HEALTH LAW COLLOQUIUM

WIDENER SCHOOL OF LAW — HEALTH LAW SOCIETY

Volume 4, Issue 1

Fall, 2012

Inside This Issue

HEALTH LAW SOCIETY

The Health Law Society (HLS) is an interdisciplinary organization of students, faculty and alumni dedicated to exploring the career opportunities and current issues in health law. The Society strives to explore the range of possibilities in health law from beyond the traditional practice area of medical malpractice to managed and long-term care, bioethics, corporate issues, and health care reform. We also participate in health-related public service activities benefiting the community throughout the tri-state area. HLS draws on the diverse resources available at Widener - students, faculty, and alumni - to build a greater understanding of health law practice.

MESSAGE FROM THE EDITOR-IN-CHIEF

Health law's unyielding expansion and evolution has made academics, medical professionals, and legal advocates collaborate together on multiple fronts. 2012 marks a historic year for the United States. The Supreme Court's decision to uphold the Affordable Care Act's individual mandate as a congressional taxing power will have major implications in the years to come. President Obama's subsequent reelection guarantees that the Affordable Care Act will remain as the law of the land.

While healthcare and law coexist together, they evolve in separate ways. Law evolves in the retrospect—*stare decisis* becomes the foundation we solve our future legal problems with. Healthcare evolves in a future prospective—past theories on medicine and science become outdated and replaced with more accurate and rewarding approaches.

The Health Law Society's goal is to educate and update students and other members of the legal community on how the law is evolving and perhaps, where the law should move forward. The Colloquium gives interested writers a chance to inform interested readers and to promote an area of the law (which I believe) is not only fascinating, but important and necessary to the lives of all people.

-Dan Baum
Editor-in-Chief

CAREER GUIDE FOR THE FUTURE HEALTHCARE ATTORNEY

BY THADDEUS MASON POPE, JD, PHD [1]

INTRODUCTION

Law students are well aware that the 2013 market for law school graduates is scary. While the supply of new lawyers has been growing, the demand for those lawyers has remained flat.[2] Consequently, many have seriously questioned whether law school is still a good investment.[3]

Fortunately, even in the face of this dismal legal employment landscape, there is some good news. Legal Jobs are expanding in the healthcare sector. Here are just two reasons. First, healthcare spending already consumes 17% of the GDP and is expected to rise to 20% by 2019.[4] While only one contributing factor, in its first ten years, the Patient Protection and Affordable Care Act (PPACA) will spend 938 billion dollars on healthcare.[5] Moreover, since healthcare is comparatively more extensively regulated than other industries, this increase is spending correlates to a disproportionate surge in health care jobs.[6]

A second reason for the increase in health law jobs is the dramatic growth of the elderly population. In 2009, there were 40 million persons aged 65 years or older (13% of the U.S population, about 1 in 8 Americans). By 2030, there will be about 72 million older persons (19% of the population).[7] This is significant, because the elder population is responsible for 40% (soon 50%) of healthcare spending. In short, health lawyers appear to have a safe and bright future.[8]

I have two objectives in this Article. First, I will outline the wide range of career paths available to you as a health lawyer. Second, I will describe the experience and credentials that you should acquire to make yourself a competitive candidate for these jobs.

CAREER PATHS IN HEALTH LAW

The plethora of health law career opportunities can be roughly grouped into twelve categories.[9] As an entry-level lawyer, you could (1) clerk for a judge or (2) complete a health policy fellowship. As an attorney, you could do either (3) litigation or (4) transactional work for healthcare clients. Or you could practice in the particularly fast-growing areas of (5) public health law or (6) elder law.

But I hasten to add that not all health law jobs involve working as an attorney or lawyer. Law school is excellent training for legal non-attorney careers in: (7) compliance, (8) regulatory affairs, (9) risk management, (10) clinical ethics consultation, (11) legal nurse consulting, and (12) dispute resolution.

The Judicial Law Clerk

Working as a law clerk to a judge is a valuable and respected credential no matter where your professional path takes you.[10] Moreover, many specialty courts focus on health law issues. At the federal level, consider clerking for either an administrative law judge or appeals board within the Department of Health and Human Services.[11] At the state level, consider clerking for a mental health court, a probate court, or an administrative tribunal within your state Department of Health or Department of Social Services.[12]

Fellowships & Internships

The Kaiser Family Foundation maintains a large database that summarizes and links to a wide range of fellowships and internships in health policy and related fields. These programs emphasize training, professional development, and mentoring. The Kaiser database includes fellowships located across the United States that are available both to law students and to recent law graduates.[13]

Litigation

As a health law litigator, you may represent parties in medical malpractice actions or in product liability lawsuits against drug and device manufacturers. Or you might advocate in administrative hearings involving reimbursement rates or the medical necessity of clinical interventions. Your clients can include: insurers, providers, consumers, or the state and federal governments.

Transactional

As a transactional health lawyer, you might advise and assist clients in structuring hospital-physician relationships, joint ventures, merger and acquisition transactions, physician employment, and health information technology. Some of the most explosive growth over the next five years is expected in life sciences and FDA law.[14]

Public Health Law

Most of health law involves legal concerns related to the medical treatment of individuals. In contrast, public health law involves law and policies intended to prevent health problems and promote health across the population. Public health law is often described as "what we do as a society to create the conditions in which people can be healthy."[15]

Many public health law jobs are in the government, at the federal, state and local levels. Other jobs are in public interest law firms and organizations. There are also international opportunities, for example, at the World Health Organization and USAID.[16] Students who want to work in this area should join both the Student Network for Public Health Law[17] and the Law Section of the American Public Health Association.[18] They should also seriously consider enrolling in a J.D.-M.P.H joint degree program.

Elder Law

Elder law has traditionally focused on drafting wills and handling estate and probate matters. But elder law now overlaps significantly with health law. Today, elder law attorneys deal with everything from Medicaid eligibility changes and long-term care planning, to guardianship arrangements and elder abuse. Students who want to work in this area should join the National Academy of Elder Law Attorneys (NAELA).[19]

Compliance

Compliance officers work for hospitals, manufacturers, and insurers to assure compliance with federal and state regulations and standards. Key areas include fraud and abuse laws and patient privacy. While compliance had already been a rapidly growing field, the PPACA assures continued growth by making compliance programs mandatory as a condition of enrollment in federal healthcare programs.[20] Notably, some law schools have become CCB-accredited.[21] This can facilitate your personal certification in Healthcare Compliance, enhancing your credibility and marketability. One recent survey shows that 80% of healthcare employers require or prefer CHC certification prior to hire.

Regulatory Affairs

Regulatory affairs specialists (RA) facilitate the development of drug and device products. First, they prepare, submit and monitor submissions to administrative agencies like the FDA. Second, they address

issues raised in the review process, manage reports, and track post-market functions. Third, RA professionals are involved with products during their research and development phases, for example, in the design and monitoring of clinical studies. Fourth, RA professionals are involved in the manufacturing, packaging and distribution, and in business strategy, particularly as related to international regulatory submission strategies and policies.[22]

Risk Management

Risk managers work in a wide variety of organizations such as hospitals, insurance carriers, long-term care, hospice, physician practices, manufacturers, and government agencies.[23] Risk managers investigate any incident (e.g. a medical treatment error) that might result in financial liability or loss. They resolve disputes and act as liaison to attorneys, insurance companies, and individuals. But risk managers also play a proactive, preventative role. They create policies to comply with safety legislation, and coordinate and develop programs for quality and risk-free care.

Clinical Ethics Consultant

Ethics consultants work for hospitals and health systems. They address uncertainty and conflict involving value-laden treatment issues such as: informed consent, decision-making capacity, confidentiality, and end of life decisions. Depending on the needs of the requesting clinician or family, the ethics consultant serves as moral analyst, information clearing house, dispute mediator, and/or educator. In addition to working on specific patient cases, ethics consultants also typically develop and review institutional policies and procedures involving patient rights. To develop or hone their bedside skills, most law school graduates now working as ethics consultants have completed either a clinical fellowship or a Masters or Certificate in bioethics.[24]

Legal Nurse Consultant

Many law students interested in health law come from a prior career in nursing. Some of these students might consider a career as a Legal Nurse Consultant (LNC). LNCs assist attorneys in litigation matters such as medical malpractice, products liability, and worker's compensation. They screen cases for merit, locate and interview medical experts, analyze medical records, research medical literature, and coordinate independent medical examinations. Some LNCs work in law firms and insurance companies. Others work as independent consultants.[25]

Dispute Resolution

As in other areas of law, dispute resolution in healthcare is "hot." You can work as: an ombudsman, a mediator, an arbitrator, or a peer review hearing officer. There are a variety of applications for ADR in health care, ranging from disputes caused by a stressful work environment to medical malpractice lawsuits.

LAW SCHOOL STRATEGIES FOR SUCCESS

Most of the strategies for success for aspiring health lawyers are the same are those for any other law student. I have taken the liberty to customize these strategies for the future healthcare attorney. I have grouped my law school strategies for success into five categories: (1) work experience, (2) moot courts, (3) writing, (4) networking, and (5) coursework.

