA's oversight of clinical trials and a series of news articles expressing similar concerns, the Office of the Inspector General (OIG), Department of Health and Human Services, carried out a two-pronged review to (1) determine the extent to which the FDA conducted inspections of clinical trials during fiscal years (FY) 2000-2005, and (2) assess the FDA's process for inspecting clinical trials.

In a report released September 2007, the OIG concluded that the FDA's efforts to effectively oversee clinical trials were hampered by a lack of data and departmental coordination. The agency did not know how many clinical trials were on-going, or how many clinical trial sites were involved. The FDA was also unable to identify all IRBs. Using data extrapolated from other government sources, the OIG estimated that of the likely 350,000 clinical trial sites associated with new drugs or medical devices, the FDA inspected less than

one percent of these sites between FY 2000-2005. In addition, the OIG found that most of the FDA's inspections focused on completed trials rather than the on-going trials where human subject protection was most critical. There were also inconsistent classifications of the violations found at trial sites and, in many cases, the most serious violations were downgraded to less serious classifications. To further exacerbate the problem, the FDA's guidance and regulations for clinical trials are outdated, and do not address the complexities of large clinical trials involving multiple sites within and outside of the United States.

The OIG identified several important steps that the FDA should take to improve its oversight of clinical trials, including: (1) develop a clinical trial database that includes all clinical trials; (2) create an Institutional Review Board registry; (3) create a cross-center database that allows for complete tracking of FDA inspections; (4) establish a mechanism to provide feedback to investigators on their inspection reports and findings; and (5) seek legal authority to provide oversight that reflects current clinical trial practices.

To read the complete OIG report visit: www.oig.hhs.gov/oei/reports/oei-01-06-00160.pdf.

Creating a Private Cause of Action for Healthcare Privacy Violations

The Health Insurance Portability and Accountability Act (HIPAA), more commonly known as the HIPAA Privacy Rule, has increased the prominence of patient privacy as a health law issue. However, since HIPAA became effective in 2003, the U.S. Department of Health and Human Services (HHS) has not imposed any civil monetary penalties for HIPAA violations. HIPAA's enforcement authority is limited to action by the HHS Office of Civil Rights, and no private or state-based litigation is sanctioned under the current regulations. This has led to concerns about the effectiveness of HIPAA's current enforcement approach – an approach that has focused on voluntary compliance, corrective actions, and resolution agreements. In an effort to improve HIPAA's enforcement scheme, Senators Patrick Leahy (D-VT) and Edward Kennedy (D-MA) introduced the Health Information Privacy and Security Act of 2007 (HIPSA), or Senate Bill 1814, a new healthcare privacy bill designed to provide more stringent privacy standards and safeguards in addition to harsher civil and criminal penalties for privacy violations.

One of the notable provisions of HIPSA would alter the existing privacy framework by creating of a private right of enforcement for patients who suffer healthcare privacy violations under HIPSA. Under this proposal, individuals could stand to receive compensatory damagers, attorney's fees, and punitive damages for certain blatant violations. Perhaps as significantly, HIPSA would extend the existing enforcement authority to the State Attorney General's offices and any local agencies they recognize. The State Attorney General's offices and other authorities given permission to do so will specifically be permitted to file a civil action in federal district court as a means of potentially obtaining civil penalties from entities that fail to adequately protect patients' privacy rights. HIPSA would override any inconsistent provisions of HIPAA.

For the moment, the bill has stalled after being referred to the Committee on Health, Education, Labor, and Pensions. HIPSA has received sparse public attention and support so far, but this could easily change if one of the presidential candidates takes a stance on this proposal. The Bush administration has not expressed any interest in this bill, which was expected since bill implies the current administration's approach to HIPAA enforcement is failing. Given its progressive construction, HIPSA's eventual passage in any form may depend on which party succeeds in winning the Presidency in 2008.

Small Business Healthcare Reform

The Senate Finance Committee has recently considered expanding health care coverage for employees of small businesses. The recent Senate hearing covered the following topics: making coverage more portable; creating association health plans; reducing the cost of individual market coverage; and creating health care tax credits.

Half of the nation's 47 million uninsured citizens work for small businesses. Continually increasing healthcare costs negatively and disproportionately affect small businesses. One proposal to address this problem includes arranging for small companies to coalesce with other small businesses for the limited purpose of purchasing an insurance policy, thereby spreading risks associated with health care costs across a larger pool of employees. However, critics of this proposal note that member companies who have healthier employees will not likely be amenable to a plan of this nature.