Work Experience

Employers care not only about what you "know" but also about what you can "do." What you can "do" is best demonstrated by what you have already done. After all, there is no better indication of the quality of your future legal work than your past legal work. The traditional time for law students to seek employment is

during their two summers. But you should do far more than just this. There are four other ways for law students to build experience and demonstrate commitment to health law.

First, most law schools have externships through which you can earn credit by working in the "field" (e.g. hospital, device manufacturer, government agency). Unless you already have lots of other work experience, do two or three different externships. Second, your law school may also have a clinic (e.g. Veterans benefits, Medical-Legal Partnership, HIV-AIDS) in which you can represent clients under the supervision of faculty. Third, many students have part-time jobs throughout the academic year, often developed from an externship or summer job. Fourth, even if you cannot get a paying job, you can get relevant health law experience either through an unpaid internship or through satisfying your school's pro bono requirement. In short, get legal work experience. Add new entries to your resume while building a network of references and contacts.

Moot Court Competitions

While "real life" work experience is best, you can engage in valuable experiential learning in other ways too. For example, moot courts simulate certain skills that lawyers employ in practices.[26] There are three moot court competitions focused on health law. First, the National Health Law Moot Court Competition at Southern Illinois University, in November, offers great training in appellate litigation.[27] Second, the L. Edward Bryant Jr. National Health Law Transactional Competition at Loyola University Chicago, in March, helps you develop corporate and transactional lawyering skills.[28] Third, the Health Law Regulatory & Compliance Competition at the University of Maryland, in February, provides the opportunity to take the perspective of a corporate compliance officer. The competitors use federal health regulations, rules, and agency documents, to present a legal and policy solution and/or recommendations.[29]

Writing

Perhaps the most widely respected credential from law school is membership on law review. But even if you are not on law review, there are several ways in which you can demonstrate your writing competence. First, be strategic about the seminars you take. Write about topics that matter to the future employers you want to impress. Or write about topics you already know or need to master. Second, develop your seminar papers for health law writing competitions. Winning such competitions will earn you cash prizes and valuable credentials. Third, get your manuscript published.[30]

Networking

If you follow the advice above, then you will already be engaged in a good bit of networking. For example, you will get to know more lawyers at your externships and at your part-time jobs. And, perhaps more importantly, they will get to know you. But you should also be engaged in networking more broadly.

Most professional bar associations welcome law students at zero or nominal cost. Your state and county bar associations probably have both a Health Law section and an Elder Law section. They might even have a Food and Drug Law section. At the national level, both the American Health Lawyers Association[31] and the American Bar Association Health Law Section[32] invite student participation. Attend their live CLE programs. Arrive early and introduce yourself. I have lost count of the number of law students who have secured coveted jobs in this fashion.

Coursework

Students interested in pursuing a career in health law should take at least one basic course in healthcare law. They should also take at least three, but ideally six or more, credits of experiential learning in health law externships or clinics. And they should complete a major health law writing project through: a seminar or independent study paper, a moot court competition, a journal note, or a health law writing competition. Many law schools offer a "certificate" in health law. One recent survey indicates that employers value this credential.[33]

CONCLUSION

Health law is a broad and exciting field and its demand curve is shifting to the right. Private firms and government agencies are eager to hire new lawyers with a focus on healthcare law. I wish you luck in your years at law school and in furthering your career.

-Thaddeus Mason Pope

---

[1]Thaddeus Mason Pope, J.D., Ph.D. is Director of the Health Law Institute at Hamline University. He taught at Widener University School of Law from 2007 to 2011. His research focuses on medical futility, internal dispute resolution, tort law, public health law, bioethics and end-of-life decisions. Professor Pope also clerked for the U.S. Court of Appeals for the Seventh Circuit and practiced for seven years as a corporate litigator with Arnold & Porter LLP in Los Angeles and Washington, DC. Professor Pope was graduated from Georgetown University, where he received his J.D., and a Ph.D. in philosophy and Bioethics. The Widener Health Law Society is proud to dedicate our fall article in recognition to his service as a professor, as a faculty advisor, and for his contributions to academia. On behalf of the Society, we wish him the best in his future endeavors and we thank him for his contributions to our school.

[2] Joe Palazzolo, *Law School Grads Face Brutal Job Market,* WALL ST. J., June 25, 2012.

[3] Herwig J. Schlunk, Mamas 2011: *Is a Law Degree a Good Investment Today?* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1957139.

[4] Christopher J. Truffer et. al., *Health Spending Projections Through 2019: The Recession's Impact Continues*, 29(3) HEALTH AFFAIRS 522-29 (2010).

[5] Letter from Congressional Budget Office to Speaker Nancy Pelosi, *available at* http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/amendreconprop.pdf.

[6] *Health Law Jobs Expected to Get Red Hot,* NATIONAL JURIST (July 17, 2012); Robert Denney Associates, *Legal Communiqué: What's Hot and What's Not in the Legal Profession* (Dec. 2011), http://www.robertdenney.com/pdf/comm-legal-hot_not_2011.pdf; Lisa Stansky, *Hot Practice: Health Law*, STUDENT LAWYER, Mar. 2009, at 8-9; Rachel Breitman, *Drug Supplement*, AMERICAN LAWYER (July 1, 2009).

[7] Administration on Aging, Aging Statistics, http://www.aoa.gov/aoaroot/aging_statistics/index.aspx.

[8] Peter M. Leibold, The Enduring Strength of Health Law, AHLA CONNECTIONS, Dec. 2009, at 60 ("Surmising future trends and examining current survey data, one can legitimately forecast that health law will retain its economic strengths into the future... An investment of time and energy in developing health law expertise will be worth it."); Robert L. Schwartz, *Where is Health Law Going? Follow the Money*, 14 HEALTH MATRIX 219-23 (2004).

[9]Others have organized potential job paths differently. See, e.g., Jennifer S. Bard, *I'm Interested in Health Law - Now Where Can I Get a Job?* 14(1) NYSBA HEALTH L. J. 73-85, *available at* http://repository.law.ttu.edu/handle/10601/288; CATHERINE PATTANAYAK ET AL., HEALTH LAW: A CAREER GUIDE (2012), *available at* http://www.law.harvard.edu/current/careers/opia/toolkit/guides/career-and-specialty-guides.html.

[10] *See generally* ALIZA MILNER, JUDICIAL CLERKSHIPS: LEGAL METHODS IN MOTION (2011); MARY L. DUNNEWOLD, BETH HONETSCHLAGER, & BRENDA L. TOFTE, JUDICIAL CLERKSHIPS: A PRACTICAL GUIDE (2010); http://nalp.org/judicialclerkships; http://www.judicialclerkships.com

[11]These are typically announced on USAJobs.gov. http://www.nalp.org/judicialclerkshipsection. See also http://www.hhs.gov/ogc/careers/openings.html. DHHS also runs an "Emerging Leaders Program", http://hhsu.learning.hhs.gov/elp/.

[12] Unfortunately, these types of clerkships are not discussed in some popular materials like the University of Vermont, *The Guide to State Judicial Clerkships*.

[13] http://www.kaiseredu.org/Fellowships-and-Internships.aspx.

[14] Peter M. Leibold, *A Career in Health Law*, Presentation at Loyola University Chicago (Nov. 9, 2010); Lisa Stansky, *Hot Practice: The Drug Industry Creates a Significant Demand for Lawyers*, 33(4) STUDENT LAWYER (Dec. 2004).

[15] INSTITUTE OF MEDICINE, FOR THE PUBLIC'S HEALTH: REVITALIZING LAW AND POLICY TO MEET NEW CHALLANGES (2011).

[16] Network for Public Health Law, *Career Paths in Public Health Law,* http://www.networkforphl.org/_asset/zjk2ng/Public-Health-Law-Career-Paths-FINAL.pdf.

[17] http://networkforphl.org/about_the_network/student_network/.

[18] http://apha.org/.

[19] http://www.naela.org/public/. The ABA Commission on Law and Aging is also a great resource. http://www.americanbar.org/groups/law_aging.html.

[20] Patient Protection and Affordable Care Act of 2010, Pub. L. 111-148, §§ 6102 & 6401 (Mar. 23, 2010).

[21]http:/www.hcca-info.org.

[22] REGULATORY AFFAIRS PROFESSIONALS SOCIETY, REGULATORY AFFAIRS PROFESSIONAL DEVELOPMENT FRAMEWORK: AN OVERVIEW (2007), *available at* http://www.raps.org/Portals/0/Documents/PDF_Framwork_Whitepaper.pdf. *See also* David G. Jensen, *Tooling Up: The Regulatory Affairs Career Track*, SCIENCE CAREERS (Sept. 18, 2009); Robin Arnette, *Scientists in Regulatory Affairs*, SCIENCE CAREERS (Nov. 7, 2003).

[23]The American Society for Healthcare Risk Management invites student membership. http://www.ashrm.org/.

[24] See AMERICAN SOCIETY FOR BIOETHICS AND HUMANITIES, IMPROVING COMPETENCIES IN CLINICAL ETHICS CONSULTATION: AN EDUCATION GUIDE (2009).

[25] ANN M. PETERSON & LYNDA KOPISHKE EDS., LEGAL NURSE CONSULTING,: PRINCIPLES AND PRACTICES (3d ed. 2010); The Association of Nurse Attorneys, http://www.taana.org.

[26] Gerald Lebovits, Drew Gewuerz & Christopher Hunker, *Winning the Moot Court Oral Argument: A Guide for Intra- and Intermural Moot Court Competitors,* 41 CAPITAL U. L. REV. (forthcoming 2013), *available at* http://papers.ssrn.com/sol3papers.cfm?abstract_id=2160641.

[27] http://www.law.siu.edu/healthlaw/healthlawmootcourt%20.php.

[28] http://www.luc.edu/law/centers/healthlaw//events/transactional_comp.html.

[29] http://www.law.umaryland.edu/programs/health/events/hlrc_competition.html.

[30] Two good guidebooks are EUGENE VOLOKH, ACADEMIC LEGAL WRITING: LAW REVIEW ARTICLES, STUDENT NOTES, SEMINAR PAPERS, AND GETTING ON LAW REVIEW, (4th ed. 2010); ELIZABETH FAJANS & MARY R. FALK, SCHOLARLY WRITING FOR LAW STUDENTS, SEMINAR PAPERS, LAW REVIEW NOTES AND LAW REVIEW COMPETITION PAPERS (4th ed. 2011).

[31] http://www.healthlawyers.org/hlresources/Academics/Pages/Students.aspx.

[32] http://www.americanbar.org/groups/health_law/resources/resources_for_law_students.html.

[33] *AHLA/BU Health Law Survey*, AHLA CONNECTIONS (Sept. 2011).

TECHNOLOGY AND THE INFORMED CONSENT PROCESS IN CLINICAL RESEARCH:

FINALLY, A USE FOR AN IPAD OTHER THAN PLAYING "ANGRY BIRDS"

BY FRANK V. INGIOSI, JD

Introduction

As vital as nearly any element in the enrollment and screening process, ensuring the sufficient and adequate informed consent of a clinical research subject appears to be taking the none-too-drastic leap that has long been suggested for years. This is being done through electronic mediums that can obtain the patient's consent.

The doctrine of informed consent in the U.S. has been a long evolving element of both clinical research and patient safety, with beginnings fleshed out over generally accepted case law and by jurisdictional and industry practices. At its most basic level, informed consent has as its primary focus the understanding that the patient—likely lacking the same level of training and expertise as the treating physician—should retain some level of control or determination as to what is done with his own body, as detailed so eloquently, yet simply, by Justice Cardozo nearly a century ago.[1] The same still holds true today when applied to a patient undergoing treatment for an underlying condition who chooses to participate in a clinical study.

Fraught with potential liability for the physician and often criticized of halting clinical innovation, the informed consent process is one of the most vital portions of the enrollment process for a clinical study. The problem is that a patient's confusion with clinical trials often leads to their reluctance to participate. Patients often know little more of their diagnoses than what is available to them through general treatment planning with their primary physician along with the bounty of horror stories accessed via the Web. For a patient considering joining a clinical trial, the informed consent process is truly the first chance they will have to dig deeply into how technology and innovation in medicine could have an everyday impact on their condition.

Current initiatives

In September, Mytrus, a San Francisco-based clinical technology and services company announced that it had secured the right for its proprietary patient enrollment iPad application to be utilized in a multi-center clinical trial.[2] With a projected subject enrollment base of over 4,000 patients across 120 identified research institutions worldwide, the National Institute of Neurological Disorders and Stroke (NINDS) sponsored trial should prove to be a tremendous testing ground for the efficacy and efficiency of such an innovative move.[3] Participating sites will use iPads, on loan from Mytrus, that are preloaded with the consent information and documentation tailored directly from the study protocol.[4]

Billed as the first of its kind for clinical research, the Mytrus iPad application's primary function will be to draw upon multiple methods of clarification and explanation including; graphics and videos to outline trial specifics and ensure a clearer, standardized, less onerous consent process.[5] "The informed consent documents required at the initiation of a clinical trial are complicated; even with a clinician's help, patients find it difficult to understand and retain the information," claimed Anthony Costello, CEO of Mytrus, adding, "[O]ur iPad application simplifies the patient education process, giving sponsors better control of study starts and ensuring a better and more consistent continuum of care for enrolled subjects."[6]
The FDA regulation laid out in 21 CFR Part 11 (more commonly, "Part 11") allows for the acceptance of an electronic signature on a consent form under limited circumstances assuming three basic criteria are met. First, the consent form is given to, and signed by, the subject or the subject's legally authorized

representative. Second, some form of the consent document is made available to the subject, or parent(s) of the subject (usually if children) in a format that they can retain. Finally, the electronic signature is determined to be valid in the jurisdiction where the research is to be conducted.[7]

An added benefit to researchers is that the application will instantaneously allow for subject information and project data to be included in a central repository, minimizing concerns over a clinical trial having the most relevant and recent data, including those surrounding adverse events.[8] The importance of researchers having access to the most accurate and up-to-date information cannot be understated. The research will benefit by allowing for a quicker, cleaner exchange of information amongst participating sites and allow subsequent analysis by the sponsoring entity. A better process will, in turn, make the experience less intrusive on the study enrollee and could, in theory, encourage future participation in clinical research not only by that participant but those to whom the participant shares the information.

Defensive medicine or ethical research?

Despite the immediately apparent benefits of increased utilization of technology in the informed consent process, it's perfectly reasonable to have skepticism about this move because of its wide reaching impacts. With the doctrine of informed consent largely a product of case law[9], the question that should be asked is whether technology in the informed consent process is simply a logical progression in a more ethical and responsible direction of conducting sponsored research or, perhaps, a form of defensive medicine.[10] Though, Mytrus counters that possibility with the results of an interim data analysis conducted during a randomized clinical trial at the California Pacific Medical Center in San Francisco.[11] This study indicated that 24-hours after completing the consent process via the application, 76% of participating patients passed a comprehension quiz regarding the trial risks and processes, as opposed to 52% of patients who were consented through traditional methods for the same trial.[12]

Conclusion

With the advent of technological breakthroughs in recent years, arguments against the utilization of methodologies other than the traditional recitation and ascent to a written document have become increasingly antiquated. The greatest irony being that patients, in most cases, are participating in clinical research projects in order to gain access to cutting edge, albeit experimental, technology with the hopes that a viable treatment or cure is within sight. The Mytrus iPad application, for now, is the first in what will no doubt be a long line of tools at the clinical research team's disposal with a focused goal of streamlining and simplifying vital administrative areas of clinical research.

---

[1] eNotes, *Healthcare: Informed Consent*, (2012), http://www.enotes.com/healthcare-reference/informed-consent.

[2] Marketwire, *Mytrus and Its iPad(R) Application to Be Used to More Quickly Enroll Patients in a Large, Multi-Year Global Clinical Study Mytrus-Enabled Mobile Devices Being Deployed at 120 Clinical Test Sites Around the Globe to Speed Enrollment and Patient Education During the Informed Consent Process*, (2012), http://www.pr-inside.com/mytrus-and-its-ipad-r-application-to-r3373824.htm

[3] *Id.*

[4] CenterWatch News Online, *Mytrus rolls out informed consent iPad app*, (2012), http://www.centerwatch.com/news-online/article/3193/mytrus-rolls-out-informed-consent-ipad-app.

[5] Marketwire, *supra* note 2.

[6] Illingworth Research, *Clinical Trial Terminology: The Informed Consent iPad Application*, (2012), http://illingworthresearch.com/2012/04/10/clinical-trial-technology-the-informed-consent-ipad-application/.

[7] U.S. Dep't of Health & Human Services, *Informed Consent-FAQs Can An Electronic Signature Be Used To Document Consent Or Parental Permission*, (2012), http://answers.hhs.gov/ohrp/categories/1566

[8] Marketwire, *supra* note 2.

[9] Marcela G. del Carmen & Steven Joffe, *Informed Consent for Medical Treatment and Research: A Review*, THE ONCOLOGIST, 10 J. Soc'y Translational Ocology 636 (2005), *available at* http://theoncologist.alphamedpress.org/content/10/8/636.full.

[10] Ronald L. Scott, *Using Technology to Improve Informed Consent and Protect the Physician*, (2007), http://www.hcplive.com/publications/internal-medicine-world-report/2006/2006-05/2006-05_35.