Presidential candidates from both parties have released proposals for healthcare reform. Senator Hillary Clinton (D-NY) proposes a health care plan which will require all Americans to obtain insurance. Her plan will offer tax breaks to small companies and subsidies for low-income individuals. Senator Barack Obama (D-IL) proposes a national health care plan similar to the insurance plan that federal employees are currently entitled to receive. Former Senator John Edwards (D-NC) suggests a plan that includes combining insurance pools, tax credits, and expanding the Medicare Program.

Republican candidates tend to propose health care reforms that favor tax credits over government subsidies. Former New York Mayor Rudy Giuliani proposes expanding health savings accounts. Former Massachusetts Governor Mitt Romney proposes deregulating the private insurance market in an effort to drive down premiums. Senator John McCain (R-AZ) proposes allowing insurers to cover individuals who move from state-to-state.

Regardless of which plan may be implemented in the future, experts predict that no changes will be made to current health care policy until after the presidential election in November 2008.

Sherine B. Abdul-Khaliq, Jit Chatterjee, Chandana Kolavala, and Rebecca Wolf contributed to this column.

Oregon to Consider Smoking Tax Increase To Fund Healthcare for Children

Oregon Governor Ted Kulongoski (D) recently proposed a bill that would increase the state's cigarette tax and direct the funds towards the state's health plan, which provides health insurance to uninsured children. The bill, known as Measure 50, could create a tax revenue between $150 million and $170 million. If passed, the bill may have implications for a similar national initiative. As a result, all stakeholders are watching closely to see whether the bill passes, and if it does, whether it proves successful.

New French Law Allows DNA Testing for Visa Applicants

On October 23, 2007, the French Parliament passed a new immigration bill that may discourage foreigners who hope to join relatives in France from traveling there. The new bill offers DNA testing of foreign visa applicants and permits researchers to collect racial and ethnic statistics. The bill is controversial in France, where both genetics and ethnicity have long been considered taboo reminders of the anti-Semitic laws adopted during World War II under German occupation. Supporters of the bill claim that it will accelerate immigration applicants' ability to prove familial relationships with French citizens and cite equivalent laws in other European nations. At the same time, some civil rights activists congratulated the government for eliminating the long-standing national ban on all forms of ethnic counting, which could lead to a more accurate counting of minorities in France. The bill has been extremely controversial, however, prompting protests across the country and complaints of racism from leaders of other countries, particularly African nations. As a result, some of the bill's original proposals for DNA testing have already been diluted. Under the modified version passed by Parliament, DNA tests will only be used in cases where children are applying to join mothers in France to prove their biological connection to family in France.

Tamper-Resistant Prescription Pads under Medicaid

Prescriptions for Medicaid beneficiaries must now be written on tamper-resistant prescription forms. A new regulation issued by Congress in May 2007 intends to reduce prescription fraud. To comply with the law, paper prescription pads must contain industry-recognized features designed to prevent unauthorized copying of completed or blank forms, possible erasure or modification, and the use of counterfeit prescription forms. The law requires states to comply with at least one characteristic defined by the Centers for Medicare & Medicaid Services by April 2008, and to be compliant with all three characteristics by October 2008. The original implementation date for the first phase was extended after complaints were made that implementation within such a short time period was unrealistic.

Youth Drinking Addressed

There are nearly 11 million underage drinkers in the U.S. and the vast majority are considered binge drinkers. While many programs exist to stop teenage alcohol abuse, Stanton Peele, Ph. D., J.D., psychologist, parent, and author of "Addiction-Proof Your Child," presents an innovative approach to the problem, advocating to teach teenagers to "drink in a civilized fashion." Peele contends that in other countries, like Italy, Greece, and Israel, teenagers are less likely to binge drink because they are allowed to consume small quantities of alcohol early on at special occasions. According to Peele, allowing teenagers to drink legally, in turn, diminishes the "temptation" of alcohol. In contrast, the U.S. Surgeon General's Office states that alcohol consumption is harmful to children's brains, yet alcohol remains the "most heavily abused substance by America's youth." The Surgeon General's Call to Action to Prevent and Reduce Underage Drinking 2007 aims to stop current underage drinkers from using alcohol and keep other youths from starting.