[11] CenterWatch News Online, *supra* note 4

[12] *Id.*

PHYSICAL AND CULTURAL BARRIERS IN A HEALTH CARE MARKET:

IMPLICATIONS OF COSTA RICA'S TARGETED MARKETING TO MEDICAL TOURISTS WITHIN THE UNITED STATES AND POTENTIAL EFFECTS OF THE PATIENT PROTECTION ACT ON COSTA RICA'S MEDICAL TOURISM INDUSTRY

BY KRISTEN S. SWIFT

Medical tourism is a practice where citizens from one country travel to another country for medical procedures to decrease expenses they would normally incur from a procedure in their home country. Medical tourism is a growing international industry and Costa Rica is at the forefront, catering to medical tourists through Promed, an agency whose aims are to ensure medical tourists have an easy and successful experience. Costa Rica is renowned for its social healthcare system, Joint Commission International (JCI) certified hospitals, and beautiful surroundings.

There are stark ideological and structural differences between the US and Costa Rican healthcare systems, yet US citizens seek medical procedures in Costa Rica to save money. The recent United States Supreme Court (USSC) decision upholding the Patient Protection and Affordable Care Act (PPACA) may reconcile some structural differences in the two healthcare systems but ideological differences are harder to overcome, especially regarding women's reproductive health. Healthcare exists in a global market, and the PPACA may negatively affect the medical tourism industry in Costa Rica by lowering costs for healthcare delivery to US citizens. Yet medical tourists may continue to seek elective cosmetic and dental procedures that insurers do not cover.

A Comparative Look at the Healthcare Delivery Systems in Costa Rica and the US

The current national healthcare system in Costa Rica began in 1941 with the creation of the Costa Rican Social Security Fund (CCSS).[1] The Ministry of Health acts as a steward, developing health care policies to coordinate service delivery to the citizens.[2] State controlled public health programs are categorized under "social security" and therefore fall under the CCSS, making it the sole provider of public hospital care.[3] When the Costa Rican army was abolished in 1948 the CCSS system gained increased funding, however in the 1990's health care spending rose unmatched by the GDP leading to a system-wide restructure of the program.[4]

The public system is financed by employers who contribute 9.25% of wages paid, employees who contribute 5.5% of wages earned, and the State which contributes 0.25% of the wage bill.[5] Today, five bodies make up Costa Rica's public health sector: the Ministry of Health (MH), the CCSS, the National Insurance System (INS), the Costa Rican Institute of Water Supply and Sewage System (AyA), and the University of Costa Rica.[6] The INS and CCSS are overseen by a Board of Directors and Executive President and have independent statutes.[7] CCSS is constitutionally mandated to provide all public health insurance and maternity services. This is done through three levels of care.[8] The first level delivers general care in health posts, centers and clinics through Basic Comprehensive Health Teams or EBAIS. The second in specialized consults, hospitalizations and medical/surgical treatment of four specialties. The third provides specialized care in three general and five specialized hospitals (children, women, psychiatry, rehabilitation and geriatric).[9]

To deal with limited resources within the public hospitals CCSS contracts with private enterprises, but Costa Ricans still face long waiting lists when they need surgery.[10] This has led to growth in the private health sector, funded by private payment from users and through contracted payments by the INS and CCSS.[11] The private sector is also fueled by attracting medical tourists who pay privately.

The healthcare system in the US has a variety of systems for care delivery. The government plays a central role in administering Medicare and Medicaid, while paying for almost half of all health care expenses.[12] Private insurance can also be purchased and is often offered by an employer as a job benefit. Many of these plans have co-pays and/or deductibles which require a certain amount be paid into them prior to covering medical services. Therefore a percentage of the cost of a individual healthcare service will be taken from the consumer's pocket in addition to what they are paying under the insurance policy. Even with these different systems a large percentage of Americans remain uninsured, in contrast to Costa Rica's coverage of 90% of their population.[13] This is what the PPACA aimed to reform; requiring US residents to have health insurance or be penalized, creating Exchanges where Americans and small business can purchase coverage, and expanding Medicaid eligibility.[14] The PPACA is set to take effect in 2014 so the impact of these changes has yet to be realized, but the overall effect may set up a system similar to Costa Rica's, with public insurance programs for poorer citizens and private access to healthcare for those who can afford it.

Recognizing a Right to Healthcare: the Ideological Struggle over Women's Reproductive Rights in Costa Rica

Neither the Costa Rican nor US Constitution prescribe a right to healthcare. Unlike the US, Costa Rica is a Catholic nation.[15] This is reflected in Article XXI of the Costa Rican Constitution, which says that, "Human life is inviolable."[16] This means that Costa Rican law regards an embryo as a life. Through judicial interpretation, the Sala Cuarta, or Constitutional Chamber of the Supreme Court, has recognized Article XXI to mean a right to healthcare. Specifically, in 1997, the Sala Cuarta interpreted Article XXI in the *Garcia* case to ensure a right to life and health for all people.[17] The Sala Cuarta has ultimate authority over constitutional issues in Costa Rica.[18] Also, unlike the US, the Costa Rican Constitution has a provision under Article VII that allows for Costa Rican international treaties to have supremacy over their constitution.[19] This means that international human rights treaties that Costa Rica has ratified, such as the UN's International Covenant on Economic, Social and Cultural Rights (ICESCR) may have more force than Costa Rica's domestic law. In fact, Sala Cuarta relied on international treaty law in the *Garcia* decision in addition to Article XXI of the Costa Rican Constitution.[20] The ICESCR, via Article XII, guarantees a right to the enjoyment of health to all.[21] Though the US has adopted the ICESCR and other international treaties, none are recognized as supreme to US domestic law in the healthcare arena.

> *The irony is that women, the segment of the population that Costa Rica discriminates against under the ICHAR, could become Costa Rica's target US market.*

Attempting to honor the ICESCR above domestic law, while recognizing human embryonic life as inviolable, creates a conflict within Costa Rican law regarding women's reproductive rights. For example, unlike the US, abortion is only legal in Costa Rica when the maternal life is in jeopardy. The problem is that there are no active guidelines for medical professionals to follow when providing an abortion.[22] Guidelines have been drafted, yet heavy Roman Catholic influence within the country and the stigma associated with abortion has made obtaining political support to approve the guidelines difficult.[23] On average, five legal abortions occur within Costa Rica in a year, while at least ten-thousand occur outside of the public health system unsafely.[24] Though abortion is legal in Costa Rica under some circumstances, it is rarely accessible. This directly violates ICESCR Article XII's right to access healthcare because abortion is an essential health service for women.[25]

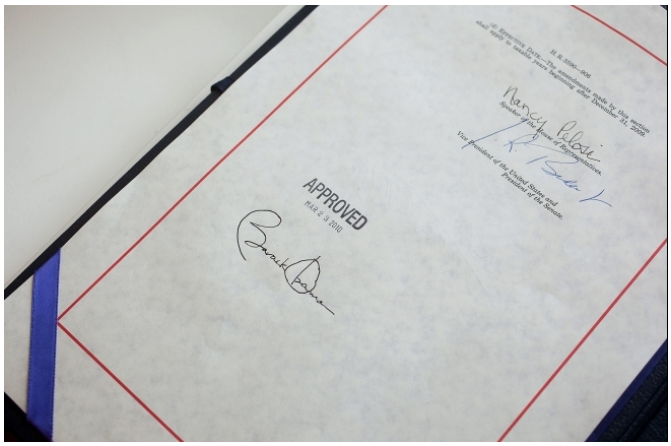
Blocking women's reproductive rights also defies the Costa Rican government's initiative to encourage medical tourism in their country by losing potential patients for in-vitro fertilization (IVF) treatments. Currently, many US insurance programs do not cover IVF treatments and the out-of-pocket cost is extremely high. If Costa Rica were able to offer cheaper IVF treatments, there would be a niche market from the US and

other countries seeking this service. However, Costa Rica has a ban on all IVF treatments. This violates General Comment 14, which was published to address implementing Article XII of the ICESCR. The ICESCR imposes three obligations on members: to respect, protect and fulfill.[26] Specifically, the IVF ban violates Costa Rica's obligation to *respect*, which means that the state will not interfere in any person's enjoyment to the right to health.[27] In *Ana Victoria Sanchez Villalobos et. al. v. Costa Rica*, the IVF ban was challenged in front of the Inter-American Commission on Human Rights (IACHR).[28] The IACHR found that the IVF ban violated several human rights owed to women including the right to equality and personal autonomy, and made several recommendations to change this.[29] Despite the preference the Costa Rican Constitution gives to international treaties, the IACHR's decision has not prompted a lift on the IVF ban.[30]

Regardless, Costa Rica encourages foreigners to take advantage of their private health system. Medical tourism reflects the globalization of wealthy industrialized nations and the decreasing importance of physical boundary lines. Although these lines may become less significant, the ideological struggle in Costa Rica outlines how social and cultural differences may be harder to overcome than people anticipate. Yet medical tourism continues to flourish in Costa Rica.

Potential Effects of the US Patient Protection and Affordable Care Act on Medical Tourism from the US to Costa Rica

Costa Rica is unique among medical tourist locations because of its non-profit organization, the Official Council for the International Promotion of Costa Rica Medicine, or Promed, dedicated to the medical tourism industry. [31] Promed's mission is to "secure Costa Rica's position internationally as a medical tourism … destination."[32] This reflects the global competition growing in healthcare. Promed has been established to supervise the private sector, to make sure the tourists are receiving quality care and to promote growth in the industry.[33] Promed is comprised of six specialized committees that govern: education, ethics, admissions, legal, regulations and promotion.[34] It is overseen by a board of directors.[35] Promed reports that in 2008, roughly 25,000 medical tourists traveled to Costa Rica, most of whom sought dental work (36%), surgeries (22%), unspecified medical treatments (14%) and aesthetic surgeries (12%).[36] By contrast, in 2006 only 250,000 foreigners traveled to the US for care: the US has 300 million more residents than Costa Rica, whose population totals roughly 4 million.[37]



Medical tourism is a huge industry that continues to grow. It is estimated to gross $100 billion dollars worldwide in 2012.[38] Promed projects that by 2015 the potential market will include 220 million people over the age of 50 in the US alone.[39] According to its 2007 report, the National Center for Policy Analysis concludes that US citizens travel for medical care based on financial incentives.[40] One-quarter of uninsured US citizens would travel abroad to save $1,000-2,400.00, but to save over $10,000, 38% of uninsured and 25% of the insured would travel abroad.[41]

The PPACA's aim to create global competition in the healthcare market and universal coverage may drive treatment costs in the US down and dampen the market for medical tourism for which Costa Rica hopes to corner. However, even with global competition and the PPACA's goal of universal insurance coverage, there will still likely be niche markets for uncovered cosmetic procedures. In 2011 there were over 9 million cosmetic procedures performed in the US, a 197% increase since 1997.[42] 91% of these procedures were for women.[43] This amounted to 8.4 million cosmetic procedures in 2011, showing a 208% increase since 1997.[44] The irony is that women, the segment of the population that Costa Rica discriminates against under the ICHAR, could become Costa Rica's target US market.

There are a variety of reasons why Costa Rica and other countries can offer cheaper medical care than the US can. First, medical equipment is cheaper. For example, an MRI in Costa Rica may cost $300 compared to over

$1,000 in the US.[45] Second, doctors in Costa Rica earn 40% less than US doctors and Costa Rican nurse salaries are 1/5 to 1/20 of nurse's salaries in the US.[46] Third, the market in the US is controlled mainly by third parties instead of consumers directly, with third parties paying for about 87% of healthcare costs.[47] This leads to a less competitive marketplace because third parties are not as likely to comparison shop.[48]

Dental insurance is another US weakness that medical tourism exploits. Promed's website indicates that as of 2010, 108 million Americans did not have dental insurance.[49] Considering most medical tourists entering Costa Rica are from the US and Canada, it is not surprising that dental services lead Costa Rica's medical tourism industry. Under the PPACA only self-insured dental plans will not be subject to lifetime spending limits.[50] Also, pediatric dental services are considered essential, not subject to spending limits and access to these services is mandated.[51] The fact that children can stay on their parents' insurance plans until the age of 26 may also provide them with dental coverage, depending on the plan. The problem is that it leaves a gap for adult dental services that medical tourism continues to fill.

Costa Rica is taking every step possible to ensure they remain competitive in the medical tourist industry, including having three of their five private hospitals Joint Commission International (JCI) certified. To be Promed certified, healthcare agencies have to have at least one certification from an international board such as JCI.[52] JCI is the international division of the US Joint Commission, whose focus is to improve safety and quality and provide accreditation in an international setting.[53] JCI accreditation is voluntary and consists of an on-site evaluation by consultants who are accredited by the International Society for the Quality in Health Care. In 2010, the average fee for a JCI hospital survey was $46,000, and this does not include the travel team's hotel, food and transportation costs.[54]

Conclusion

First, Costa Rica's private health sector is targeting US citizens. Medical tourists from the US are financially motivated and benefit from services outside the country. However, the PPACA may re-direct US medical tourists back into the US healthcare market. Second, despite being on the forefront of medical tourism, Costa Rica struggles to balance women's access to reproductive healthcare with the nation's Catholic ideals. This highlights how, in a global marketplace, physical barriers are becoming easier to transcend while cultural barriers remain.[55]

---

[1] Brian Jacob, *Closing the Gaps: The Challenge to Protect Costa Rica's Health Care System*, 15 GEO. PUB. POL'Y REV. 77, 78 (2010).
[2] *Id.*
[3] *Id.*
[4] *Id.* at 79.
[5] PAN AMERICAN HEALTH ORGANIZATION, PROFILE OF THE HEALTH SERVICES SYSTEM OF COSTA RICA, 14 (May 27, 2002), *available at* http://new.paho.org/hq/dmdocuments/2010/Health_System_Profile-Costa_Rica_2002.pdf.
[6] *Id.* at 5.
[7] *Id.* at 14.
[8] *Id.* at 6.
[9] *Id.*
[10] *Id.*
[11] *Id.* at 7.
[12] DEVON M. HERRICK, MEDICAL TOURISM: GLOBAL COMPETITION IN HEALTHCARE, 26 (NCPA Policy Report No. 304, Nov. 2007), *available at* http://www.ncpa.org/pdfs/st304.pdf.
[13] PAN AMERICAN HEALTH ORGANIZATION, *supra* note 5, at 14.
[14] Kaiser Family Foundation, *Summary of New Health Reform Law*, (April 15, 2011), http://www.kff.org/healthreform/upload/8061.pdf.
[15] CONST. (1975), tit. VI, art. 75 (Costa Rica), *available at* http://www.costaricalaw.com/legalnet/constitutional_law/engtit6.html.
[16] *Id.*
[17] Kate Kaiser, *The Fight for Access to AIDS Medications: How the Central American Free Trade Agreement Conflicts with Costa Rica's Constitutional Courts*, 25 WIS. INT'L L.J. 535, 543 (2007).
[18] *Id.* at 539.
[19] *Id.* at 541.
[20] *Id.* at 543.
[21] International Covenant on Social, Cultural and Economic Rights art. XII, Jan. 3, 1976, OCHCR, *available at* http://www2.ohchr.org/english/law/cescr.htm.

[22] Letter from Monica Arango Olaya, et. al to the United Nations Committee on the Elimination of Discrimination Against Women, 2 (May 25, 2011), *available at* http://www2.ohchr.org/english/bodies/cedaw/docs/ngos/JointNGORepor_CostaRica49.pdf.

[23] Planned Parenthood, *Costa Rica Country Program* (2012), http://www.plannedparenthood.org/about-us/international-program/costa-rica-country-program-18998.htm.

[24] Arango Olaya, *supra* note 22, at 3.

[25] *Id*. at 4.

[26] Eleanor D. Kinney, *The International Human Right to Health in Domestic and Statutory Law*, 60 RUTGERS L. REV. 337, 341 (2008).

[27] *Id*.

[28]Arango Olaya, *supra* note 22, at 10.

[29] *Id*.

[30] *Id*. at 11.

[31] Promed, *Goals*, (2010), http://promedcostarica.com/insti/objectives.html.

[32] *Id*.

[33] *Id*.

[34] Promed, *FAQ about Promed,* (2010,) http://promedcostarica.com/insti/faq.html.

[35] *Id*.

[36] Promed, *About Costa Rica,* (2010), http://promedcostarica.com/insti/costa_rica_opportunities.html.

[37] Herrick, *supra* note 12, at 6.

[38] Promed, *Medical Tourism X-ray*, (2010), http://promedcostarica.com/insti/tourismguide.html.

[39] *Id*.

[40] Herrick, *supra* note 12, at 2.

[41] *Id*.

[42] AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY, 15TH ANNUAL COSMETIC SURGERY DATABANK STATISTIC REPORT, 3 (2011), *available at* http://www.surgery.org/sites/default/files/ASAPS-2011-Stats.pdf.

[43] *Id*.

[44] *Id*.

[45] *Id*. at 9.

[46] *Id*. at 10.

[47] AMERICAN SOCIETY FOR AESTHETIC PLASTIC SURGERY, *supra* note 42 at 10.

[48] *Id*.

[49] *Medical Tourism X-ray*, *supra* note 37.

[50] SIBSON CONSULTING: A DEVISION OF SEGAL, IMPACT OF THE AFFORDABLE CARE ACT ON DENTAL AND VISION BENEFITS, 3 (2010), *available at* http://www.sibson.com/publications/HCRI/dec2010DV.pdf.

[51] *Id*.

[52] Promed, *Certifications*, (2010), http://promedcostarica.com/insti/certification.html.

[53] Joint Comm'n Int'l, *About Joint Commission International*, (2011), http://www.jointcommissioninternational.org/About-JCI/.

[54] Joint Comm'n Int'l, *Costs of Accreditation*, (2011), http://www.jointcommissioninternational.org/Cost-of-Accreditation/.