Proposed Bill to Reform Medical Malpractice

On May 24, 2007 Senator Max Baucus (D-MT) and Senator Mike Enzi (R-WY) introduced the Fair and Reliable Medical Justice Act. The bill seeks to reform the various problems associated with medical malpractice litigation, including costly premiums, a lack of incentive to admit medical errors, and unresolved compensation claims. The bill proposed to fund state pilot programs to evaluate tort alternatives for medical malpractice. One of the models proposed by the bill describes a situation in which states could create an alternative "court" with the following key features: judges who are experts in health care, experts hired by a health court, a modified form of negligence defined as "avoidability" (i.e., the injury would not have happened had optimal care been given), a compensation schedule, no juries, and no access to civil court review. One of the main problems arising from the creation of specialized health courts is the absence of the trial by jury afforded by the U.S. Constitution. The Supreme Court assesses constitutionality of removing common law claims from civil courts by relying on a public right/private right distinction, stating that the Seventh Amendment does not allow Congress to assign adjudication of a private right that is legal in nature to an administrative agency or specialized court without a jury.

Sathyan Mathai, Vashti Mercado, Eduardo Pezo, and Dawn Sequiera contributed to this column.

WCL Health Law Project Announce

Health Law and Policy Institute: June 16-20, 2008

With pleasure, the Health Law Project, Program on Law and Government is pleased to announce the establishment of the inaugural Summer Session Health Law and Policy Institute. This one-week program, which will be held from June 16-20, 2008, will provide J.D. and LL.M. students and practitioners with intensive training in a broad spectrum of health law and policy topics. Custom-developed courses* taught by leading practitioners from private practice, academia, health care organizations, government, and non-governmental organizations will provide an intensive learning experience for participants. Academic and CLE credit will be available for program participants.

The Summer Session Health Law and Policy Institute is designed for legal professionals who are practicing or preparing to practice health care law, and offers training in theoretical and practical aspects of health law and policy. American University's Washington College of Law's location in the nation's capital also provides students with an opportunity to combine participation in the Institute with exciting externships or summer positions that will enrich their health care law experience.

*Courses may be taken for academic credit or for Continuing Legal Education. These credits can also be applied toward an LL.M. degree with a Health Law specialization in the Law and Government Program. A Certificate of Attendance will be presented to participants who do not wish to receive academic credit. Course schedule and offerings are subject to change. International Participants should apply at least five weeks in advance and bear the sole responsibility for applying for and obtaining a visa at the American Embassy or Consulate in their country. Applicants whose first language is not English must submit a minimum TOEFL score of 580 or a written certificate of proficiency from an accredited language institution, unless applicant holds a degree from an accredited U.S. institution. Completed application and a $65 non-refundable application fee should be mailed directly to the Registrar's Office.

Registration Information:

2008 Calendar

Completed Application and Fee Due: **May 2**

Registration ends: **May 15**

Classes begin: **June 16**

Classes end: **June 20**

Take-home exams/papers**: **July 12**
**if applying for academic credit

Tuition and Fees for Students

Tuition per credit for 2008: **$1350**

Non-refundable Application Fee: **$65**

Student Activity Fee: **$30**

Note: Tuition does not include expenses for books and other reading materials.

To inquire more about the program, receive an official brochure, or request an application, please contact:

Health Law and Policy Institute,
American University Washington College of Law

ATTN: Corrine Parver, Esq.

Health Law Project, Program on Law and Government
4801 Massachusetts Avenue, NW
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ces New Summer Session Program

Courses

Introduction to International Health, Human Rights and Public Health

Houeida Saad (1 credit)

Introduces students to the substance and theory of human rights law through a focus on public health. This course explores the link between human rights, international public health policy, and international law, and examines the right to health vis-à-vis other human rights, as framed by international treaties and covenants.

Introduction to Medical Issues for Lawyers

Steve Pavsner, Corrine Parver, select physicians (1 credit)

Provides up-to-date knowledge and information in an introduction to basic medical principles and practices, and reviews medical negligence law for those students and lawyers interested in medical liability issues.

Intersection of Intellectual Property and Health Care

Josh Sarnoff, Sean Flynn (tentative), others (1 credit)

Provides significant exposure to the many relationships between U.S. patent, trademark and copyright laws and health care, including: access to medicines, data privacy, genetics, and biotechnology.

Legal Issues in Health Care Fraud and Abuse

Carrie Valiant, Jack Boese, Corrine Parver (1 credit)

Examines fraud and abuse in the delivery of health care through discussions of the major criminal and civil laws and regulations combating 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 programs.

Introduction to Health Care and Life Sciences Fundamentals

Lewis Grossman, Joel Michaels, Lynn Shapiro Snyder, Robert Dinerstein, others (1 credit)

Addresses the unique issues attorneys face in counseling health industry clients, including: coding, coverage, reimbursement, billing, compliance and other regulatory matters. Includes a Washington Insiders' Health Care Update, which analyzes Democratic and Republican Presidential candidates' health care reform platforms, Congressional and state legislative initiatives, and recent Federal government regulatory actions.

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