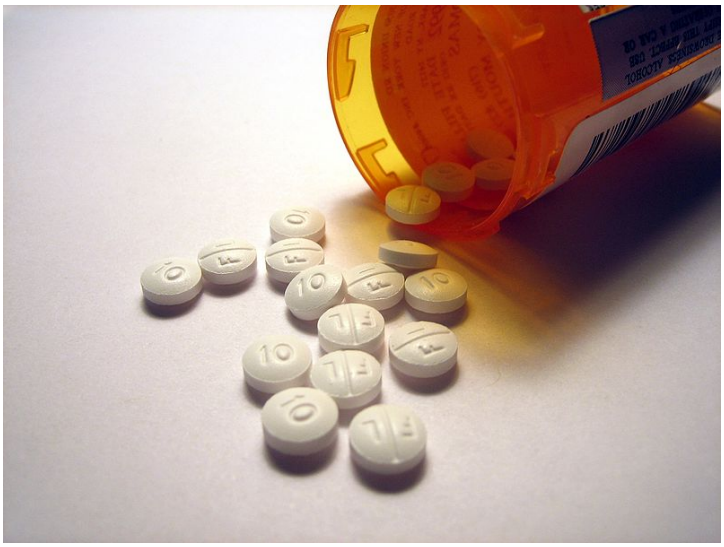
STATES STRUGGLE WITH PHYSICIAN-ASSISTED SUICIDE LAWS

BY CAITLIN LUTZ

Imagine you are a doctor. You have a 65-year old cancer patient and predict that he has six months left to live. He is suffering through treatments that may or may not help, he is tired most of the time and has little strength. Your patient's family is paying for the medical bills, which makes it difficult to pay for food and living expenses. They visit your patient daily, spending hours in a hospital room simply sitting at his bedside so that he is not alone. Your patient feels that he is putting a strain on his family and he asks you to prescribe medication that he could take to end his life. Would you do it? As an attorney, would you support and defend a physician who said yes?

Introduction

Lawyers and medical professionals have debated the moral and ethical implications of physician-assisted suicide since Dr. Kevorkian's controversial acts and beliefs struck the nation. On October 27, 1997, Oregon became the first state to legalize physician-assisted suicide, Washington, the second, and now Montana following behind. By examining several state laws it is easy to see why some medical professionals, and others involved in the debate, believe it is a person has the right to end his or her life, while others believe that a doctor is violating their ethical obligations when providing a patient with the means to an end.



Euthanasia and Physician-Assisted Suicide

It is worthwhile to differentiate euthanasia from physician-assisted suicide. *Euthanasia* is the practice of injecting a person with a drug that is intended to end their life. Euthanasia is currently illegal in the United States and viewed by most as incredibly unethical; in fact, legitimate euthanasia decisions normally arise in end of life decisions regarding domesticated animals, not in family members and with loved ones. *Physician-assisted suicide* is when a physician is treating a terminally ill patient and prescribes them a medication that the patient fills and takes voluntarily in order to end their own life. The major distinction from euthanasia is that the patient remains in control during the procedure. For a physician assisted suicide to be performed the sick patient must have a treatment relationship with a physician so he or she can be prescribed the correct medication and dosage.

State Law

Delaware law prohibits the assistance in another's suicide,[1] as do most other states. Despite the widespread ban, physician-assisted suicide is legal in two states through their Death with Dignity Acts. The Death with Dignity Act, adopted in Oregon[2] and Washington,[3] provide terminally ill patients an avenue for ending their life in a humane and dignified manner. Patients must meet several requirements before a physician can legally prescribe a lethal dose of medication. To qualify, the patient must be terminally ill, as defined by the statute.[4] Also, the patient must make a written request, endure the waiting period before obtaining the prescription and must reassure the physician they are making an informed decision.[5] These statutes also provide for proper disposal of unused medication and guarantee the patient's family the appropriate insurance benefits.[6]

Montana is the third state to expressly address the legalization of physician-assisted suicide. In *Baxter v. State*, the Montana Supreme Court held that physician-assisted suicide was not contrary to public policy and the state assisted suicide statute would not apply to physician-assisted suicide cases.[7] The court concluded that a physician could not be criminally liable under the Montana assisted suicide statute because the patient in the relationship would have "consented" to the suicide, leaving the physician free from prosecution.[8] Furthermore, the court determined that consent to physician-assisted suicide is not against public policy because the physician is not involved in the final act.[9] In sum, the patient is free to take the prescription or to not take it at all and the act of the patient self-administering the medication does not "breach public peace or endanger others."[10]

Physician-assisted suicide has been controversial and states continue to struggle with the decision of whether or not to legalize the practice.

Other Montana statutes, such as the Rights of the Terminally Ill Act, provide safeguards that protect a patient's wishes and ensure their decisions are followed at the end of their life.[11] The court in *Baxter* found this statute to provide insight on whether physician-assisted suicide was against public policy. The court found the Terminally Ill Act not only shielded physicians from liability but also that "the statute's message is clear: failure to give effect to a terminally ill patient's life-ending declaration is a crime."[12] The court chose not to rule on the constitutional issues of dignity and privacy in regards to physician-assisted suicide, but one can imagine how these constitutional rights could become intertwined in the debate.[13]

Conclusion

Those who support the practice of physician-assisted suicide argue a person who is terminally ill should have the autonomous decision to take their life in a humane and dignified way. On the other hand, those who oppose physician-assisted suicide believe a physician is violating their Hippocratic Oath to act with beneficence and nonmaleficence – a pledge to "do good" and "do no harm." The long-standing debate surrounding physician-assisted suicide has been controversial and states continue to struggle with the decision of whether or not to legalize the practice.

---

[1] DEL. CODE ANN. tit. 11, § 645 (1995).
[2] OR. REV. STAT. ANN. § 127.805 (1999).
[3] WASH. REV. CODE ANN. § 70.245.020 (2009).
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Baxter v. State*, 354 Mont. 234 (2009).
[8] *Id.* at 240.
[9] *Id.*
[10] *Id.* at 242.
[11] MONT. CODE ANN. § 50-9.
[12] *Baxter*, at 246.
[13] *Id.*

RECOMMENDATIONS FOR THE PROBLEMS IN GLOBAL ACCESS TO PAIN MEDICATION

BY STEPHANIE STOTLER

Current drug regulations in various countries are often over restrictive. This has hindered access to medication for palliative care. Harsh regulations that were adopted to stop illicit drug use have restricted the proper use of pain medicine. Statistics show that countries with harsh regulations hinder pain management. In 2003 "six developed countries accounted for 79% of the total global morphine consumption, while developing countries, representing 80% of the world's population, accounted for just 6%."[1] Reform needs to start with the deregulation of pain medication and focus on a correct balance that would enable proper medical use.

Limitations on Access to Palliative Care

It is important for healthcare organizations to collaborate and create a comprehensive plan to make palliative care more available to regions, specifically regions that are currently not using it regularly. Based upon a survey conducted by the Human Rights Watch, there are three regulations that are most reported to limit access; special licensing requirements for healthcare workers, use of special prescription forms and other special prescription requirements, and limitations on the amount of morphine that can be prescribed using one prescription or the length of time that a prescription can cover.[2]

It would be of great value for the World Health Organization to supervise another meeting with doctors and medical professionals to address the needs of medicine accessibility. Illicit drug use agencies and medical professionals should work together to create a better balance, ensuring proper licensing methods and pain management plans.

Addressing the Accessibility of Medicine

Regulations need to balance access to controlled medicines for the treatment of medical conditions while at the same time minimizes availability for abuse and dependency. The World Health Organization response was to develop the Access to Controlled Medications Programme (ACMP) with consultation with the International Narcotics Control Board (INCB). The program plays three distinct roles. First, it reviews relevant national legislation and administrative procedures. Second, it promotes continuing medical education and rational use of controlled medications by health care professionals. Third, it provides assistance in ensuring an uninterrupted supply of opioid analgesics at affordable prices.

The World Health Organization should continue to implement its Access to Controlled Medications Programme and focus on deregulating strict government laws. Pain medication would become more safely and appropriately accessible by educated medical professionals. Given the scope of global public health concern, it is critical to enhance the technical and regulatory capacity of each government in order to advance medical availability of pain medicine.[3]

The United Nation's "drug control" scheme substantially interferes with the capacity of states to broaden drug availability for legitimate public health purpose.[4] The restrictions should be no more restrictive than reasonable necessary to prevent its diversion to misuse.[5] The need for palliative care is important and denial of pain medication should be considered cruel and inhuman. Unfortunately, the overwhelming fear of criminal prosecutions for the unlawful drug prescription has made physicians and other medical

professionals more reluctant to prescribe pain medication to people who need it. The focus should identify the factors that impede prescribing medicine first and ensure that the special license required to prescribe pain medication is obtainable within the medical community.[6] Furthermore, the special prescription requirements and limitations can be more easily and adequately obtained by assessment from qualified medical professionals.[7] The World Health Organization should put together a team of medical professionals to evaluate the countries regulations and make recommendations for effective licensing and pain management treatment plans. This would balance the restrictions of illegal drug use.

Conclusion

A committee of medical professionals that could evaluate pain management regulations would bring a balance to the law enforcement prospective by advocating for what is best for the patient. The current regulations are overly restrictive and need to be reevaluated and reassessed. With the help of the World Health Organization Access Programme finding a fair balance should be more plausible. In turn this will make pain management more accessible.

---

[1] World Health Organization, *Medicines: access to controlled medicines* (January 25, 2012), http://www.who.int/mediacentre/factsheets/fs336/en/index.html (January 25, 2012).

[2] Human Rights Watch, *Global State of Pain Treatment, II. Survey Findings: Global Overview of Barriers to Pain Treatment* (January 25, 2012), http://www.hrw.org/node/98902/section/5.

[3] *Id.*

[4] *Id.*

[5] Human Rights Watch, *Global State of Pain Treatment* (January 25, 2012), http://www.hrw.org/reports/2011/06/01/global-state-pain-treatment-0.

[6] *Id.*

[7] *Id.*

HEALTHCARE RATIONING: EXPLICIT DEBATE, IMPLICIT CONSEQUENCES

BY JON LANDUA

Introduction

In a 1974 Supreme Court opinion Justice Douglas wrote a fable about a place called Gourmand to illustrate the problems associated with government paying for the healthcare of its citizens.[1] The citizens of Gourmand, obsessed with good food, let government policy evolve to a point where excess was the norm and the government had to foot the bill for all of its citizens to eat wherever and whatever they want.[2] He envisioned a system in which "large numbers of people spent all of their time ordering incredibly elaborate meals. Kitchens became marvels of new, expensive equipment. All of those who were not consuming restaurant food were in the kitchen preparing it. [And] since no one in Gourmand did anything except prepare or eat meals, the country collapsed."[3] Thankfully, the US healthcare system has not evolved to similar levels of excess for the simple reason that we are a nation with finite resources.

In a world with limited resources it is unlikely that any healthcare system will reach a point where every available resource gets poured into providing for, or consumption of, its own services. Therefore we unlikely have to worry about the fate that Justice Douglas envisioned in Gourmand. Gourmand's fate is unlikely to occur in reality because society, be it in the United States or the United Kingdom will find a way to distribute what is available.

Today's resources have reached a level where they are so limited that a balancing act between cost and quality has begun to emerge.

Healthcare Rationing

In healthcare this idea is expressed through the concept of rationing. In the United States a system of implicit rationing has developed, wherein one's ability to obtain healthcare services is dependent on either their ability to pay the service directly, or through access to health insurance which will pay for services rendered.[4] Under implicit rationing, the government has a limited role, more or less allowing for the invisible hand of the market to dictate the distribution of resources.

On the other hand, explicit rationing consists of governmental policies created to most cost-effectively allocate a limited number of healthcare resources to the general public.[5] In the United Kingdom the National Institute for Clinical Excellence (NICE) fills this role by acting as a guide, moving resources through the healthcare system in the most cost-effective way possible.[6]

Ideally, both methods of rationing work well, using different means to reach the same end - providing quality healthcare to all who need it. Unfortunately, today's resources have reached a level where they are so limited that a balancing act between cost and quality has begun to emerge. When discussing healthcare policy some people refer to the "Iron Triangle." Symbolic of the give-and-take which must take place during the creation of policy, the "Iron Triangle" is the notion that good healthcare. Whether it be within the framework of an explicit or implicit rationing system has three core ingredients: cost, access, and quality. These components are so interrelated that one cannot improve the efficiency of one point of the triangle without detrimentally affecting the other two.[7] Where the overall cost of healthcare per capita in the US is increasing on average at a rate of 2.5% over the rate of inflation there should be a growing concern about the cost and how to balance it with access and quality.[8]

The Good News

Quality and cost may not be as closely related as one might think. The Organization for Economic Co-Operation and Development ("OECD") in 2008 found that "health care spending was 16% of the gross

domestic product in the United States, while it was only 8.7% in the United Kingdom."[9] The UK at almost half the cost achieved a life expectancy in newborn males of 77.7 years from 2007 – 2009, but in the US in 2010 newborn males only achieved a life expectancy of 75.78 years.[10]

So more is not always better; US healthcare costs have increased and arguably not outpaced quality of care. From 1980 to 1993 health care costs rose from 8.9% of the gross domestic product to 13.5%, and have since increased again while quality of care has remained about the same as other developed nations who spend less money on health care.[11]

This phenomenon has been explained, at least in part by Roemer's Law. Roemer's Law is the concept that supply creates demand.[12] In the US's implicit rationing system, doctors used to get paid on a fee-for-service basis whereby the more services they provided, the more money they made.[13] Under this model it made sense both economically and medically for a doctor to order as many available tests as he or she could justify in an attempt to serve the patient's best interest and her own economic need. If a test or service existed there was usually an automatic demand for it. This model did not encourage either the doctor or patient to use resources judiciously or render efficient care.

This ration system changed when insurance companies stopped allowing doctors carte blanche over what services were ordered for a given patient and instead began to institute the "managed care" solution. The idea behind managed care is to provide "a range of diverse health care benefit designs that combine health care services with payment for those services, giving the payer substantial control over both the provision of services and the amount that will be paid for the services provided."[14] Through this system the "payers" (insurance companies) would in essence control how much and when doctors got paid. The implications went beyond simply *what* doctors got paid and crept into the realm of what services doctors could provide.

In the new "managed care" framework not only are services rationed *externally*, by filtering out those that can't afford to purchase insurance and enter the system; resources also are rationed *internally* by the insurance companies who hire "Physician Managers" to make determinations about which services are medically necessary and therefore covered under a given policy.[15] What is determined to be "medially necessary" is up to the insurance company. Medical necessity has been defined in one instance as "essential" and "consistent with accepted standards of medical practice," as determined by the insurance company's Physician Managers.[16]

Thus a problem has emerged with rationing in the US; (1) the Physician Manager ("PM") making medical decisions which pertain to an individual who is not under their direct care and (2) not allowing a patient to receive the treatment he needs. In many states a PM does not have to be licensed to practice medicine in the state in which he works, nor is he limited to making decisions within the scope of his expertise.[17]

Case law illustrates good examples of what can go wrong when a PM attempts to ration medically necessary treatment without experience in the field about which he is making a decision.[18] In *Pappas v. Asbel*, an emergency room doctor wanted to transfer the Plaintiff to a hospital that had the appropriate facilities to perform an operation on the Plaintiff's spine.[19] The PM not only wouldn't approve a transfer to the hospital because it was not under contract with his insurance company, the PM would not even speak to the emergency room doctor.[20] As a result of this, the PM never understood that time was a factor in determining the outcome of the surgery.[21] Because the PM (a pediatrician) did not follow the recommendations of a practicing neurologist to transfer the Plaintiff immediately the Plaintiff suffered quadriplegia paralysis.[22]

The Judicial System

The legal solution to this conflict of interest and lack of accountability of PM's for their decisions rests with the courts, but they seem reluctant to take

on that roll. Admittedly, this is a difficult job in a court system where one decision can dictate how lower courts must rule. The Supreme Court hinted either at its acceptance of this kind of rationing, or reluctance to dictate how the process should run when it said "health care rationing is an immutable characteristic of managed care organizations."[23] In the UK Court of Appeals, arguments against rationing based on the European Convention on Human Rights were criticized as "unhelpful" and "unfocused."[24]

Courts of civil law in countries where health care is a constitutional right have been more accepting of being the ultimate rationer of healthcare resources. It seems in part due to the lack of affect their decisions will have on the healthcare system as a whole, in contrast to what ripples might emerge from a decision made by the US Supreme Court. In South Africa, another civil law court system, they scrutinized "the relevance of the rationales offered by the Government for its policy of restricting the availability," of healthcare resources.[25]

In Summary

Within the UK and other civil law countries, where healthcare is considered a right, rationing is necessarily governed by the courts. There, the judiciary will make the ultimate decisions as to where, where and how resources get allocated. However, in the US, where healthcare has emerged as a privilege for those who can afford it, the courts view healthcare as a business and are reluctant to use their power to allocate resources. Decisions are left in the hands of PMs, who may or may not be qualified and sufficiently informed, so as to make the proper decision about a customer's health care.

---

[1] *Memorial Hospital v. Maricopa County*, 415 U.S. 250 (1974).
[2] *Id*, at 274.
[3] *Id*, at 275.
[4] Amanda Swanson, *Rationing As A Necessity*, 19 ANNALS HEALTH L. 1, 2 (2009).
[5] Leonard J. Nelson III, *Rationing Health Care In Britain And The United States*, 7 J. HEALTH & BIOMEDICAL L. 175, 180 (2011).
[6] K. Syrett, *Deference Or Deliberation*, 24 J. MED. & L. 309, 312 (2005).
[7] Leonard J. Nelson III, *supra* note 5 at 181.
[8] *Id.* at 184.
[9] *Id.* at 178.
[10] *Id.*
[11] Gail B. Agrawal, *Resuscitating Professionalism: Self-Regulation In The Medical Marketplace*, 66 MO. L. REV. 341, 347 (2001).
[12] Amanda Swanson, *supra* note 4 at 4.
[13] David Orentlicher, MD, JD, *Rationing Health Care*, 19 ANNALS HEALTH L. 449, 461 (2010).
[14] Gail B. Agrawal, *supra* note 11 at 351.
[15] *Id.* at 352.
[16] *Friends Hospital v. Metrahealth Service Corp.*, 9 F. Supp. 2d 528, at 530 (E.D. Pa. 1998).
[17] Gail B. Agrawal, *supra* note 11 at 363.
[18] *Pappas v. Asbel*, 768 A.2d 1089 (Pa. 2001).
[19] *Id.* at 1091.
[20] *Id.* at 1092.
[21] *Id.* at 1092.
[22] *Id.*
[23] *Pelgram v. Herdrich*, 530 U.S. 211, 220–21 (2000).
[24] K. Syrett, *supra* note 6 at 319 (2005).
[25] *Id.*

THE CORPORATE PRACTICE OF MEDICINE DOCTRINE

BY DOMINIQUE DIAZGRANADOS

As the healthcare industry continues to evolve, the way in which it's managed must evolve as well. The corporate practice of medicine doctrine provides that, absent legislative authorization, a business entity may not employ medical professionals to practice in the corporation's capacity.[1] The rationale behind the doctrine is that because only a human-being can obtain the education and experience necessary to obtain a professional license and because a corporation cannot receive a medical license, a corporation should not be able to legally practice in the profession.[2] While this idea may seem simple enough, it is riddled with exceptions and applied inconsistently across neighboring states. By one estimate, as many as 37 states have statutory or common law prohibitions on the corporate practice of medicine, but relevant precedent is quite old and in some cases widely ignored; 13 states either reject the doctrine or have no authority establishing it.[3] In today's health care industry the name of the game is efficiency; trying to juggle a large volume of patients in the most cost effective way. In a time where state inconsistency in applying the corporate doctrine reduces the efficiency of the healthcare system, while local physicians are replaced by Health Maintenance Organizations (HMOs), it begs the question, "[h]as the time come to put the corporate practice of medicine doctrine to a rest?"

It is important to recognize that the corporate practice of medicine doctrine is not without its merits. The doctrine was introduced at the beginning of the twentieth century by the American Medical Association in an effort for physicians to gain better control over the medical field and to prevent commercialization of the profession through the introduction of profit-making incentives.[4] The most compelling arguments in support of the corporate practice of medicine doctrine revolve around public policy. The courts are concerned with issues of corporate control over professional judgment, commercial exploitation of health care practice, and physician loyalty conflicts between his patient and his employer. [5]

At its core, the doctrine exists to protect the relationship between the professional and the patient.[6] Corporate control, usually an HMO, may cause conflicting loyalties for a physician. First, physicians are expected to balance the interests of their patients with the interests of other patients. When deciding whether to order a test or procedure, the physician must consider whether the slot should be saved for another patient or not used at all to conserve resources.[7] Second, managed care organizations may place the needs of patients in conflict with the financial interests they provide to physicians. Managed care plans use bonuses and fee withholds to make physicians cost conscious. As a result, when physicians are deciding whether to order a test, they will recognize that it may have an adverse impact on their income.[8] This corporate involvement in medicine through contract and corporate practice is what the supporters of the doctrine seek to prevent.

While the doctrine may have served a purpose at an earlier point in time, there seems to be mounting reasons to now put it to rest. In the 1970's, HMOs became the popular mechanism to combat the increasing cost of health care.[9] Many states have enacted legislation, specifically allowing HMOs to employ physicians in order to eliminate the corporate practice ban as an obstacle to HMO growth. [10] The acceptance of HMOs in the health care industry can be said to signify accepting the risk of corporations obtaining lay control over medical decisions in order to gain the efficiency driven by profit-centered managed care.[11] If HMOs are not included as an exception, the doctrine may place an additional barrier preventing efficiency in the health care industry.[12] HMOs are continually attempting to streamline administrative procedures to be more time and

cost effective. Holding them liable under the doctrine would hinder a progression in efficiency for the overall system.

Currently, a majority of courts have accepted certain exceptions to the doctrine. However, these exceptions tend to undermine the validity of courts holding on to the original rule. Allowing HMOs to employ physicians has become the most significant exception due to the immense presence of HMOs in the health care system. Other states do not apply the doctrine to nonprofit corporations. The rationale behind this is that nonprofit organizations lack a profit motive; therefore there is less chance of commercial exploitation or division in loyalty.[13] While this exception would have made sense before the existence of HMOs, there no longer seems a need to make a distinction between for-profit and non-profit organizations. The HMO exception is now treating them identically under the law for the sake of employing medical professionals.

Another exception exists for professional corporations, partnerships, and group practices owned and managed by professionals.[14] And there is another exception, usually either judicially or statutorily, for hospitals. These exceptions demonstrate the movement away from enforcing the corporate practice of medicine doctrine, making the continued existence of the doctrine virtually meaningless.

In doing away with the corporate practice of medicine ban, states will lose all protections against lay interference with medical decisions. Regardless, medical physicians would continue to be subject to professional ethical standards and state licensing requirements. Together, these requirements would prevent physicians from succumbing to lay decisions that contravene their medical judgments. [15]

Elimination of the corporate practice of medicine doctrine would also do away with litigation that has extended the doctrine beyond its intended scope and impeded continued improvement towards efficiency in health care.[16] Such cases involve the "illegality defense", in which physicians try to avoid their contractual employment obligations by asserting that their employment violated the corporate practice of medicine prohibition and so the contract was in turn illegal and void.[17] This seems contrary to promoting an efficient health care system because time and money will be spent on litigation, which may result in the organization still losing its medical professionals and having services interrupted while a replacement is found.

The corporate practice of medicine doctrine, while once addressing a legitimate concern, seems to no longer have a valid purpose. There has been widespread inconsistency in state laws regarding the corporate practice of medicine and it has hindered the continued growth in efficiency of the health care system. The time has come where this growth may be best served through corporate ownership of physician practices, which would allow for increased efficiency and oversight. Furthermore, the concerns that once governed the corporate practice of medicine doctrine's assistance in preventing physician divided loyalty and lay control of medical decisions seem to have become tolerated in order to achieve the efficiencies of managed care in light of the mechanisms in place, physician licensing and ethical requirements, that continue to ensure medical decisions are in the hands of physicians.

---

[1] *Columbia Physical Therapy, P.S. v. Benton Franklin Orthopedic Assoc.,* 168 Wash. 2d 421, 430-31 (2010).

[2] *Berlin v. Sarah Bush Lincoln Health Ctr.*, 688 N.E.2d 106 (Ill. 1997).

[3] Adam M. Freiman, *The Abandonment of the Antiquated Corporate Practice of Medicine Doctrine: Injecting A Dose of Efficiency into the Modern Health Care Environment*, 47 EMORY L.J. 697, 697-98 (1998).

[4] *Id.*

[5] *Isles Wellness, Inc. v. Progressive N. Ins. Co.*, 725 N.W.2d 90, 93 (Minn. 2006)

[6] *Columbia Physical Therapy*, 168 , 168 Wash. 2d at 430-31.

[7] *Id.*

[8] George C. Harris & Derek F. Foran, *The Ethics of Middle-Class Access to Legal Services and What We Can Learn from the Medical Profession's Shift to A Corporate Paradigm*, 70 FORDHAM L. REV. 775, 817-19 (2001).

[9] Adam M. Freiman, *supra* note 3 at 707.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] Adam M. Freiman, *supra* note 3 at 707.
[15] *Id.*
[16] *Id.*
[17] *Berlin,* 688 N.E.2d at 106.

HEALTH LAW COLLOQUIUM CONTRIBUTORS

Many thanks to all students and professionals who contributed to this issue of the *Health Law Colloquium*. Without your diligence and willingness to contribute, this issue would not have been possible:

Thaddeus Mason Pope, JD, PhD.
Frank V. Ingiosi, JD
Kristen S. Swift
Caitlin Lutz
Stephanie Stotler
Jon Landua
Dominique Diazgranados

HEALTH LAW COLLOQUIUM EDITORIAL STAFF

Dan J. Baum, Editor-in-Chief
Sean P. Quinn, Editor

HEALTH LAW SOCIETY BOARD

Tiffany D. Coleman, President
Dan Baum, Vice President
Caitlin Lutz, Treasurer
Kristen S. Swift, Secratery
Erie Coney, Jr., SBA Representative
Arielle Williams, SBA Representative

UPCOMING EVENTS

Widener Health Law Society will be competing in the University of Maryland: Francis King Carey School of Law's Second Annual Health Law Regulatory & Compliance Competition. For more information, contact Tiffany Coleman at Tdcoleman@mail.widener.edu.

Our Annual Health Law Society Writing Competition will occur next semester in the Spring of 2012.
If you are interested in submitting an article, please contact Dan Baum at Djbaum@mail.widener.edu.

∗ All images in this newsletter were supplied either by Widener pages, student albums or through Wikipedia Commons, a public media repository.